

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Privacy Act of 1974; Annual Publication of Systems of Records

**AGENCY:** Public Health Service, DHHS.

**ACTION:** Privacy Act: Annual republication of notices of revised systems of records.

**SUMMARY:** The National Institutes of Health (NIH) has conducted a comprehensive review of all Privacy Act systems of records and is publishing the resulting revisions. None of the revisions meet the OMB criteria for a new or altered system of records requiring an advance period for public comment. These changes are in compliance with Circular A-130, Appendix 1. The notices republished below are complete and accurate as of January 5, 1995.

#### SUPPLEMENTARY INFORMATION:

The following information summarizes the current status of systems of records which had minor modifications during 1994 and lists all systems maintained by NIH:

**A. System name.** The following systems have been updated to reflect a change in the name of the system:

- 09-25-0093, Administration: Administration Authors, Reviewers and Members of the Journal of the National Cancer Institute, HHS/NIH/NCI.
- 09-25-0105, Administration: Health Records of Employees, Visiting Scientists, Fellows, Contractors and Others who Receive Medical Care Through the Employee Health Unit, HHS/NIH/ORS.
- 09-25-0165, National Institutes of Health Loan Repayment Program, HHS/NIH/OD.
- 09-25-0166, Administration: Radiation and Occupational Safety and Health Management Information System, HHS/NIH/ORS.
- 09-25-0170, Diabetes Control and Complications Trial (DCCT) Data System, HHS/NIH/NIDDK.
- 09-25-0203, National Institute on Drug Abuse, Addiction Research Center, Federal Prisoner and Non-Prisoner Research Files, HHS/NIH/NIDA.
- 09-25-0207, Subject—Participants in Pharmacokinetic Studies on Drugs of Abuse and on Treatment Medications, HHS/NIH/NIDA.
- 09-25-0209, Subject—Participants in Drug Abuse Research Studies on Drug Dependence and in Research Supporting New Drug Applications, HHS/NIH/NIDA.

**B. System location.** The following systems have been updated to reflect a change in the system locations or location address. These changes do not affect the access by the individual to the individual's records.

- 09-25-0011, Clinical Research: Blood Donor Records, HHS/NIH/CC.
- 09-25-0012, Clinical Research: Candidate Normal Volunteer Records, HHS/NIH/CC.
- 09-25-0014, Clinical Research: Student Records, HHS/NIH/CC.
- 09-25-0042, Clinical Research: National Institute of Dental Research Patient Records, HHS/NIH/NIDR.
- 09-25-0044, Clinical Research: Sensory Testing Research Program, HHS/NIH/NIDR.
- 09-25-0054, Administration: Property Accounting, HHS/NIH/ORS.
- 09-25-0099, Clinical Research: Patient Medical Records, HHS/NIH/CC.
- 09-25-0102, Administration: Grants Associates Program Working Files, HHS/NIH/OER.
- 09-25-0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.
- 09-25-0118, Contracts: Professional Services Contractors, HHS/NIH/NCI.
- 09-25-0154, Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and (2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD.
- 09-25-0165, National Institutes of Health Loan Repayment Program, HHS/NIH/OD.
- 09-25-0166, Administration: Radiation and Occupational Safety and Health Management Information System, HHS/NIH/ORS.
- 09-25-0168, Invention, Patent and Licensing Documents Submitted to the Public Health Service by its Employees, Grantees, Fellowship Recipients and Contractors, HHS/PHS/NIH/OTT.
- 09-25-0170, Diabetes Control and Complications Trial (DCCT) Data System, HHS/NIH/NIDDK.
- 09-25-0202, Patient Records on PHS Beneficiaries (1935-1974) and Civilly Committed Drug Abusers (1967-1976) Treated at the PHS Hospitals in Fort Worth, Texas, or Lexington, Kentucky, HHS/NIH/NIDA.
- 09-25-0203, National Institute on Drug Abuse, Addiction Research Center, Federal Prisoner and Non-Prisoner Research Files, HHS/NIH/NIDA.
- 09-25-0209, Subject—Participants in Drug Abuse Research Studies on Drug Dependence and in Research Supporting New Drug Applications, HHS/NIH/NIDA.

**C. Categories of individuals covered by the system.** The following systems have been updated to reflect a change in the categories covered by the system. This change does not alter the character or purpose of the system.

- 09-25-0105, Administration: Health Records of Employees, Visiting Scientists, Fellows, Contractors and Others who Receive Medical Care Through the Employee Health Unit, HHS/NIH/ORS.
- 09-25-0154, Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and (2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD.

- 09-25-0165, National Institutes of Health Loan Repayment Program, HHS/NIH/OD.
- 09-25-0166, Administration: Radiation and Occupational Safety and Health Management Information System, HHS/NIH/ORS.
- 09-25-0170, Diabetes Control and Complications Trial (DCCT) Data System, HHS/NIH/NIDDK.
- 09-25-0207, Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse and on Treatment Medications, HHS/NIH/NIDA.

**D. Categories of records.** The following systems have been updated to reflect a change in the categories of records in the system. This change does not alter the character or purpose of the system.

- 09-25-0166, Administration: Radiation and Occupational Safety and Health Management Information System, HHS/NIH/ORS.
- 09-25-0170, Diabetes Control and Complications Trial (DCCT) Data System, HHS/NIH/NIDDK.

**E. Authority.** The following system has been updated to reflect a change in the authority. This change does not alter the character or purpose of the system.

- 09-25-0165, National Institutes of Health Loan Repayment Program, HHS/NIH/OD.

**F. Storage.** The following systems have been updated to reflect a change in system storage practices:

- 09-25-0026, Clinical Research: Nervous System Studies, HHS/NIH/NINDS.
- 09-25-0028, Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD.
- 09-25-0077, Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI.
- 09-25-0140, International Activities: International Scientific Researchers in Intramural Laboratories at the National Institutes of Health, HHS/NIH/FIC.
- 09-25-0166, Administration: Radiation and Occupational Safety and Health Management Information System, HHS/NIH/ORS.
- 09-25-0209, Subject-Participants in Drug Abuse Research Studies on Drug Dependence and in Research Supporting New Drug Applications, HHS/NIH/NIDA.

**G. Retrieval.** The following systems have been updated to reflect a change in retrieval practices.

- 09-25-0140, International Activities: International Scientific Researchers in Intramural Laboratories at the National Institutes of Health, HHS/NIH/FIC.
- 09-25-0142, Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA.
- 09-25-0203, National Institute on Drug Abuse, Addiction Research Center, Federal Prisoner and Non-Prisoner Research Files, HHS/NIH/NIDA.
- 09-25-0209, Subject-Participants in Drug Abuse Research Studies on Drug

Dependence and in Research Supporting New Drug Applications, HHS/NIH/NIDA.

**H. Safeguards.** The following systems have been updated to reflect a change in safeguard practices.

- 09-25-0028, Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD.
- 09-25-0093, Administration: Administration Authors, Reviewers and Members of the Journal of the National Cancer Institute, HHS/NIH/NCI.
- 09-25-0166, Administration: Radiation and Occupational Safety and Health Management Information System, HHS/NIH/ORS.
- 09-25-0207, Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse and on Treatment Medications, HHS/NIH/NIDA.
- 09-25-0209, Subject-Participants in Drug Abuse Research Studies on Drug Dependence and in Research Supporting New Drug Applications, HHS/NIH/NIDA.

**I. Retention and disposal.** The following systems have been updated to reflect a change in retention and disposal:

- 09-25-0152, Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR.
- 09-25-0207, Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse and on Treatment Medications, HHS/NIH/NIDA.
- 09-25-0209, Subject-Participants in Drug Abuse Research Studies on Drug Dependence and in Research Supporting New Drug Applications, HHS/NIH/NIDA.
- 09-25-0212, Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH.

**J. System manager(s) and address(es).** The following systems have been updated to reflect a change in the system manager or the address of the system manager. These changes do not affect the access by the individual to the individual's records.

- 09-25-0001, Clinical Research: Patient Records, HHS/NIH/NHLBI.
- 09-25-0005, Administration: Library Operations and User I.D. File, HHS/NIH/OD.
- 09-25-0011, Clinical Research: Blood Donor Records, HHS/NIH/CC.
- 09-25-0012, Clinical Research: Candidate Normal Volunteer Records, HHS/NIH/CC.
- 09-25-0014, Clinical Research: Student Records, HHS/NIH/CC.
- 09-25-0026, Clinical Research: Nervous System Studies, HHS/NIH/NINDS.
- 09-25-0028, Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD.
- 09-25-0042, Clinical Research: National Institute of Dental Research Patient Records, HHS/NIH/NIDR.
- 09-25-0044, Clinical Research: Sensory Testing Research Program, HHS/NIH/NIDR.

- 09-25-0054, Administration: Property Accounting, HHS/NIH/ORS.
- 09-25-0078, Administration: Consultant File, HHS/NIH/NHLBI.
- 09-25-0093, Administration: Administration Authors, Reviewers and Members of the Journal of the National Cancer Institute, HHS/NIH/NCI.
- 09-25-0099, Clinical Research: Patient Medical Records, HHS/NIH/CC.
- 09-25-0102, Administration: Grants Associates Program Working Files, HHS/NIH/OER.
- 09-25-0106, Administration: Office of the NIH Director and Institute/Center/Division Correspondence Records, HHS/NIH/OD.
- 09-25-0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.
- 09-25-0118, Contracts: Professional Services Contractors, HHS/NIH/NCI.
- 09-25-0126, Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI.
- 09-25-0128, Clinical Research: Neural Prosthesis and Biomedical Engineering Studies, HHS/NIH/NINDS.
- 09-25-0129, Clinical Research: Clinical Research Studies Dealing with Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/NIDCD.
- 09-25-0140, International Activities: International Scientific Researchers in Intramural Laboratories at the National Institutes of Health, HHS/NIH/FIC.
- 09-25-0148, Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological Disorders and Stroke and the National Institute on Deafness and Other Communication Disorders, HHS/NIH/NINDS and HHS/NIH/NIDCD.
- 09-25-0152, Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR.
- 09-25-0153, Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHHD.
- 09-25-0154, Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and (2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD.
- 09-25-0156, Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD.
- 09-25-0161, Administration: NIH Consultant File, HHS/NIH/DRG.
- 09-25-0166, Administration: Radiation and Occupational Safety and Health Management Information System, HHS/NIH/ORS.
- 09-25-0168, Invention, Patent and Licensing Documents Submitted to the Public Health Service by its Employees, Grantees, Fellowship Recipients and Contractors, HHS/PHS/NIH/OTT.
- 09-25-0170, Diabetes Control and Complications Trial (DCCT) Data System, HHS/NIH/NIDDK.

- 09-25-0202, Patient Records on PHS Beneficiaries (1935-1974) and Civilly Committed Drug Abusers (1967-1976) Treated at the PHS Hospitals in Fort Worth, Texas, or Lexington, Kentucky, HHS/NIH/NIDA.
- 09-25-0203, National Institute on Drug Abuse, Addiction Research Center, Federal Prisoner and Non-Prisoner Research Files, HHS/NIH/NIDA.
- 09-25-0205, Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/NIDA and HHS/NIH/NIMH.
- 09-25-0208, Drug Abuse Treatment Outcome Study (DATOS), HHS/NIH/NIDA.

**K. Record access.** The following systems have been updated to reflect a change in the record access procedures.

- 09-25-0012, Clinical Research: Candidate Normal Volunteer Records, HHS/NIH/CC.
- 09-25-0156, Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD.

**L. Notification procedures.** The following systems have been updated to reflect a change in the office, official, and/or address to write to in order to determine whether or not the system contains a record about the individual.

- 09-25-0042, Clinical Research: National Institute of Dental Research Patient Records, HHS/NIH/NIDR.
- 09-25-0044, Clinical Research: Sensory Testing Research Program, HHS/NIH/NIDR.
- 09-25-0078, Administration: Consultant File, HHS/NIH/NHLBI.
- 09-25-0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.
- 09-25-0152, Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR.
- 09-25-0153, Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHHD.
- 09-25-0156, Records of Participants in Programs and Respondents in Surveys Used To Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD.

**M.** The following systems have been changed for clarity and editing purposes.

- 09-25-0036, Extramural Awards and Chartered Advisory Committees: IMPAC (Grant/Contract/Cooperative Agreement/Chartered Advisory Committee, HHS/NIH/DRG and HHS/NIH/CMO).
- 09-25-0093, Administration: Administration Authors, Reviewers and Members of the Journal of the National Cancer Institute, HHS/NIH/NCI.
- 09-25-0154, Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and (2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD.

- 09-25-0165, National Institutes of Health Loan Repayment Program, HHS/NIH/OD.
- 09-25-0166, Administration: Radiation and Occupational Safety and Health Management Information System, HHS/NIH/ORS.
- 09-25-0168, Invention, Patent and Licensing Documents Submitted to the Public Health Service by its Employees, Grantees, Fellowship Recipients and Contractors, HHS/PHS/NIH/OTT.
- 09-25-0170, Diabetes Control and Complications Trial (DCCT) Data System, HHS/NIH/NIDDK.
- 09-25-0207, Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse and on Treatment Medications, HHS/NIH/NIDA.
- 09-25-0209, Subject-Participants in Drug Abuse Research Studies on Drug Dependence and in Research Supporting New Drug Applications, HHS/NIH/NIDA.
- 09-25-0212, Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH.

**N. Organization name change.** There are no changes in this category.

**O. Deleted systems of records.** The following systems of records which appeared in the December 29, annual publication are now being deleted because:

- 09-25-0100, Clinical Research: Neuropharmacology Studies, HHS/NIH/NINDS. The records have been destroyed.
- 09-25-0151, Administration: Public Health Service ALERT Records Concerning Individuals Under Investigation for Possible Misconduct In Science or Subject to Sanctions for Such Misconduct, HHS/PHS/OSR. The system has been officially transferred to the Office of the Assistant Secretary for Health (OASH), Office of Research Integrity (ORI).

The following is a list of active systems of records maintained by NIH. Table of Contents.

- 09-25-0001, Clinical Research: Patient Records, HHS/NIH/NHLBI, published **Federal Register**, Vol. 56, Number 247, December 24, 1991.
- 09-25-0005, Administration: Library Operations and User I.D. File, HHS/NIH/OD, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0007, Administration: NIH Safety Glasses Issuance Program, HHS/NIH/ORS, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0010, Research Resources: Registry of Individuals Potentially Exposed to Microbial Agents, HHS/NIH/NCI, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0011, Clinical Research: Blood Donor Records, HHS/NIH/CC, published **Federal Register**, Vol. 56, Number 247, December 24, 1991.
- 09-25-0012, Clinical Research: Candidate Normal Volunteer Records, HHS/NIH/CC, published, **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0014, Clinical Research: Student Records, HHS/NIH/CC, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.
- 09-25-0015, Clinical Research: Collaborative Clinical Epilepsy Research, HHS/NIH/NINDS, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.
- 09-25-0016, Clinical Research: Collaborative Perinatal Project HHS/NIH/NINDS, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0026, Clinical Research: Nervous System Studies, HHS/NIH/NINDS, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0028, Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD, published **Federal Register**, Vol. 58, No. 8, January 13, 1993.
- 09-25-0031, Clinical Research: Serological and Virus Data in Studies Related to the Central Nervous System, HHS/NIH/NINDS, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0033, International Activities: Fellowships Awarded by Foreign Organizations, HHS/NIH/FIC, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0034, International Activities: Scholars-in-Residence Program, HHS/NIH/FIC, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.
- 09-25-0035 International Activities: Health Scientist Exchange Programs, HHS/NIH/FIC, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0036, Extramural Awards and Chartered Advisory Committees: IMPAC (Grant/Contract/Cooperative Agreement/Chartered Advisory Committee, HHS/NIH/DRG and HHS/NIH/CMO, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0037, Clinical Research: The Baltimore Longitudinal Study of Aging, HHS/NIH/NIA, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0038, Clinical Research: Patient Data, HHS/NIH/NIDDK, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0039, Clinical Research: Diabetes Mellitus Research Study of Southwestern American Indians, HHS/NIH/NIDDK, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0040, Clinical Research: Southwestern American Indian Patient Data, HHS/NIH/NIDDK, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0041, Research Resources: Scientists Requesting Hormone Distribution, HHS/NIH/NIDDK, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.
- 09-25-0042, Clinical Research: National Institute of Dental Research Patient Records, HHS/NIH/NIDR, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0044, Clinical Research: Sensory Testing Research Program, HHS/NIH/NIDR, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0046, Clinical Research: Catalog of Clinical Specimens from Patients,

- Volunteers and Laboratory Personnel, HHS/NIH/NIAID, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0053, Clinical Research: Vision Studies, HHS/NIH/NEI, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0054, Administration: Property Accounting, HHS/NIH/ORS, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0057, Clinical Research: Burkitt's Lymphoma Registry, HHS/NIH/NCI, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.
- 09-25-0060, Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0067, Clinical Research: National Cancer Incidence Surveys, HHS/NIH/NCI, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.
- 09-25-0069, NIH Clinical Center Admissions of the National Cancer Institute, HHS/NIH/NCI, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0074, Clinical Research: Division of Cancer Biology and Diagnosis Patient Trials, HHS/NIH/NCI, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.
- 09-25-0077, Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0078, Administration: Consultant File, HHS/NIH/NHLBI, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.
- 09-25-0087, Administration: Senior Staff, HHS/NIH/NIAID, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0091, Administration: General Files on Employees, Donors and Correspondents, HHS/NIH/NEI, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0093, Administration: Administration Authors, Reviewers and Members of the Journal of the National Cancer Institute, HHS/NIH/NCI, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.
- 09-25-0099, Clinical Research: Patient Medical Records, HHS/NIH/CC, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0102, Administration: Grants Associates Program Working Files, HHS/NIH/OER, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.
- 09-25-0105, Administration: Health Records of Employees, Visiting Scientists, Fellows, Contractors and Relatives of Inpatients, HHS/NIH/ORS, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0106, Administration: Office of the NIH Director and Institute/Center/Division Correspondence Records, HHS/NIH/OD, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0108, Personnel: Guest Researchers, Special Volunteers, and Scientists Emeriti, HHS/NIH/OHRM, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.

- 09-25-0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0115, Administration: Curricula Vitae of Consultants and Clinical Investigators, HHS/NIH/NIAID, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0118, Contracts: Professional Services Contractors, HHS/NIH/NCI, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0121, International Activities: Senior International Fellowships Program, HHS/NIH/FIC, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0124, Administration: Pharmacology Research Associates, HHS/NIH/NIGMS, published **Federal Register**, Vol. 58, No. 8, January 13, 1993.
- 09-25-0126, Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI, published **Federal Register**, Vol. 58, No. 8, January 13, 1993.
- 09-25-0128, Clinical Research: Neural Prosthesis and Biomedical Engineering Studies, HHS/NIH/NINDS, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0129, Clinical Research: Clinical Research Studies Dealing with Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/NIDCD, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0130, Clinical Research: Studies in the Division of Cancer Cause and Prevention, HHS/NIH/NCI, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.
- 09-25-0134, Clinical Research: Epidemiology Studies, National Institute of Environmental Health Sciences, HHS/NIH/NIEHS, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0140, International Activities: International Scientific Researchers in Intramural Laboratories at the National Institutes of Health, HHS/NIH/FIC, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0142, Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA, published **Federal Register**, Vol. 58, No. 8, January 13, 1993.
- 09-25-0143, Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0145, Clinical Trials and Epidemiological Studies Dealing with Visual Disease and Disorders in the National Eye Institute, HHS/NIH/NEI, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0148, Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological Disorders and Stroke and the National Institute on Deafness and Other Communication Disorders, HHS/NIH/NINDS and HHS/NIH/NIDCD, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0152, Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR, published **Federal Register**, Vol. 58, No. 8, January 13, 1993.
- 09-25-0153, Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHHD, published **Federal Register**, Vol. 58, No. 8, January 13, 1993.
- 09-25-0154, Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and (2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD, published **Federal Register**, Vol. 58, Number 8, January 13, 1993.
- 09-25-0156, Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0158, Administration: Records of Applicants and Awardees of the NIH Intramural Research Training Awards Program, HHS/NIH/OD, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0160, United States Renal Data System (USRDS), HHS/NIH/NIDDK published **Federal Register**, Vol. 56, No. 8, January 11, 1991.
- 09-25-0161, Administration: NIH Consultant File, HHS/NIH/DRG, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0165, National Institutes of Health Loan Repayment Program, HHS/NIH/OD, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0166, Administration: Radiation and Occupational Safety and Health Management Information System, HHS/NIH/ORS, published **Federal Register**, Vol. 56, No. 247, December 24, 1991.
- 09-25-0167, National Institutes of Health (NIH) Transshare Program, HHS/NIH/OD, published **Federal Register**, Vol. 57, No. 171, September 2, 1992.
- 09-25-0168, Invention, Patent and Licensing Documents Submitted to the Public Health Service by its Employees, Grantees, Fellowship Recipients and Contractors, HHS/PHS/NIH/OTT, published **Federal Register**, Vol. 58, No. 164, August 26, 1993.
- 09-25-0169, Medical Staff Credentials Files, HHS/NIH/CC, published **Federal Register**, Vol. 59, No. 207, October 27, 1994.
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- 09-25-0205, Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/NIDA and HHS/NIH/NIMH, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0207, Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse and on Treatment Medications, HHS/NIH/NIDA, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0208, Drug Abuse Treatment Outcome Study (DATOS), HHS/NIH/NIDA, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0209, Subject-Participants in Drug Abuse Research Studies on Drug Dependence and in Research Supporting New Drug Applications, HHS/NIH/NIDA, published **Federal Register**, Vol. 58, No. 8, January 13, 1993.
- 09-25-0210, Shipment Records of Drugs of Abuse to Authorized Researchers, HHS/NIH/NIDA, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0211, Intramural Research Program Records of In- and Out-Patients with Various Types of Alcohol Abuse and Dependence, Relatives of Patients With Alcoholism, and Healthy Volunteers, HHS/NIH/NIAAA, published **Federal Register**, Vol. 58, No. 248, December 29, 1993.
- 09-25-0212, Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH, published **Federal Register**, Vol. 58, No. 8, January 13, 1993.

Dated: January 10, 1995.

**Cdr. Cheryl A. Seaman,**

*Acting Director, Division of Management Support, OMA, OA, OD, National Institutes of Health.*

**09-25-0001**

**SYSTEM NAME:**

Clinical Research: Patient Records, HHS/NIH/NHLBI.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

National Institutes of Health, Building 10, 9000 Rockville Pike, Bethesda, MD 20892

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Patients of the National Heart, Lung, and Blood Institute (NHLBI) under study at the National Institutes of Health (NIH).

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical histories, diagnostic studies, laboratory data, treatment.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

42 USC 241(e), 287, 287a.

**PURPOSE(S):**

(1) For use by physicians in evaluation and treatment of patients under study at NIH. (2) To furnish patient data to patients, their families, and with patients' consent, to their private physicians.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Clinical research data are made available to approved or collaborating researchers, including HHS contractors and grantees.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

4. (a). PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS

employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

(b). PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:****STORAGE:**

File folders, card index, laboratory books, computer memory.

**RETRIEVABILITY:**

Indexed by name or patient number.

**SAFEGUARDS:**

Measures to prevent unauthorized disclosures are implemented as appropriate for each location. Each site implements personnel, physical, and procedural safeguards such as the following:

1. *Authorized users:* Employees who maintain records in this system are instructed to grant regular access only to authorized physicians and their assistants.

2. *Physical safeguards:* Records are kept in secure locked metal or wood file cabinets and, in some instances, in locked offices.

3. *Procedural safeguards:* Access to files is strictly controlled by files staff. Access to computerized records is controlled by keyword codes available only to authorized users.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—

"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific conditions on disposal.

**SYSTEM MANAGER(S) AND ADDRESS:**

Administrative Officer, Division of Intramural Research, National Heart, Lung, and Blood Institute, 10/7N220, 10 Center Drive, MSC 1670, Bethesda, MD 20892-1670

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact: National Institutes of Health, Privacy Act Coordinator, NHLBI, Building 31, Room 5A08, 9000 Rockville Pike, Bethesda, MD 20892.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORDS ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Contact the official under notification procedures above, and specify the information to be contested, the corrective action sought, and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Referring physicians, hospitals and medical centers, patients and families, results of procedures and tests of NIH patients.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0005****SYSTEM NAME:**

Administration: Library Operations and User I.D. File, HHS/NIH/OD.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

This system of records is an umbrella system comprising separate sets of

records located in National Institutes of Health (NIH) facilities in Bethesda, Maryland, or facilities of contractors of the NIH. Write to the appropriate system manager listed below for list of current contractor locations.

National Institutes of Health, Building 10, Room 1L07, 9000 Rockville Pike, Bethesda, MD 20892

and

National Institutes of Health, Building 12A, Room 3018, 9000 Rockville Pike, Bethesda, MD 20892

and

National Institutes of Health, Building 38, Room 1S33, 8600 Rockville Pike, Bethesda, MD 20894

and

National Institutes of Health, Building 38, Room 1N21, 8600 Rockville Pike, Bethesda, MD 20894

and

National Institutes of Health, Building 38, Room B1E21, 8600 Rockville Pike, Bethesda, MD 20894

and

National Institutes of Health, Building 38A, Room 4N419, 8600 Rockville Pike, Bethesda, MD 20894

and

National Technical Information Service, Accounting Department, 8001 Forbes Place, Room 208F, Springfield, Virginia 22151

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Users of Library Services.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Name, organization, address, phone number, user code and identification number; and when applicable, credit card number and billing information.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 301 of the Public Health Service Act, describing the general powers and duties of the Public Health Service relating to research and investigation (42 U.S.C. 241).

**PURPOSES**

(1) To monitor library material, services, and circulation control; (2) to provide user documentation; (3) to provide copying services (duplication of library materials); and (4) to manage invoice and billing transactions for library services.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the government party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

3. Disclosure may be made to contractors and staff to monitor library material, services, circulation control; to provide user documentation; and to process or refine the records. Recipients are required to maintain Privacy Act safeguards with respect to those records.

4. Disclosure may be made for billing purposes to: (a) Contractors providing copying services; and (b) NTIS for Medlars Services.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored on computer tape and disc, microfiche, paper and file cards.

**RETRIEVABILITY:**

Records are retrieved by name, user code and/or identification number.

**SAFEGUARDS:**

1. *Authorized users:* Employees who maintain records in this system are instructed to grant regular access only to Library staff members who need to verify that Library identification cards have been issued to those Library users requesting services such as MEDLINE and other computer online bibliographic searches, translations and interlibrary loans. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager. The contractor maintains a list of personnel having authority to access records to perform their duties.

2. *Physical safeguards:* The offices housing the cabinets and file drawers for storage of records are locked during all library off-duty hours. During all duty hours offices are attended by employees who maintain the files. The contractor has secured records storage areas which are not left unattended during the working hours and file cabinets which are locked after hours.

3. *Procedural safeguards:* Access to the file is strictly controlled by employees who maintain the files. Records may be removed from files only at the request of the system manager or other authorized employees. Access to computerized records is controlled by the use of security codes known only to authorized users. Contractor personnel receive instruction concerning the significance of safeguards under the Privacy Act.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 8000-D-2, which allows records to be kept until superseded or for a maximum period of 6 years. Refer to the NIH Manual Chapter for specific conditions on disposal.

**SYSTEM MANAGER(S) AND ADDRESS:**

The Policy Coordinating Official for this system is the Management Analyst, Office of Administration, National Library of Medicine; Building 38, Room 2N21; 8600 Rockville Pike; Bethesda, MD 20894.

Chief, Reference and Bibliographic Services Section, Library Branch, National Center for Research Resources, National Institutes of Health, Building 10, Room 1L21, 9000 Rockville Pike, Bethesda, MD 20892

and  
Chief, Division of Computer Research and Technology Library, National Institutes of Health, Building 12A, Room 3018, 9000 Rockville Pike, Bethesda, MD 20892

and  
Supervisory Librarian, Preservation and  
Collection Management Section,  
Public Services Division, Library  
Operations, National Library of  
Medicine, National Institutes of  
Health, Building 38, Room B1E21,  
8600 Rockville Pike, Bethesda, MD  
20894

and  
Chief, Public Services Division, Library  
Operations, National Library of  
Medicine, National Institutes of  
Health, Building 38, Room 1S33, 8600  
Rockville Pike, Bethesda, MD 20894

and  
Head, Prints and Photographs  
Collection, History of Medicine  
Division, NLM, NIH, Building 38,  
Room 1N21, 8600 Rockville Pike,  
Bethesda, MD 20894

and  
Chief, Medlars Management Section,  
Bibliographic Services Division,  
Library Operations, National  
Institutes of Health, National Library  
of Medicine, Building 38A, Room  
4N419, 8600 Rockville Pike, Bethesda,  
MD 20894

**NOTIFICATION PROCEDURE:**

Write to the System Manager to  
determine if a record exists. The  
requester must also verify his or her  
identity by providing either a  
notarization of the request or a written  
certification that the requester is who he  
or she claims to be and understands that  
the knowing and willful request for  
acquisition of a record pertaining to an  
individual under false pretenses is a  
criminal offense under the Act, subject  
to a five thousand dollar fine.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures.  
Requesters should also reasonably  
specify the record contents being  
sought. Individuals may also request an  
accounting of disclosures that have been  
made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Write to the official at the address  
specified under notification procedures  
above, and reasonably identify the  
record and specify the information to be  
contested, the corrective action sought,  
and the reasons for the correction, along  
with supporting information to show  
how the record is inaccurate,  
incomplete, untimely, or irrelevant. The  
right to contest records is limited to  
information which is incomplete,  
irrelevant, incorrect, or untimely  
(obsolete).

**RECORD SOURCE CATEGORIES:**

Individual, NIH Library ID card data.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS  
OF THE ACT:**

None.

**09-25-0011**

**SYSTEM NAME:**

Clinical Research: Blood Donor  
Records, HHS/NIH/CC.

**SECURITY CLASSIFICATION:**

None

**SYSTEM LOCATION:**

National Institutes of Health,  
Transfusion Medicine Department, 10  
Center Drive MSC 1184, Bethesda,  
MD 20892-1184

**CATEGORIES OF INDIVIDUALS COVERED BY THE  
SYSTEM:**

Donors of blood and blood  
components to be used in the NIH  
Clinical Center for patient infusions.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Past donations, blood types,  
phenotypes. Laboratory results of  
hepatitis testing, serologic reactions on  
all blood samples, donations of blood or  
blood components.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Preparation of Biological Products"  
of the Public Health Service Act (42  
U.S.C. 263).

**PURPOSE(S):**

(1) To provide a means for contacting  
blood donors for patient care and  
research. (2) To provide a medical  
history of all donors for the transfusion  
records of each blood unit.

**ROUTINE USES OF RECORDS MAINTAINED IN THE  
SYSTEM, INCLUDING CATEGORIES OF USERS AND  
THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to HHS  
contractors and their staff in order to  
accomplish the purposes for which the  
records are collected. The recipients are  
required to comply with the  
requirements of the Privacy Act with  
respect to such records.

2. Certain diseases and conditions,  
including infectious diseases, may be  
reported to State or Federal government  
as required by State or Federal law.

3. Disclosure may be made to a  
congressional office from the record of  
individual in response to an inquiry  
from the congressional office made at  
the request of that individual.

4. In the event of litigation where the  
defendant is (a) the Department, any  
component of the Department, or any  
employee of the Department in his or  
her official capacity; (b) the United  
States where the Department determines  
that claim, if successful, is likely to  
directly affect the operations of the

Department or any of its components; or  
(c) any Department employee in his or  
her individual capacity where the  
Justice Department has agreed to  
represent such employee, for example in  
defending against a claim based upon an  
individual's mental or physical  
condition and alleged to have arisen  
because of activities of the Public Health  
Service in connection with such  
individual, the Department may  
disclose such records as it deems  
desirable or necessary to the Department  
of Justice or other appropriate Federal  
agency to enable that agency to present  
an effective defense, provided that such  
disclosure is compatible with the  
purpose for which the records were  
collected.

5. (a). PHS may inform the sexual  
and/or needle-sharing partner(s) of a  
subject individual who is infected with  
the human immunodeficiency virus  
(HIV) of their exposure to HIV, under  
the following circumstances: (1) The  
information has been obtained in the  
course of clinical activities at PHS  
facilities carried out by PHS personnel  
or contractors; (2) The PHS employee or  
contractor has made reasonable efforts  
to counsel and encourage the subject  
individual to provide the information to  
the individual's sexual or needle-  
sharing partner(s); (3) The PHS  
employee or contractor determines that  
the subject individual is unlikely to  
provide the information to the sexual or  
needle-sharing partner(s) or that the  
provision of such information cannot  
reasonably be verified; and (4) The  
notification of the partner(s) is made,  
whenever possible, by the subject  
individual's physician or by a  
professional counselor and shall follow  
standard counseling practices.

(b). PHS may disclose information to  
State or local public health departments,  
to assist in the notification of the subject  
individual's sexual and/or needle-  
sharing partner(s), or in the verification  
that the subject individual has notified  
such sexual or needle-sharing partner(s).

**POLICIES AND PRACTICES FOR STORING,  
RETRIEVING, ACCESSING, RETAINING, AND  
DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in a computer file,  
on donor cards, and on microfilm.

**RETRIEVABILITY:**

Records are retrieved by a unique  
control number assigned to each  
individual donor.

**SAFEGUARDS:**

Access is granted only to authorized  
employees in the Department of  
Transfusion Medicine including

physicians, nurses, technologists, computer operators, and the department's administrative officer.

1. *Authorized users:* Access is granted only to authorized employees of the Department of Transfusion Medicine including physicians, nurses, technologists, computer operators and the secretary to the Chief.

2. *Physical safeguards:* Record facilities are locked when system personnel are not present.

3. *Procedural safeguards:* Access to manual files is limited to authorized users. Access to computerized records is controlled by the use of security codes known only to the authorized users.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

#### RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the HIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-E-50. Refer to the NIH Manual Chapter for specific conditions on disposal.

#### SYSTEM MANAGER AND ADDRESS:

Chief, Transfusion Medicine Department, National Institutes of Health, 10 Center Drive MSC 1184, Bethesda, MD 20892-1184.

#### NOTIFICATION PROCEDURE:

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

#### RECORD ACCESS PROCEDURE:

To obtain access to a record, contact the system manager at the address specified above. Requestors should provide the same information as is required under the notification procedures above. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

#### CONTESTING RECORD PROCEDURE:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

#### RECORD SOURCE CATEGORIES:

Data are collected from the individual.

#### SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

#### 09-25-0012

#### SYSTEM NAME:

Clinical Research: Candidate Normal Volunteer Records, HHS/NIH/CC.

#### SECURITY CLASSIFICATION:

None.

#### SYSTEM LOCATION:

National Institutes of Health, Social Work Department, 10 Center Drive MSC 1160, Bethesda, MD 20892-1160.

#### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Normally healthy individuals who volunteer to participate in NIH studies.

#### CATEGORIES OF RECORDS IN THE SYSTEM:

Program application, health questionnaire and record of participation.

#### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, 263.

#### PURPOSE(S) OF THE SYSTEM:

(1) To determine suitability for participation in the normal volunteer program, (2) to document remuneration of normal volunteers, (3) to provide a record of participation to be used (a) in writing letters of recommendation/reference for the volunteer, and (b) preparing reports on the normal volunteer program.

#### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Clinical research data are made available to approved or collaborating researchers, including HHS contractors and grantees.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

3. Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

4. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

#### POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

##### STORAGE:

Program applications and health questionnaires are stored in file folders. Records of participation are stored on index cards.

##### RETRIEVABILITY:

Records are retrieved by name.

##### SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, procedural safeguards such as the following:

1. *Authorized users:* Access is granted only to the Normal Volunteer Program staff and to NIH physicians who have requested the recruitment of volunteers for their clinical research projects.

2. *Physical safeguards:* Access to the files is strictly controlled by the files staff. Records may be removed from the file only at the request of the system manager or other authorized employees. Record facilities are locked when system personnel are not present.

3. *Procedural safeguards:* Access to the files is strictly controlled by the files staff. Records may be removed from the file only at the request of the system manager or other authorized employees.

##### RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-E-61, which allows records to be kept until

superseded for a maximum period of 3 years. Refer to the NIH Manual Chapter for specific conditions on disposal.

**SYSTEM MANAGER AND ADDRESS:**

Chief, Social Work Department,  
National Institutes of Health, Social  
Work Department, 10 Center Drive  
MSC 1160, Bethesda, MD 20892-  
1160.

**NOTIFICATION PROCEDURES:**

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

**RECORD ACCESS PROCEDURE:**

To obtain access to a record, contact: Chief, Social Work Department, National Institutes of Health, Social Work Department, 10 Center Drive MSC 1160, Bethesda, MD 20892-1160 and provide the information described under Notification Procedures above. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Write to the official at the address specified under notification procedures above, and reasonably identify the record and specify the information to be contested, the corrective action sought, and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Volunteer, sponsoring contractor.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0014**

**SYSTEM NAME:**

Clinical Research: Student Records,  
HHS/NIH/CC.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

National Institutes of Health, Office of Education, 10 Center Drive MSC 1158, Bethesda, MD 20892-1158.

Write to the system manager at the address below for the address of any Federal Records Center where records from this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Potential and accepted Medical Staff and Research Fellows, medical students, and other students in NIH training programs.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Application form, transcripts, references, evaluations.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

42 U.S.C. 241.

**PURPOSE(S):**

(1) To identify candidates for Medical Staff and Research Fellow, clinical elective, and other training positions. (2) To maintain a permanent record of those individuals who have received clinical research training at the NIH for historical and reference uses.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Information may be used to respond to congressional inquiries for constituents concerning admission to the program.  
2. Information may be used to respond to prospective future employers of these individuals who wish to confirm their presence at NIH.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders.

**RETRIEVABILITY:**

Records are retrieved by name and year.

**SAFEGUARDS:**

Measures to prevent unauthorized disclosures are implemented as

appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, procedural safeguards such as the following:

1. *Authorized users:* Employees who maintain records in this system are instructed to grant regular access only to health care personnel of the NIH who are involved in the evaluation and selection of training candidates.

2. *Physical safeguards:* Records are maintained in locked cabinets with access limited to authorized personnel, including the systems manager and staff of the Normal Volunteer Program.

3. *Procedural safeguards:* Access to the files is strictly controlled by the files staff. Records may be removed from the file only at the request of the system manager or other authorized employees.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—“Keeping and Destroying Records” (HHS Records Management Manual, Appendix B-361), items 2300-320-1-13, which allows records to be kept up to a maximum period of 10 years. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Director, Office of Education, National Institutes of Health, 10 Center Drive MSC 1158, Bethesda, MD 20892-1158.

**NOTIFICATION PROCEDURE:**

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

**RECORD ACCESS PROCEDURE:**

To obtain access to a record, contact the system manager at the above address and provide the information described under Notification Procedures above. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Write to the system manager at the address specified above, and reasonably identify the record and specify the information to be contested, the

corrective action sought, and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Applicants, universities and teachers.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0026**

**SYSTEM NAME:**

Clinical Research: Nervous System Studies, HHS/NIH/NINDS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Building 36, Room 5B20, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

Write to the system manager at the address below for the address of any Federal Records Center where records from this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Research patients in NIH-related studies having nervous system disorders.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical and demographic data.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

42 U.S.C. 241, 289a, 289c.

**PURPOSE(S):**

Clinical research by HHS scientists on patients with special diseases of the nervous system, with particular emphasis on those diseases known or thought to be caused by slow or latent viruses.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Clinical research data are made available to approved or collaborating researchers, including HHS contractors and grantees.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

3. Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center. In the event of litigation where the defendant is: (a) The Department, any component of the Department, or any employee of the

Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:****STORAGE:**

Records are stored in file folders, in computer-accessible forms, bound notebooks, graphs, and imaging films.

**RETRIEVABILITY:**

Records are retrieved by name, disease and attending physician name.

**SAFEGUARDS:**

1. *Authorized users:* Employees who maintain records in this system are instructed to grant access only to scientists on the staff of the Central Nervous System Studies Laboratory and their assistants.

2. *Physical safeguards:* Records are kept in a locked location.

3. *Procedural safeguards:* Personnel having access to system are informed of Privacy Act requirements.

This system of records will be protected according to the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual,

Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Assistant Director, CNP, DIR, NINDS, NIH, Building 10, Room 5N226, 9000 Rockville Pike, Bethesda, MD 20892.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact: Chief, Administrative Services Branch, NINDS, Building 31, Room 8A49, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record and specify the information to be contested. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Attending physicians.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0028**

**SYSTEM NAME:**

Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Building 10, Building 31, and Building 36, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

Write to the system manager at the address below for the address of any Federal Records Center where records from this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Past and present patients of the National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute on Deafness and Other Communication Disorders (NIDCD), and individuals being referred for admission to the NIH Clinical Center.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical histories and diagnoses.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

42 U.S.C. 241, 289a, 289c.

**PURPOSE(S):**

Clinical research on various diseases of the nervous system and hearing, hearing loss, and communication disorders by HHS scientists and their authorized collaborators, with the specific aim of improving patient care and treatment by evaluating therapeutic procedures.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Clinical research data are made available to approved or collaborating researchers, including HHS contractors and grantees. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

2. Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

3. In the event of litigation where the defendant is: (a) The Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such

individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:****STORAGE:**

Records are stored in file folders and in computer-accessible forms, bound notebooks, charts, graphs, and imaging films.

**RETRIEVABILITY:**

Records are retrieved by name.

**SAFEGUARDS:**

1. *Authorized users:* Employees who maintain records in this system are instructed to grant access only to HHS researchers and their authorized collaborators.

2. *Physical safeguards:* Records are kept locked in file cabinets when not in use and in locations which are locked during non-working hours. Data stored in computer-accessible form is accessed through the use of codes and key words known only to principal investigators or authorized personnel.

3. *Procedural safeguards:* Records are returned to the files at the close of each working day and are used only in the system location or in a designated work area.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Assistant Director, Clinical Neurosciences Program, Building 10, Room 5N226, NIH, 9000 Rockville Pike, Bethesda, MD 20892

and

Acting Director of Intramural Research, NIDCD, Building 31, Room 3C02, NIH, 9000 Rockville Pike, Bethesda, MD 20892

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact:

Chief, Administrative Services Branch, NINDS, Building 31, Room 8A49, NIH, 9000 Rockville Pike, Bethesda, MD 20892

or

Chief, Administrative Management Branch, NIDCD, Building 31, Room 3C21, NIH, 9000 Rockville Pike, Bethesda, MD 20892

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine. An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record and specify the information to be contested, the corrective action sought, and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Referring and attending physicians, hospital records.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

09-25-0036

**SYSTEM NAME:**

Extramural Awards and Chartered Advisory Committees: IMPAC (Grant/Contract/Cooperative Agreement Information/Chartered Advisory Committee Information), HHS/NIH/DRG and HHS/NIH/CMO.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892, and Building 12, NIH Computer Center, 9000 Rockville Pike, Bethesda, MD 20892.

For information pertaining to the chartered advisory committees of the National Institutes of Health: Building 31, Room 3B-55, 9000 Rockville Pike, Bethesda, MD 20892.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicant and Principal Investigators; Program Directors; NRSA Trainees and Fellows; Research Career Awardees; and Chartered Advisory Committee members.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Applications, awards, associated records, trainee appointments, and current and historical information pertaining to chartered advisory committees.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

42 U.S.C. 241c, 58 Stat. 691c & d repealed.

**PURPOSE(S):**

(1) To support centralized grant programs of the Public Health Service. Services are provided in the areas of grant application assignment and referral, initial review, council review, award processing and grant accounting. The data base is used to provide complete, accurate, and up-to-date reports to all levels of management.

(2) To maintain communication with former fellows and trainees who have incurred a payback obligation through the National Research Service Award Program.

(3) To maintain current and historical information pertaining to the establishment of chartered advisory committees of the National Institutes of Health and the appointment or designation of their members.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to the National Technical Information Service (NTIS), Department of Commerce, for dissemination of scientific and fiscal information on funded awards (abstract of research projects and relevant administrative and financial data).

2. Disclosure may be made to the cognizant audit agency for auditing.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. Disclosure may be made to qualified experts not within the definition of Department employees as prescribed in Department Regulations for opinions as a part of the application review process.

5. Disclosure may be made to a Federal agency, in response to its request, in connection with the letting of a contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision in the matter.

6. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

7. The Department contemplates that it may contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to maintain Privacy Act safeguards with respect to such records.

8. Disclosure may be made to the grantee institution in connection with performance or administration under the conditions of the award.

9. Disclosure may be made to the Department of Justice, or to a court or other tribunal, from this system of records when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:****STORAGE:**

Records are stored on discs and magnetic tapes.

**RETRIEVABILITY:**

Records are retrieved by name, application, grant or contract ID number.

**SAFEGUARDS:**

1. *Authorized users:* Employees who maintain records in this system are instructed to grant regular access only to PHS extramural and committee management staff. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. *Physical safeguards:* Physical access to DRG work areas is restricted to DRG employees.

3. *Procedural safeguards:* Access to source data is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employee. Access to computer files is controlled by the use of registered accounts, registered initials, keywords, etc. The computer system maintains an audit record of all attempted and successful requests for access.

These practices are in compliance with the standards of Chapter 45-13 of

the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 4000-A-2, which allows records to be destroyed when no longer needed for administrative purposes. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Information Systems Branch,  
Division of Research Grants,  
Westwood Building, 5333 Westbard  
Avenue, Bethesda, MD 20892  
and

For chartered advisory committees of  
the National Institutes of Health:  
NIH Committee Management Officer,  
Building 31, Room 3B-55, 9000  
Rockville Pike, Bethesda, MD 20892.

**NOTIFICATION PROCEDURE:**

To determine if a record exists write to:  
Privacy Act Coordinator, Division of  
Research Grants, Westwood Building,  
Room 449, 5333 Westbard Avenue,  
Bethesda, MD 20892  
and

For information pertaining to the  
chartered advisory committees of the  
National Institutes of Health:  
NIH Committee Management Officer,  
Building 31, Room 3B-55, 9000  
Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or  
her identity by providing either a  
notarization of the request or a written  
certification that the requester is who he  
or she claims to be and understands that  
the knowing and willful request for  
acquisition of a record pertaining to an  
individual under false pretenses is a  
criminal offense under the Act, subject  
to a five thousand dollar fine.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures.  
Requesters should also reasonably  
specify the record contents being  
sought. Individuals may also request

listings of accountable disclosures that  
have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Contact the official under notification  
procedures above, and reasonably  
identify the record and specify the  
information to be contested, and state  
the corrective action sought and the  
reasons for the correction, with  
supporting justification. The right to  
contest records is limited to information  
which is incomplete, irrelevant,  
incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Individual, individual's educational  
institution and references.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS  
OF THE ACT:**

None.

**09-25-0042**

**SYSTEM NAME:**

Clinical Research: National Institute  
of Dental Research Patient Records,  
HHS/NIH/NIDR.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

National Institutes of Health, Building  
10, Room 1B01, 10 Center Drive MSC  
1190, Bethesda, MD 20892-1190.

Write to system manager at the  
address below for the address of the  
Federal Records Center where records  
from this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE  
SYSTEM:**

Patients and other participants in  
current and past research projects of the  
National Institute of Dental Research  
(NIDR).

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical and dental histories, dental  
pathologies and therapies.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Sections 301, 401, 405 and 453 of the  
Public Health Service Act (42 U.S.C.  
241, 281, 284, 285h). These sections  
establish the National Institute of Dental  
Research and authorize the conduct and  
support of dental oral research and  
related activities.

**PURPOSE(S):**

(1) To record the diagnosis and  
treatment of patients with diseases of  
the mouth, tongue, teeth and  
surrounding tissues; (2) To record the  
normal condition of the mouth, tongue,  
teeth and surrounding tissues of  
individuals referred to the dental clinic;  
(3) To provide clinical data for research

into the etiology, treatment and  
prevention of oral diseases; (4) For  
review and planning of the NIDR  
clinical program.

**ROUTINE USES OF RECORDS MAINTAINED IN THE  
SYSTEM, INCLUDING CATEGORIES OF USERS AND  
THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to HHS  
contractors, grantees and collaborating  
researchers and their staff in order to  
accomplish the clinical and research  
purposes for which the records are  
collected. The recipients are required to  
maintain Privacy Act safeguards with  
respect to these records.

2. Certain diseases and conditions,  
including infectious diseases, may be  
reported to appropriate representatives  
of State or Federal Government as  
required by State or Federal law.

3. Information may be used to  
respond to congressional inquiries for  
constituents concerning admission to  
the NIH Clinical Center.

4. In the event of litigation where the  
defendant is (a) the Department, any  
component of the Department, or any  
employee of the Department in his or  
her official capacity; (b) the United  
States where the Department determines  
that the claim, if successful, is likely to  
directly affect the operations of the  
Department or any of its components; or  
(c) any Department employee in his or  
her individual capacity where the  
Justice Department has agreed to  
represent such employee, for example,  
when a claim is based upon an  
individual's mental or physical  
condition and is alleged to have arisen  
because of activities of the Public Health  
Service in connection with such  
individual, the Department may  
disclose such records as it deems  
desirable or necessary to the Department  
of Justice to enable that Department to  
present an effective defense, provided  
that such disclosure is compatible with  
the purpose for which the records were  
collected.

**POLICIES AND PRACTICES FOR STORING,  
RETRIEVING, ACCESSING, RETAINING, AND  
DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders.

**RETRIEVABILITY:**

Records are retrieved by name and  
hospital ID number.

**SAFEGUARDS:**

Measures to prevent unauthorized  
disclosures are implemented as  
appropriate for each location and for the  
particular records maintained in each  
project. Each site implements personnel,  
physical, and procedural safeguards  
such as the following:

1. *Authorized users:* Employees who maintain records in this system are instructed to grant regular access only to dentists, physicians, dental hygienists, dental assistants and other health care personnel involved in the care and treatment of patients in the NIDR dental clinic, and to referring professionals. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. *Physical safeguards:* Records are stored in a cabinet which is locked at all times when not in use.

3. *Procedural safeguards:* Access is controlled by clerical staff of the Dental Clinic during clinic hours, and by the Officer of the Day when the clinic is closed.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER(S) AND ADDRESS:**

National Institutes of Health, Deputy Clinical Director, NIDR, Building 10, Room 1N-113, 10 Center Drive MSC 1190, Bethesda, MD 20892-1190

**NOTIFICATION PROCEDURE:**

To determine if a record exists contact:  
NIDR Privacy Act Coordinator, Building 31, Room 2C-35, 10 Center Drive MSC 1190, Bethesda, MD 20892-1190.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine. An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or

other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Individual, parents or guardians.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0044**

**SYSTEM NAME:**

Clinical Research: Sensory Testing Research Program, HHS/NIH/NIDR.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

National Institutes of Health, Building 10, Room 1-N-114, 10 Center Drive, MSC 1190, Bethesda, MD 20892-1190.

Write to System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Infants, children and adults participating in the Sensory Testing Research Program of the National Institute of Dental Research (NIDR).

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Test results, extracts from medical records.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Sections 301, 401, 405 and 453 of the Public Health Service Act (42 U.S.C. 241, 281, 284, 285h). These sections establish the National Institute of Dental Research and authorize the conduct and support of dental and oral research and related activities.

**PURPOSE(S)**

(1) To record the medical/dental histories of individuals participating in the Sensory Testing Research Program; (2) To record the results of chemosensory tests of individuals participating in the Sensory Testing Research Program; (3) For research on sensitivity to oral nasal stimulation; (4) For review and planning of the Clinical Investigations and Patient Care Branch program.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to HHS contractors, grantees, referring health professionals and collaborating researchers and their staff in order to accomplish the clinical and research purposes for which the records are collected. The recipients are required to maintain Privacy Act safeguards with respect to these records.

2. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

3. Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example, when a claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders, data books and in a mini-computer maintained by the NIDR Scientific Systems Section.

**RETRIEVABILITY:**

Records are retrieved by name, date of observation and age of subject.

**SAFEGUARDS:**

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. *Authorized users:* Employees who maintain records in this system are instructed to grant regular access only to Clinical Investigations Section staff, to scientist colleagues by invitation of the principal investigator and to referring professionals. Other one time and special access by other employees is granted on a need to know basis as specifically authorized by the System Manager.

2. *Physical safeguards:* Records are stored in rooms which are locked at all times when not in use. Computer terminals are in secured areas. Access to computer file is controlled by software protection codes associate with each site.

3. *Procedural safeguards:* Access is controlled by Clinical Investigation Section staff.

These safeguards are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Research Psychologist, Clinical Investigations, NIDR, Building 10, Room 1N114, 10 Center Drive, MSC 1190, Bethesda, MD 20892-1190.

**NOTIFICATION PROCEDURE:**

To determine if a record exists contact: NIDR Privacy Act Coordinator,

31 Center Drive, MSC 2290, Building 31, Room 2C-35, Bethesda, MD 20892-2290.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine. An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Subject individual, cooperating clinician or health agency, family members

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

09-25-0054

**SYSTEM NAME:**

Administration: Property Accounting, HHS/NIH/ORS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

National Institutes of Health, Building 13, Room 2E43, 9000 Rockville Pike, Bethesda, MD 20892

and

National Institutes of Health, Computer Center, Building 12, 9000 Rockville Pike, Bethesda, MD 20892

and

National Institutes of Health, Building 31, Room B3B16, 9000 Rockville Pike, Bethesda, MD 20892

and

National Institute of Environmental Health Sciences, Office of Facilities Engineering, 102-01, P.O. Box 12233, Research Triangle Park, N.C. 27709

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Employees of the National Institutes of Health who are issued tools or card keys.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Property management.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

5 U.S.C. 301; 5 U.S.C. 5901; 5 U.S.C. 7903; 40 U.S.C. 318a; 42 U.S.C. 241.

**PURPOSE OF THE SYSTEM:**

Used for tool and card keys issuance and control.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether federal, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or

(c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders, and on magnetic media.

**RETRIEVABILITY:**

Records are retrieved by name.

**SAFEGUARDS:**

1. *Authorized users:* Employees who maintain records in this system are instructed to grant regular access only to officials whose duties require use of the information. Other one time and special access by other employees is granted on a need to know basis as specifically authorized by the system manager.

2. *Physical safeguards:* Textual records are stored in offices which are locked when not in use.

3. *Procedural safeguards:* Computer files are password protected.

This system of records will be protected according to the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 1300-C-14, which allows records to be destroyed after all listed credentials are accounted for or 3 months after the return of credentials to the issuing office. Refer to the NIH Manual Chapter for specific instructions.

**SYSTEM MANAGER AND ADDRESS:**

For tools: National Institutes of Health, Administrative Officer, DES, Building 13, Room 13/2E43, 9000 Rockville Pike, Bethesda, MD 20892.

**For card keys:**

National Institutes of Health, Chief, Crime Prevention Branch, Division of Security Operations, ORS, Building 31, Room B3B16, 9000 Rockville Pike, Bethesda, MD 20892.

National Institute of Environmental Health Sciences, Chief, Office of Facilities Engineering, 102-01, P.O. Box 12233, Research Triangle Park, NC 27709

**NOTIFICATION PROCEDURE:**

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Data is obtained from the individual.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0077**

**SYSTEM NAME:**

Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

National Institutes of Health, Executive Plaza North, Rm. 540, 6130 Executive Blvd., Bethesda, MD 20892

and at private organizations under contract. Write to the system manager for a list of current locations.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Cancer and other patients, and normal donors of biopsy and tumor specimens, who are seen at clinically-oriented organizations under contract to the National Cancer Institute. Both adults and children are covered.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical history and diagnostic information about the donor, information on the type of specimen, location of repository (if specimen is stored before use), and distribution record.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

42 U.S.C. 241, 281, 282: "Research and Investigation," "National Cancer Institute," and "Cancer Research and Other Activities."

**PURPOSE(S):**

(1) For cancer research, using by-products of cancer treatment, such as biopsy and tumor specimens that would normally be discarded, to allow interpretation of experimental results; (2) To project future research needs; (3) To monitor and evaluate the NCI distribution system.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. The Department contemplates that it may contract with a private firm for storage and preservation of specimens. Records necessary for identification, retrieval and research use will be disclosed to such a contractor. The contractor will be required to comply with the requirements of the Privacy Act with respect to such records.

2. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that

Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Magnetic tape and discs.

**RETRIEVABILITY:**

Retrieved by name of donor and cross-referenced by identifying number, procurement source, and various epidemiological characteristics.

**SAFEGUARDS:**

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. *Authorized users:* Employees who maintain records in this system are instructed to grant regular access only to physicians, scientists and support staff of the National Cancer Institute, or its contractors, whose duties require the use of such information. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. *Physical safeguards:* Records, computers and computer terminals are kept in limited access areas. Offices are locked during off-duty hours. Input data for computer files is coded to avoid individual identification.

3. *Procedural safeguards:* Access to manual files is strictly controlled by files staff. Files may be accessed only at the request of the system manager or other authorized employee. Access to computer files is controlled through security codes known only to authorized users.

Contractor compliance is assured through inclusion of Privacy Act requirements in contract clauses, and through monitoring by contract and project officers. Contractors who maintain records in this system are instructed to make no disclosure of the records except as authorized by the system manager.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology

Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Program Director, Research Resources, Biological Carcinogenesis Branch, Division of Cancer Etiology, NCI, National Institutes of Health, Executive Plaza North, Room 540, 6130 Executive Blvd., Bethesda, MD 20892

**NOTIFICATION PROCEDURE:**

Write to System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Contact the official under notification procedures above, and reasonably identify the record and specify the

information to be contested, and state your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Specimen Report Form filled out by the organization providing specimens.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0078**

**SYSTEM NAME:**

Administration: Consultant File, HHS/NIH/NHLBI.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

National Institutes of Health, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

List of consultants available for use in evaluation of National Heart, Lung, and Blood Institute special grants and contracts.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Names and résumés.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

42 U.S.C. 241(d), 281.

**PURPOSE(S):**

(1) To identify and select experts and consultants for program reviews and evaluations. (2) For use in evaluation of NHLBI special grants and contracts.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to

represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computer disc and file folders.

**RETRIEVABILITY:**

Records are retrieved by name.

**SAFEGUARDS:**

1. *Authorized users:* Data on computer files is accessed by keyword known only to authorized users.

2. *Physical safeguards:* Rooms where records are stored are locked when not in use.

3. *Procedural safeguards:* During regular business hours, rooms are unlocked but are controlled by on-site personnel.

This system of records will be protected according to the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 1100-G. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Chief, Review Branch, National Heart, Lung, and Blood Institute, Westwood Building, Room 557A, 5333 Westbard Avenue, Bethesda, MD 20892

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact:

Privacy Act Coordinator, NHLBI, National Institutes of Health, 31/5A10, 31 Center Drive, MSC 2490, Bethesda, MD 20892-2490

The requester must also verify his or her identity by providing either a

notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Subject individual.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0093**

**SYSTEM NAME:**

Administration: Authors, Reviewers, Editorial Board, and Members of the Journal of the National Cancer Institute, HHS/NIH/NCI.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Building 82, Room 239, 9030 Old Georgetown Road, Bethesda, MD 20814.

Write to System Manager at the address below for the address of the Federal Records Center where records may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Authors and manuscript reviewers and members of the Journal of the National Cancer Institute (JNCI) editorial board.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Accepted, rejected and pending manuscripts and review comments.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

42 U.S.C. 241, 281.

**PURPOSE(S):**

Manuscript review by NCI staff of manuscripts submitted for possible

publication in the Journal of the National Cancer Institute or JNCI Monographs.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. Disclosure may be made to qualified experts not within the definition of Department employees for opinions as a part of the review of manuscripts.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders.

**RETRIEVABILITY:**

Records are retrieved by name and manuscript number.

**SAFEGUARDS:**

1. *Authorized users:* Employees who maintain records in this system are instructed to grant access only to JNCI staff personnel, the Editor in Chief, and members of the Board of Editors whose duties require the use of such information.

2. *Physical safeguards:* Records are kept in a limited access area where an employee is present at all times during working hours. The Building is locked during off-duty hours.

3. *Procedural safeguards:* Access to manual files is tightly controlled by office staff. Only authorized users may have access to the files.

Information that identifies reviewers is not maintained in computer files.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records

Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 8000-A-1(b), which allows records to be kept for a maximum period of one year after year in which published or presented. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

System Specialist, Scientific Publications Branch, Building 82, Room 239, 9030 Old Georgetown Road, Bethesda, MD 20814.

**NOTIFICATION PROCEDURE:**

Write to System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Authors and reviewers.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0099**

**SYSTEM NAME:**

Clinical Research: Patient Medical Records, HHS/NIH/CC.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

National Institutes of Health, Medical Record Department, 10 Center Drive MSC 1192, Bethesda, MD 20892-1192.

and at private organizations under contract. Write to the system manager for a list of current locations.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Registered Clinical Center patients. Some individuals not registered as patients but seen in Clinical Center for diagnostic tests.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical treatment records.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

42 U.S.C. 241, 248: "Research and Investigation," and "Hospitals, Medical Examination, and Medical Care."

**PURPOSE(S):**

(1) To provide a continuous history of the treatment afforded individual patients in the Clinical Center; (2) To provide a data base for the clinical research conducted within the hospital.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Information may be used to respond to Congressional inquiries for constituents concerning their admission to NIH Clinical Center.

2. Social Work Department may give pertinent information to community agencies to assist patients or their families.

3. Referring physicians receive medical information for continuing patient care after discharge.

4. Information regarding diagnostic problems, or having unusual scientific value may be disclosed to appropriate medical or medical research organizations or consultants in connection with treatment of patients or in order to accomplish the research purposes of this system. For example, tissue specimens may be sent to the Armed Forces Institute of Pathology; X-rays may be sent for the opinion of a radiologist with extensive experience in a particular kind of diagnostic radiology. The recipients are required to maintain Privacy Act safeguards with respect to these records.

5. Records may be disclosed to representatives of the Joint Commission on Accreditation of Hospitals conducting inspections to ensure that the quality of Clinical Center medical record-keeping meets established standards.

6. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

7. Medical information may be disclosed to tumor registries for maintenance of health statistics.

8. The Department contemplates that it may contract with a private firm for transcribing, updating, copying, or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to comply with the requirements of the Privacy Act with respect to such records.

9. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department of any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

10. (a) PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

(b) PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:****STORAGE:**

Records are stored in file folders and/or on microfiche, and on computer tapes.

**RETRIEVABILITY:**

Records are retrieved by unit number and patient name.

**SAFEGUARDS:**

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, and procedural safeguards such as the following:

1. *Authorized users:* Employees maintaining records in this system are instructed to grant regular access only to physicians and dentists and other health care professionals officially participating in patient care, to contractors, or to NIH researchers specifically authorized by the system manager.

2. *Physical safeguards:* All record facilities are locked when system personnel are not present.

3. *Procedural safeguards:* Access to files is strictly controlled by the system manager. Records may be removed only by system personnel following receipt of a request signed by an authorized user. Access to computerized records is controlled by the use of security codes known only to the authorized user. Codes are user- and function-specific.

Contractor compliance is assured through inclusion of Privacy Act requirements in contract clauses, and through monitoring by contract and project officers. Contractors who maintain records in this system are instructed to make no disclosure of the records except as authorized by the system manager.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—

"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-E-22, which allows records to be kept until no longer needed for scientific reference. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Chief, Medical Record Department,  
National Institutes of Health, 10  
Center Drive MSC 1192, Bethesda,  
MD 20892-1192.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the system manager at the above address. The requester must provide tangible proof of identity, such as a driver's license. If no identification papers are available, the requester must verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. The representative may be a physician, or other health professional, or other responsible individual. The subject individual will be granted direct access unless it is determined that such access is likely to have an adverse effect on him or her. In that case, the medical/dental record will be sent to the designated representative.

The individual will be informed in writing if the record is sent to the representative.

A parent or guardian who requests notification of or access to a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably identify the specific reports and related dates pertaining to the information to be released. There may be a fee for reproducing more than 20 pages of

material. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Contact the system manager and reasonably identify the record and specify the information to be contested, and state the corrective action sought and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Referring physicians, other medical facilities (with patient's consent), patients, relatives of patients.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0102****SYSTEM NAME:**

Grants Associates Program Working Files, HHS/NIH/OER.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Extramural Staff Training Office,  
National Institutes of Health, Building  
31, Room 5B35, 9000 Rockville Pike,  
Bethesda, Maryland 20892.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Grants Associates Training Program Participants.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Applications, curriculum vitae, reports on assignments, critiques of courses, supervisors endorsements, summary of assignments, and correspondence.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

5 U.S.C. Part III; 42 U.S.C. 241c.

**PURPOSE(S): THE PURPOSE OF THE SYSTEM IS FOR PROGRAM MANAGEMENT INCLUDING:**

1. Assisting participants in obtaining maximum benefits from the Program;
2. Providing information to current Grants Associates about assignments and opportunities;
3. Providing résumés to other HHS components for possible employment of the Grants Associates trainee;
4. Reviewing and evaluating the Programs.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:**

1. Disclosure may be made to the Office of Personnel Management for salary approval.
2. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.
3. Disclosure may be made to the Department of Justice, or to a court or other tribunal from this system of records, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such record by the Department of Justice, the court or the tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case HHS has determined that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders.

**RETRIEVABILITY:**

Records are retrieved by name.

**SAFEGUARDS:**

1. *Authorized users:* Access limited to system manager and staff. Other one-time and special access by other employees is granted on a need to know basis as specifically authorized by the system manager.
2. *Physical safeguards:* Records are stored in local cabinets in offices which are locked during off-duty hours.
3. *Procedural safeguards:* Access to the files is strictly controlled by employees who maintain the files. Records may be removed from files only at the request of the system manager or other authorized personnel.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—

“Keeping and Destroying Records” (HHS Records Management Manual, Appendix B-361), item 2300-320-1, which allows records to be destroyed after a maximum period of 2 years after completion of grants associate appointment.

**SYSTEM MANAGER AND ADDRESS:**

Director, HSA Development Programs, NIH, Building 31, Room 5B35, 9000 Rockville Pike, Bethesda, MD 20892.

**NOTIFICATION PROCEDURE:**

Write to the System Manager to determine if a record exists. The requester must also verify his or her own identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act subject to a five thousand dollar fine.

**RECORD ACCESS PROCEDURE:**

Same as notification procedure above. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Write to the official specified under the notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought and your reason for requesting the correction, along with supporting information showing how the record is inaccurate, incomplete, untimely, irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

The subject individual, educational institutions attended by the individual, personal references; and the Office of Personnel Management.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0105**

**SYSTEM NAME:**

Administration: Health Records of Employees, Visiting Scientists, Fellows, Contractors and Others who Receive Medical Care Through the Employee Health Unit, HHS/NIH/ORS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Building 10 and 13, NIH, 9000 Rockville Pike, Bethesda, MD 20892; Westwood Building, 5333 Westbard Ave., Bethesda, MD 20892; Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857; Rocky Mountain Laboratories, Hamilton, Montana 59840.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Employees, fellows, visiting scientists, relatives of inpatients, visitors, contractors, and others who receive medical care through the Employee Health Unit.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical records.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

5 U.S.C. 7901.

**PURPOSE(S):**

1. For medical treatment;
2. Upon researcher request with individual's written permission, release of record for research purposes to medical personnel;
3. Upon request by HHS personnel offices for determination of fitness for duty, and for disability retirement and other separation actions;
4. For monitoring personnel to assure that safety standards are maintained.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to Federal, State, and local government agencies for adjudication of benefits under workman's compensation, and for disability retirement and other separation actions.
2. To district office of OPEC, Department of Labor with copies to the U.S. Office of Personnel Management for processing of disability retirement and other separation actions.
3. Upon non-HHS agency request, for examination to determine fitness for duty with copies to requesting agency and to the U.S. Office of Personnel Management.
4. Disclosure may be made to a congressional office from the record of an individual in response to any inquiry from the congressional office made at the request of the individual.
5. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the

Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders.

**RETRIEVABILITY:**

Records are retrieved by name and SSN.

**SAFEGUARDS:**

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project.

Each site implements personnel, physical and procedural safeguards such as the following:

1. *Authorized users:* Access is limited to authorized personnel (system manager and staff; Occupational Medicine Service staff; and personnel and administrative officers with need for information for fitness for duty, disability, and other similar determinations.)

2. *Physical safeguards:* Files are maintained in locked cabinets.

3. *Procedural safeguards:* Access to files is strictly controlled by authorized staff.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule, Manual Chapter 1743 (HHS Records Management Manual, Appendix B-361), item 2300-792-3.

**SYSTEM MANAGER(S) AND ADDRESS:**

Deputy Director, Division of Safety,  
NIH, Building 31, Room 1C02, 9000  
Rockville Pike, Bethesda, MD 20892  
Chief, Rocky Mountain Operations  
Branch, Rocky Mountain Laboratories  
(RMS), National Institutes of Health,  
Hamilton, MT 59840.

**NOTIFICATION PROCEDURE:**

Contact System Manager at appropriate treatment location listed above, to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to 5,000 dollar fine.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requester should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURES:**

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Records contain data resulting from clinical and preventative services provided at treatment location, and data received from individual.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0106**

**SYSTEM NAME:**

Administration: Office of the NIH Director and Institute/Center/Division Correspondence Records, HHS/NIH/OD.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Executive Secretariat, Office of the Director, Building 1, Room B1-55, 9000 Rockville Pike, Bethesda, MD 20892  
Office of Legislative Policy and Analysis, Office of the Director, Building 1, Room 244, 9000 Rockville Pike, Bethesda, MD 20892  
and  
Institute/Center/Division Staff Offices that retain correspondence files. Write

to the appropriate system manager listed in Appendix I for a list of current locations and for the address of the Federal Records Center where records are stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who have contacted the NIH Director or his/her subordinates, or have been contacted in writing by one of these officials.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Correspondence and other supporting documents.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

5 USC 301 44 USC 3101.

**PURPOSE(S):**

1. To control and track all correspondence documents addressed or directed to the NIH Director or his/her subordinates, as well as documents/supporting documents initiated by them, in order to assure timely and appropriate attention.

2. Incoming correspondence and supporting documentation is forwarded to other HHS components when a response from them is warranted.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. Disclosure may be made from this system of records by the Department of Health and Human Services (HHS) to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored by computer index, optical image and in file folders.

**RETRIEVABILITY:**

Records are retrieved by name, document number, date, and subject.

**SAFEGUARDS:**

1. *Authorized users:* Access to textual records is limited to authorized personnel (system managers and staff).

2. *Physical safeguards.* Physical access to records is restricted to authorized personnel.

3. *Procedural safeguards:* Access to textual records is strictly controlled by system managers and staff. Records may be removed from files only at the request of system managers or other authorized employees. Computer files are password protected.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 1700-C, which allows records to be kept for a maximum period of 6 years. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

System Managers are listed in Appendix I; each maintains full responsibility for their specific correspondence system.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the appropriate system manager as listed in Appendix I. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under

false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Records are derived from incoming and outgoing correspondence.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**Appendix I: System Managers**

Director, Executive Secretariat, Office of the Director, Building 1, Room B1-55, 9000 Rockville Pike, Bethesda, MD 20892

Acting Associate Director, Office of Legislative Policy and Analysis, Office of the Director, Building 1, Room 244, 9000 Rockville Pike, Bethesda, MD 20892

National Cancer Institute (NCI), Secretary to the Director, Building 31, Room 11A48, Bethesda, MD 20892

National Heart, Lung and Blood Institute (NHLBI), Secretary to the Director, OD, Director's Office, Building 31, Room 5A52, 31 Center Drive, MSC 2486, Bethesda, MD 20892-2486

National Institute of Diabetes and Digestive and Kidney (NIDDK), Director, OHRR, Building 31, Room 9A04, Bethesda, MD 20892

National Institute of Environmental Health Sciences (NIEHS), Executive Secretariat, PO Box 12233, South Campus, Building 2, Room B201, Research Triangle Park, NC 27709

National Eye Institute (NEI), Administrative Officer, Building 31, Room 6A19, 31 Center Drive MSC 2510, Bethesda, MD 20892-2510

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Director, Office of Scientific and Health Communications, Building 31, Room 4C05, Bethesda, MD 20892

National Institute on Deafness and Other Communication Disorders (NIDCD), Chief, Administrative Management Branch, Building 31, Room 3C21, Bethesda, MD 20892

National Institute of General Medical Science (NIGMS), Secretary to the Director, Westwood Building, Room 926, Bethesda, MD 20892

National Library of Medicine (NLM), Executive Assistant, Office of the Director, Building 38, Room 2E17, Bethesda, MD 20894

Fogarty International Center (FIC), Secretary to the Director, Building 31, Room B2C06, Bethesda, MD 20892

Office of Aides Research (OAR), Special Assistant for Liaison Activities, Building 31, Room 5C12, Bethesda, MD 20892

National Institute on Drug Abuse (NIDA), Executive Secretariat, Room 10-15, Parklawn Building, Rockville, MD 20857

National Institute on Alcohol Abuse and Alcoholism (NIAAA), Executive Secretariat, Willco Building, Suite 400, 6000 Executive Blvd. MSC 7003, Bethesda, MD 20892-7003

National Institute of Mental Health (NIMH), Executive Secretariat, Room 17C-25, Parklawn Building, Rockville, MD 20857  
Washington National Records Center, 4205 Suitland Road, Washington, DC 20857

**09-25-0112**

**SYSTEM NAME:**

Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

See Appendix I.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Grant applicants and Principal Investigators; Program Directors; Institutional and Individual Fellows; Research Career Awardees; and other employees of Applicant and/or grantee institutions.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Grant and cooperative agreement applications and review history, awards, financial records, progress reports, payback records, and related correspondence.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Research and Investigation," "Appointment and Authority of the Directors of the National Research Institutes," "National Institute of Mental Health," "National Institute on Drug Abuse," "National Institute on Alcohol Abuse and Alcoholism," "National Cancer Institute," "National Heart, Lung and Blood Institute," "National Institute of Diabetes, and Digestive and Kidney Diseases," "National Institute of Arthritis and Musculoskeletal and Skin Diseases," "National Institute on Aging," "National Institute on Allergy and Infectious Diseases," "National Institute of Child Health and Human Development," "National Institute of

Dental Research," "National Eye Institute," "National Institute of Neurological Disorders and Stroke," "National Institute of General Medical Sciences," "National Institute of Environmental Health Sciences," "National Institute on Deafness and Other Communication Disorders," "National Institute of Nursing Research," and the "National Library of Medicine," of the Public Health Service Act. (42 U.S.C. 241, 284, 285, 285(b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), 286b-286b-7.

**PURPOSE(S):**

1. Information provided is used by NIH staff for review, award, and administration of grant programs.
2. Information is also used to maintain communication with former fellows who have incurred an obligation through the National Research Service Award Program.
3. Staff may also use curriculum vitae to identify candidates who may serve as ad hoc consultants or committee and council members in the grant peer review process.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made of assignments of research investigators and project monitors to specific research projects to the National Technical Information Service (NTIS), Department of Commerce, to contribute to the Smithsonian Science Information Exchange, Inc.
2. Disclosure may be made to the cognizant audit agency for auditing.
3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.
4. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.
5. Disclosure may be made to qualified experts not within the

definition of Department employees as prescribed in Department Regulations, 45 CFR 56.2, for opinions as a part of the application review and award administration processes.

6. Disclosure may be made to a Federal agency, in response to its request, in connection with the letting of a contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

7. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected; or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

8. Disclosure may be made to a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in a system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records;

9. Disclosure may be made to the grantee institution in connection with the review of an application or

performance or administration under the terms and conditions of the award, or in connection with problems that might arise in performance or administration if an award is made on a grant proposal.

10. Disclosure may be made to the profit institution's president or official responsible for signing the grant application in connection with the review or award of a grant application and in connection with the administration and performance of a grant under the terms and conditions of the awards.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

*Disclosures pursuant to 5 U.S.C. 552a(b)(12):* Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)).

The Department may disclose to consumer reporting agencies information on individuals who have failed to meet payback obligations incurred under awards made under authority of the National Research Service Awards Program (41 U.S.C. 2891-1). Information disclosed includes data identifying the individual, the amount, status and history of the obligation, and that the obligation arose from an award made under the National Research Service Awards Program.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Stored in file folders, on computer tapes and discs, cards and in notebooks.

**RETRIEVABILITY:**

Retrieved by name and grant number.

**SAFEGUARDS:**

A variety of physical and procedural safeguards are implemented, as appropriate, at the various locations of this system:

1. *Authorized users:* Employees who maintain records in this system are instructed to grant regular access only to officials whose duties require use of the information. These officials include review groups, grants management staff, other extramural program staff, health scientist administrators, data processing and analysis staff and management officials with oversight responsibilities for extramural programs. Other one-time and special access is granted on an individual basis as specifically authorized by the system manager. Authorization for access to

computerized files is controlled by the system manager or designated official and is granted on a need-to-know basis. Lists of authorized users are maintained.

2. *Physical safeguards:* Secured facilities, locked rooms, locked cabinets, personnel screening; records stored in order of grant numbers which are randomly assigned.

3. *Procedural safeguards:* Access to file rooms and files is strictly controlled by files staff or other designated officials; charge-out cards identifying users are required for each file used; inactive records are transferred to controlled storage in Federal Records Center in a timely fashion; retrieval of records from inactive storage is controlled by the system manager or designated official and by the NIH Records Management Officer; computer files are password protected and access is actively monitored by the Computer Center to prevent abuse. Employees are given specialized training in the requirements of the Privacy Act as applied to the grants program.

These particular safeguards are developed in accordance with Chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security", of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

#### RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), items: 4000-B-1; 4000-B-4; 4000-C-1 and, 4600-D-1. Refer to the NIH Manual Chapter for specific disposition instructions.

#### SYSTEM MANAGER AND ADDRESS:

See Appendix II.

#### NOTIFICATION PROCEDURE:

Write to Official at the address specified in Appendix II to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

#### RECORD ACCESS PROCEDURE:

Write to the official at the address specified in Appendix IV to obtain access to a record, and provide the same information as is required under the Notification Procedures above. Requesters should also reasonably specify the record contents being sought.

Individuals may also request listings of accountable disclosures that have been made of their records, if any.

#### CONTESTING RECORD PROCEDURE:

Contact the official at the address specified in Appendix II, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect or untimely (obsolete).

#### RECORD SOURCE CATEGORIES:

Information by applicant; supplemented by outside reviewers and internal staff.

#### SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

#### Appendix I: System Location

National Cancer Institute, Executive Plaza South, Suite T-42, 6120 Executive Boulevard, Bethesda, MD 20892  
 National Heart, Lung, and Blood Institute, Westwood Building, Room 4A09, 5333 Westbard Avenue Bethesda, MD 20892  
 National Library of Medicine, Building 38A, Room 5N509, 8600 Rockville Pike, Bethesda, MD 20894  
 National Institute of Allergy and Infectious Diseases, Chief, Grants Management Branch, DEA, Solar Bldg., Room 4C-09, 6003 Executive Blvd., Rockville, MD 20892  
 National Institute of Allergy and Infectious Diseases, Chief, Management Information Systems Section, FMISB, OAM, Solar Building, Room 4A-03, 6003 Executive Blvd., Rockville, MD 20892  
 National Institute of Diabetes and Digestive and Kidney Diseases, Westwood Building, Room 610, 5333 Westbard Avenue, Bethesda, MD 20892  
 National Institute of Arthritis and Musculoskeletal and Skin Diseases, Westwood Building, Room 5A03, 5333 Westbard Avenue, Bethesda, MD 20892  
 National Institute of Child Health and Human Development, 6100 Executive Blvd., Room 7A07, Bethesda, MD 20892  
 National Institute on Aging, Gateway Building, Room 2N-212, 7201 Wisconsin Avenue, Bethesda, MD 20892  
 National Institute of Dental Research, Grants Management Officer, Natcher Building, Room 4AS-55, 45 Center Drive, MSC 6402, Bethesda, MD 20892-6402

National Institute of Environmental Health Sciences, Grants Management Officer, Building 2, Room 204, 104 Alexander Drive, Research Triangle Park, NC 27709  
 National Institute of General Medical Sciences, Grants Management Officer, Natcher Building, Room 2AN52, 9000 Rockville Pike, Bethesda, MD 20892  
 National Institute of Neurological Disorders and Stroke, Federal Building, Room 10A12, 7550 Wisconsin Avenue, Bethesda, MD 20892  
 National Institute on Deafness and Other Communication Disorders, Executive Plaza South, Room 400B, 6120 Executive Boulevard, Rockville, MD 20852  
 National Eye Institute, Executive Plaza South, Room 350, 6120 Executive Boulevard, Bethesda, MD 20892  
 National Center for Research Resources, Westwood Building, Room 853, 5333 Westbard Avenue, Bethesda, MD 20892  
 National Institute of Nursing Research, Building 45, Room 3AN32 MSC 6301, Bethesda, MD 20892-6301  
 Fogarty International Center, Building 31, Room B2C32, 9000 Rockville Pike, Bethesda, MD 20892  
 Washington National Records Center, 4205 Suitland Road, Suitland, MD 20409  
 National Institute on Drug Abuse, Grants Management Branch, Room 8A-54, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857  
 National Institute on Alcohol Abuse and Alcoholism, Grants Management Branch, Willco Building, Suite 504, 6000 Executive Blvd. MSC 7003, Bethesda, MD 20892-7003  
 National Institute of Mental Health, Grants Management Branch, ORM, Room 7C-15, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857

#### Appendix II: System Manager and Address

National Cancer Institute, Grants Management Analyst, Executive Plaza South, Suite 234, 6120 Executive Boulevard, Bethesda, MD 20892  
 National Heart, Lung, and Blood Institute, Chief, Grants Operations Branch, Division of Extramural Affairs, Westwood Building, Room 4A10, 5333 Westbard Avenue, Bethesda, MD 20892  
 National Library of Medicine, Associate Director for Extramural Programs, Building 38A, Room 5N505, 8600 Rockville Pike, Bethesda, MD 20894  
 National Institute of Allergy and Infectious Diseases, Chief, Grants Management Branch, DEA, Solar Bldg., Room 4B-21, 6003 Executive Blvd., Bethesda, MD 20892  
 National Institute of Allergy and Infectious Diseases, Chief, Management Information Systems Section, FMISB, OAM, Solar Building, Room 4A-03, 6003 Executive Blvd., Bethesda, MD 20892  
 National Institute of Arthritis and Musculoskeletal and Skin Diseases, Grants Management Officer, Westwood Building, Room 407, 5333 Westbard Avenue, Bethesda, MD 20892  
 National Institute of Diabetes and Digestive and Kidney Diseases, Grants Management Officer, Room 637, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892

National Institute of Child Health and Human Development, Chief, Office of Grants & Contracts, 6100 Executive Blvd., Room 8A01, Bethesda, MD 20892

National Institute on Aging, Grants Management Officer, Gateway Building, Room 2N-212, 7201 Wisconsin Avenue, Bethesda, MD 20892

National Institute of Dental Research, Grants Management Officer, NIDR, Natcher Building, Room 4AS-55, 45 Center Drive MSC 6402, Bethesda, MD 20892-6402

National Institute of Environmental Health Sciences, Grants Management Officer, Building 2, Room 204, 104 Alexander Drive, Research Triangle Park, NC 27709

National Institute of General Medical Sciences, Grants Management Officer, NIGMS, Natcher Building, Room 2AN24, 9000 Rockville Pike, Bethesda, MD 20892

National Institute of Neurological Disorders and Stroke, Grants Management Officer, Federal Building, Room 1004A, Bethesda, MD 20892

National Institute on Deafness and Other Communication Disorders, Grants Management Officer, Executive Plaza South, Room 400B, 6120 Executive Boulevard, Rockville, MD 20852

National Institute of Nursing Research, Grants Management Officer, Building 45, Room 3AN32 MSC 6301, Bethesda, MD 20892-6301

National Eye Institute, Grants Management Officer, Executive Plaza South, Room 350, 6120 Executive Boulevard, Bethesda, MD 20892

National Center for Research Resources, Director, Office of Grants and Contracts Management, Westwood Building, Room 853, 5333 Westbard Avenue, Bethesda, MD 20892

Fogarty International Center, Scientific Review Administrator, International Studies Branch, Building 31, Room B2C32, 9000 Rockville Pike, Bethesda, MD 20892

National Institute on Drug Abuse, Chief, Grants Management Branch, Room 8A-54, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857

National Institute on Alcohol Abuse and Alcoholism, Chief, Grants Operation Section, Willco Building, Suite 504, 6000 Executive Blvd. MSC 7003, Bethesda, MD 20892-7003

National Institute of Mental Health, Grants Management Officer, ORM, Room 7C-15, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857

#### Appendix III: Notification Procedures

National Cancer Institute, See Appendix II  
National Heart, Lung, and Blood Institute, Privacy Act Coordinator, Building 31, Room 5A10, 31 Center Drive, MSC 2490, Bethesda, MD 20892-2490

National Library of Medicine, See Appendix II

National Institute of Allergy and Infectious Diseases, See Appendix II

National Institute of Diabetes and Digestive and Kidney Diseases, Administrative Officer, Building 31, Room 9A46, 9000 Rockville Pike, Bethesda, MD 20892

National Institute of Child Health and Human Development, See Appendix II

National Institute of Aging, See Appendix II  
National Institute of Dental Research, NIDR Privacy Act Coordinator, Building 31, Room 2C-35, 9000 Rockville Pike, Bethesda, MD 20892

National Institute of Environmental Health Services, See Appendix II

National Institute of General Medical Sciences, See Appendix II

National Institute of Neurological Disorders and Stroke, See Appendix II

National Institute on Deafness and Other Communication Disorders, See Appendix II

National Eye Institute, See Appendix II

National Center for Nursing Research, See Appendix II

National Center for Research Resources, See Appendix II

Fogarty International Center, See Appendix II

National Institute on Drug Abuse, See Appendix II

National Institute on Alcohol Abuse and Alcoholism, See Appendix II

National Institute of Mental Health, Privacy Act Coordinator, Room 15-81, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857

#### Appendix IV: Records Access Procedures

National Cancer Institute, Privacy Act Coordinator, Building 31, Room 10A30, 9000 Rockville Pike, Bethesda, MD 20892

National Heart, Lung, and Blood Institute, See Appendix III

National Library of Medicine, See Appendix II

National Institute of Allergy and Infectious Diseases, Privacy Act Coordinator, Solar Bldg., Room 3C-23, Bethesda, MD 20892

National Institute of Diabetes and Digestive and Kidney Diseases, See Appendix II

National Institute of Child Health and Human Development, See Appendix II

National Institute on Aging, See Appendix II

National Institute of Dental Research, Grants Management Officer, Westwood Building, Room 518, 5333 Westbard Avenue, Bethesda, MD 20892

National Institute of Environmental Health Sciences, See Appendix II

National Institute of General Medical Sciences, Privacy Act Coordinator, Natcher Building, Room 3AS43, 9000 Rockville Pike, Bethesda, MD 20892

National Institute of Neurological Disorders and Stroke, Chief, Administrative Services Branch, Building 31, Room 8A49, 9000 Rockville Pike, Bethesda, MD 20892

National Institute on Deafness and Other Communication Disorders, Chief, Administrative Management Branch, Building 31, Room 3C02, 9000 Rockville Pike, Bethesda, MD 20892

National Eye Institute, Administrative Officer, Building 31, Room 6A17, 9000 Rockville Pike, Bethesda, MD 20892

National Center for Research Resources, Privacy Act Coordinator, Westwood Building, Room 10A15, 5333 Westbard Avenue, Bethesda, MD 20892

Fogarty International Center, See Appendix II  
National Institute on Drug Abuse, See Appendix II

National Institute on Alcohol Abuse and Alcoholism, See Appendix II

National Institute of Mental Health, See Appendix II

National Institute of Nursing Research, See Appendix II.

**09-25-0118**

#### SYSTEM NAME:

Contracts: Professional Services Contractors, HHS/NIH/NCI.

#### SECURITY CLASSIFICATION:

None.

#### SYSTEM LOCATION:

Building 31, Room 3A44, DCT, 9000 Rockville Pike, Bethesda, MD 20892  
Building 31, Room 11A33, OD, 9000 Rockville Pike, Bethesda, MD 20892  
Executive Plaza North, Room 604, DEA, 9000 Rockville Pike, Bethesda, MD 20892

Building 31, Room 11A11, DCE, 9000 Rockville Pike, Bethesda, MD 20892  
Building 31, Room 10A50, DCPC, 9000 Rockville Pike, Bethesda, MD 20892

Write to System Manager at the address below for the address of the Federal Records Center where records may be stored.

#### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals under contract with the National Cancer Institute.

#### CATEGORIES OF RECORDS IN THE SYSTEM:

Professional Services Contracts.

#### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241(d), 281.

#### PURPOSE(S):

Used by staff for general administrative purposes to assure compliance with contract program requirements.

#### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to

enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Stored in file folders.

**RETRIEVABILITY:**

Retrieved by name.

**SAFEGUARDS:**

1. *Authorized users:* Access is limited to authorized personnel (system manager and staff).

2. *Physical safeguards:* Records are maintained in offices which are locked when not in use.

3. *Procedural safeguards:* Access to files is strictly controlled by system manager and staff.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 2600-A-4, which allows records to be destroyed after a maximum period of 6 years and 3 months after final payment. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Administrative Officer, DCT, Building 31, Room 3A44, 9000 Rockville Pike, Bethesda, MD 20892

Administrative Officer, OD, National Institutes of Health, Building 31, Room 11A33, 9000 Rockville Pike, Bethesda, MD 20892

Administrative Officer, DEA, Executive Plaza North, Room 604, 9000 Rockville Pike, Bethesda, MD 20892

Administrative Officer, DCE, Building 31, Room 11A11, 9000 Rockville Pike, Bethesda, MD 20892

Administrative Officer, DCPC, Building 31, Room 10A50, 9000 Rockville Pike, Bethesda, MD 20892

**NOTIFICATION PROCEDURE:**

Write to the appropriate System Manager listed above to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense

under the Act, subject to a five thousand dollar fine.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures.

Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Individuals in the system.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

09-25-0126

**SYSTEM NAME:**

Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Records included in this system are located in hospitals, universities, research centers, research foundations, and coordinating centers under contract with the National Heart, Lung, and Blood Institute, and in NHLBI facilities in Bethesda, Maryland. Write to the system manager at the address below for a list of locations, including the address of any Federal Records Center where records from this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Participants in these studies include (1) individuals who have been or who are presently being treated by the National Heart, Lung, and Blood Institute, for diseases or conditions of the heart, lung, blood vessels and blood; (2) individuals whose physical, genetic, social, economic, environmental, behavioral or nutritional conditions or habits are being studied in relation to the incidence of heart, lung, blood vessel and blood diseases among human beings; and (3) normal volunteers who have agreed to provide control data germane to these studies.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

This system consists of a variety of clinical, medical, and statistical information resulting from or contained in research findings, medical histories, vital statistics, personal interviews, questionnaires, or direct observation. The system also includes records of current addresses of study participants, photographs, fingerprints, and correspondence from or about participants in these studies.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Sec. 412, 413 of the Public Health Service Act (42 U.S.C. 287a, 287b).

**PURPOSE(S):**

(1) Summaries of data resulting from these studies are used by the National Heart, Lung, and Blood Institute to monitor and evaluate the incidence of the diseases or the conditions under investigation and the relationship of various factors to the occurrence of these diseases.

(2) The summaries are also used for program planning and evaluation purposes.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to protect such records from improper disclosure.

2. Referrals may be made of assignments of research investigators and project monitors to specific research projects to the Smithsonian Institution to contribute to the Smithsonian Science Information Exchange, Inc.

3. In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosures may be made to the Department of Justice for the purpose of obtaining its advice.

4. Where the appropriate official of the Department, pursuant to the Department's Freedom of Information Regulation determines that it is in the public interest to disclose a record which is otherwise exempt from mandatory disclosure, disclosure may be made from this system of records.

5. The Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

6. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

7. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessments, medical audits or utilization review.

8. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

9. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written

authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Data may be stored in file folders, magnetic tapes or discs, punched cards, bound note books.

**RETRIEVABILITY:**

Name and/or participant identification number.

**SAFEGUARDS:**

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. *Authorized users:* Employees who maintain records in this system are instructed to grant regular access only to authorized researchers, physicians and their assistants whose duties require the use of such information.

2. *Physical safeguards:* Records are kept in locked file cabinets and in some instances in locked offices or guarded buildings. Locations are locked during non-working hours, and are attended at all times during working hours.

3. *Procedural safeguards:* Access to the data is controlled by the System Manager and the Project Officer. Data stored in computers is accessed through the use of key words known only to principal investigators or authorized personnel.

The particular safeguards implemented at each site are developed in accordance with Chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS.hf: 45-13, and Part 6, "ADP Systems Security", of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records

Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Senior Scientific Advisor, OD, Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute, Federal Building, Room 220, 7550 Wisconsin Avenue, Bethesda, MD 20892.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact: NHLBI Privacy Coordinator, Building 31, Room 5A-08, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Requesters must provide the following information in writing:

1. Full name
2. Name and location of research study
3. Approximate dates of enrollment.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Write to System Manager as indicated above. The contestor must reasonably

specify in writing the record contents at issue and state the corrective action sought and the reasons for the correction. The right to contest with supporting justification. The record is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Information contained in these records is obtained directly from individual participants and from medical and clinical research observations.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0128**

**SYSTEM NAME:**

Clinical Research: Neural Prosthesis & Biomedical Engineering Studies, HHS/NIH/NINDS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Federal Building, Room 9C02, 7550 Wisconsin Ave., Bethesda, MD 20892 and: (1) At hospitals and medical centers under contract, and (2) Federal Records Centers. A list of locations is available upon request from the system manager.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Patients and normal volunteers, males and females, participating in clinical studies to determine the feasibility of neural prostheses, and in clinical studies related to the development of instrumentation for diagnosis and treatment of neurological and sensory disorders conducted under contract for the National Institute of Neurological Disorders and Stroke (NINDS).

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Clinical research data as related to studies which seek to determine the feasibility of neural prostheses and to develop instrumentation for diagnosis and treatment of neurological and sensory disorders.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

42 U.S.C. 421, 289a, 289c.

**PURPOSE(S):**

(1) Clinical research on the development of neural prosthesis (artificial devices) to enhance function of individuals with various disorders of the central nervous system.  
(2) Research on the development of new instruments to improve diagnosis

and treatment of disorders of the nervous system.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to protect such records from improper disclosure.  
2. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.  
3. In the event of litigation where the defendant is (a) The Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders.

**RETRIEVABILITY:**

Records are retrieved by name.

**SAFEGUARDS:**

1. *Authorized users:* Employees who maintain records in this system are instructed to grant access only to HHS scientists and their authorized collaborators.  
2. *Physical safeguards:* Records are kept in a locked room when not in use.  
3. *Procedural safeguards:* Personnel having access to this system are informed of Privacy Act requirements.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records

Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—“Keeping and Destroying Records” (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Head, Neural Prosthesis Program,  
NINDS, Federal Building, Room 916,  
7550 Wisconsin Ave., Bethesda, MD  
20892

**NOTIFICATION PROCEDURE:**

Write to:

Chief, Administrative Services Branch,  
NINDS, Building 31, Room 8A49,  
9000 Rockville Pike, Bethesda, MD  
20892

and ask if a file with your name exists in the Neural Prosthesis or Biomedical Engineering Studies. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURES:**

Write to system manager and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction.

**RECORD SOURCE CATEGORIES:**

Patients, patients' families, hospital records and clinical investigators.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

09-25-0129

**SYSTEM NAME:**

Clinical Research: Clinical Research Studies Dealing with Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/NIDCD.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

National Institute on Deafness and Other Communication Disorders (NIDCD); 6120 Executive Boulevard, Rockville, MD 20852

and at hospitals, medical centers, universities and educational settings under contract. Inactive records may be stored at a Federal Records Center. A list of locations is available upon request from the System Manager at the address below.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Patients and normal volunteers participating in clinical research studies dealing with hearing, speech, language and chemosensory disorders.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical findings, clinical research data, medical and educational histories and research data on the hearing, speech, language, cognition and chemosensory systems of subjects being tested.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

42 U.S.C. 241, 289a, 289c.

**PURPOSE(S)**

Clinical research on the disorders of speech, language, and hearing to discover factors leading to these disorders and to improve prevention, diagnoses, and treatment.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to protect such records from improper disclosure.

2. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines

that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as its deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:****STORAGE:**

Records are stored in file folders.

**RETRIEVABILITY:**

Name or identifier code.

**SAFEGUARDS:**

1. *Authorized users:* Employees who maintain the system are instructed to grant access only to the principal investigator and staff assigned to a particular project, and to other authorized personnel (project officer, contracting officer).

2. *Physical safeguards:* Records are locked in cabinets when not in actual use and system location is locked during non-working hours.

3. *Procedural safeguards:* Personnel having access to system are trained in Privacy Act requirements. Records are returned to locked file cabinets at end of working day.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—“Keeping and Destroying Records” (HHS Records Management Manual, Appendix B—3610, item 3000—G—3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Director, Division of Human Communication, NIDCD, Executive Plaza South, Room 400B, 6120 Executive Boulevard, Rockville, MD 20852

**NOTIFICATION PROCEDURE:**

Write to:  
Chief, Administrative Management Branch, NIDCD, Building 31, Room 3C21, 9000 Rockville Pike, Bethesda, MD 20892

and ask if a file exists with your name in studies of the Division of Communication Sciences and Disorders. Please supply the following information:

1. Approximate date and place of examination and/or treatment.

2. Name of the study, if known.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Write to system manager and reasonably identify the record, specify the information to be contested, and state the corrective action sought and the reasons for the correction. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Information provided by patients, patients' families, hospital records, school records, and clinical investigators.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

09-25-0140

**SYSTEM NAME:**

International Activities: International Scientific Researchers in Intramural Laboratories at the National Institutes of Health, HHS/NIH/FIC.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Fogarty International Center, Building 16A, Room 101, 9000 Rockville Pike, Bethesda, MD 20892

and

Division of Computer Research and Technology, Building 12A, Room 3061, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892

Ancillary records are located in the Office of the Associate Director for Intramural Affairs, laboratories, administrative and personnel offices where participants are assigned. Write to System Manager at the address below for the address of the Federal Records Center where records are stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Health scientists at all levels of their postdoctoral or equivalent research careers who are invited to the National Institutes of Health for further training or to conduct research in their biomedical specialties under the auspices of FIC's administration of International Activities. Most of these scientists are foreign, however, some may be resident aliens or U.S. citizens.

Individuals in these categories include Visiting Associates, Visiting Scientists, Foreign Special Experts who are employees and Visiting Fellows, Guest Researchers, Exchange Scientists, International Research Fellows, Fogarty Scholars, Special Volunteers, Adjunct Scientists and Residents who are not employees.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

History of fellowship, employment and/or stay at NIH; education, immigration data and references. For payroll purposes, social security numbers are requested of all applicants accepted into the program.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

42 USC 2421 and section 307 of the Public Health Service Act.

**PURPOSE(S)**

To document the individual's presence at the NIH, to record immigration history of the individual in order to verify continued eligibility in existing programs, and to meet requirements in the Code of Federal Regulations (8 CFR, "Aliens and Nationality," and 22 CFR, "Foreign Relations").

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Information is made available to authorized employees and agents of the U.S. Government including, but not limited to, the General Accounting Office, the Internal Revenue Service, and the FBI and Immigration and Naturalization Service, Department of Justice, for purposes of investigations, inspections and audits.

2. Disclosures may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

3. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:****STORAGE:**

Records are stored in file folders, computer tapes, and computer disks.

**RETRIEVABILITY:**

By name, country of citizenship, country of birth, gender, fellowship case number, visa and immigration status, program category, NIH Institute and lab, sponsor, degree attained, stipend or salary level, dates of stay at NIH, termination date, work address and telephone number, and home address.

**SAFEGUARDS:**

A variety of safeguards is implemented for the various sets of records included under this system according to the sensitivity of the data they contain.

1. *Authorized users:* NIH administrative and personnel staff screened by FIC staff to access information on a need-to-know basis. Only FIC staff are authorized to add, change, or delete data. Access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. *Physical safeguards:* The records are maintained in file cabinets in offices that are located during off-duty hours.

3. *Procedural safeguards.* Access to files is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employees. For computerized records, access is controlled by the use of security codes known only to authorized users; access codes are changed periodically. The computer system maintains an audit record of all requests for access.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 2300-320, which allows records to be destroyed after a maximum period of 6 years after the close of a case. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Chief, International Services and Communications Branch, National Institutes of Health, Fogarty International Center, Building 16A, Room 101, 16A Center Drive MSC 6710, Bethesda, MD 20892-6710

**NOTIFICATION PROCEDURE:**

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an

individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

**RECORD ACCESS PROCEDURE:**

Same as notification procedure. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Contact the official listed under notification procedure above, and reasonably identify the record, and specify the information to be contested, and state the corrective action sought and the reasons for the correction. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Subject individuals and other federal agencies.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0142**

**SYSTEM NAME:**

Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Records included in this system will be located in hospitals and clinics, research centers and research foundations, and in facilities of the National Institute on Aging (NIA) in Bethesda, MD. They may be stored at Federal Records Centers. A list of locations is available upon request from the System Manager.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Participants in these studies will include: (1) Individuals whose physical, genetic, social, psychological, cultural, economic, environmental, behavioral, pharmacological, or nutritional conditions or habits are studied in relationship to the normal aging process and/or diseases and other normal or abnormal physical or psychological conditions of the aged, and (2) normal volunteers who are participants in such studies.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

This system will consist of a variety of health, demographic, and statistical

information resulting from or contained in research findings, medical histories, vital statistics, personal interviews, questionnaires, or direct observations. The system will also include records of current addresses of study participants, and correspondence from or about participants in the studies. When supplied on a voluntary basis, Social Security numbers will also be included.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Authority is provided by Section 301, Research Contracting, and 463-4, Health Research Extension Act of 1985, Pub. L. 99-158.

**PURPOSE(S):**

The National Institute on Aging will use the data collected; (1) in research projects on (a) the health status of individuals and changes in health status over time, (b) the incidence and prevalence of certain diseases and problems of the aged in certain populations, and (c) the changes that take place as individuals age; (2) and for program planning and evaluation.

**ROUTINE USE OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Records may be disclosed to HHS contractors, collaborating researchers and their staffs in order to accomplish the basic research purpose of this system. The recipients will be required to maintain Privacy Act safeguards with respect to such records.

2. Data may be disclosed to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

3. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health

nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

4. In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice.

5. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

6. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Data may be stored in file folders, boxes, network drives, magnetic tapes or discs, punched cards, or bound notebooks. Stored data may include textual, photographic, X-ray, or other material.

**RETRIEVABILITY:**

Information will be retrieved by personal identifiers such as name, code number and/or Social Security number, when this is supplied on a voluntary basis.

**SAFEGUARDS:**

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. *Authorized users:* Access will be limited to principal investigators, collaborating researchers and necessary support staff.

2. *Physical safeguards:* Hard copy data will be maintained in locked file cabinets. Information stored in computer systems will be accessible only through proper sequencing of signal commands and access codes specifically assigned to the Project Officer or contractor.

3. *Procedural safeguards:* Access to the information will be controlled directly by the Project Officer or his or her representative at remote locations, and by the system manager at NIA locations. Contractors and collaborating researchers will be notified that they are subject to the provisions of the Privacy Act, and will be required to make formal agreements to comply with these provisions.

The particular safeguards implemented in each project are developed in accordance with Chapter 45-13 and supplementing Chapter PHS hf: 45-13 of the HHS General Administration Manual and Part 6, ADP Systems Security, of the HHS Information Resources Management Manual, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Associate Director, Epidemiology, Demography and Biometry Program, National Institute on Aging, Gateway Building, Suite 3C309, 7201 Wisconsin Avenue, Bethesda, MD 20892

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the above

address and provide the following information in writing:

1. Full name at time of participation in the study.
2. Date of birth.
3. Home address at the time of study.
4. The facility where the examination was given or where information was collected.
5. Approximate date or dates of participation.
6. Name of study, if known.
7. Current name, address and telephone number.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical or dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURE:**

Contact the system manager at the above address and provide the same information as outlined under the notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Contact the System Manager at the above address. The contestor must reasonably identify the record, specify in writing the information being contested, and state the corrective action sought and the reasons for the correction. The right to contest records is limited to information which is incomplete, irrelevant, incorrect or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Information will be obtained directly from individual participants and from medical and clinical research observations, or indirectly from existing source documents such as disease registries.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0148****SYSTEM NAME:**

Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological Disorders and Stroke and the National Institute on Deafness and Other Communication Disorders, HHS/NIH/NINDS and HHS/NIH/NIDCD.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

At National Institutes of Health facilities in Bethesda, Maryland, and at hospitals, medical schools, universities, research institutions, commercial organizations, state agencies, and collaborating Federal agencies. Inactive records may be retired to Federal Records Centers. A list of locations is available upon request from the respective System Managers of the subsystems included in this notice.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Patients with neurological diseases, communicative disorders, stroke, hearing loss, chemosensory deficits, and related diseases; normal, healthy volunteers who serve as controls for comparison with patients, relatives of patients; and other individuals whose characteristics or conditions are suited for possible connections with the occurrence of the diseases and disorders under investigations. Subject individuals include both adults and children.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

This system consists of a variety of clinical, biomedical, and epidemiological information resulting from or contained in direct observations, medical records and other histories, vital statistics reports, records on biological specimens (e.g., blood, urine, etc.), personal interviews, questionnaires, progress reports, correspondence, or research findings.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Sections 241, Research and Investigation, and 289a, Establishment of Institutes, of the Public Health Service Act (42 U.S.C. 301, 431).

**PURPOSE(S):**

This system will be used to support (1) contracted and contract-related epidemiological, clinical and biometric investigations into the causes, nature, outcome, therapy, prevention and cost of neurological and communicative

disorders, hearing loss, chemosensory deficits, and stroke; (2) review and evaluation of the progress of these research projects, and identification and planning for improvements or for additional research.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to protect such records from improper disclosure.

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessments, medical audits or utilization review.

3. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

4. The Department contemplates that it may contract with a private firm for the purpose of collating, analyzing,

aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to maintain Privacy Act safeguards with respect to such records.

5. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example, in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

6. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Data may be stored in file folders, computer-accessible forms (e.g. tapes or discs), punched cards, bound notebooks, microfilm, charts, graphs and X-rays.

**RETRIEVABILITY:**

Information is retrieved by name and/or patient identification number.

**SAFEGUARDS:**

1. *Authorized users:* Access to or disclosure of information is limited to collaborating researchers, contractors and employees, and other authorized biomedical researchers who are involved in the conduct, support or review and evaluation of the research activities supported by this system.

2. *Physical safeguards:* Data are kept in secured areas (e.g. rooms which are locked when not in regular use, buildings with controlled access). Data stored in computer-accessible form is accessed through the use of key words known only to principal investigators or

authorized personnel; all other information is stored in locked files.

3. *Procedural safeguards:* Contractors and collaborating or other researchers are required to comply with the provisions of the Privacy Act and with HHS Privacy Act regulations.

These and other appropriate safeguards are implemented in each project in accordance with Chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS.hf: 45-13, and Part 6, "ADP Systems Security", of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER(S) AND ADDRESS:**

NINDS and NIDCD research activities are divided, functionally and administratively. In effect, there are six subsystems within this single umbrella system. NINDS has five programs and NIDCD one. System Managers have been designated for each subsystem as follows:

Director, Division of Human Communication, NIDCD, NIH, Executive Plaza South, Room 400B, 620 Executive Boulevard, Rockville, MD 20852

and

Director, Division of Fundamental Neurosciences, NINDS, NIH, Federal Building, Room 916, 7550 Wisconsin Avenue, Bethesda, MD 20892

and

Deputy Director, Division of Convulsive, Developmental and Neuromuscular Disorders, NINDS, NIH, Federal Building, Room 816, 7550 Wisconsin Avenue, Bethesda, MD 20892

and

Director, Division of Demyelinating Atrophic, and Dementing Disorders, NINDS, NIH, Federal Building, Room 810, 7550 Wisconsin Avenue, Bethesda, MD 20892

and

Director, Division of Stroke and Trauma,  
NINDS, NIH, Federal Building, Room  
8A08, 7550 Wisconsin Avenue,  
Bethesda, MD 20892

and

Assistant Director, Clinical  
Neurosciences Program, DIR, NIH,  
Building 10, Room 5N226, 9000  
Rockville Pike, Bethesda, MD 20892

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to:

NINDS Privacy Act Coordinator, Federal  
Building, Room 816, 7550 Wisconsin  
Avenue, Bethesda, MD 20892

or

NIDCD Privacy Act Coordinator,  
Building 31, Room 3C02, 9000  
Rockville Pike, Bethesda, MD 20892

and provide the following information:

1. System name,
2. Complete name and home address at the time of the study,
3. Birth date,
4. Facility conducting the study,
5. Disease type (if known),
6. Approximate dates of enrollment in the research study.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

Individuals seeking notification of or access to medical records should designate a representative (including address) who may be a physician, other health professional, or other responsible individual, who would be willing to review the record and inform the subject individual of its contents, at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) of whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

**RECORD ACCESS PROCEDURE:**

Same as notifications procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Write to the system manager and reasonably identify the record, specify the information being contested and state the corrective action sought and the reasons for the correction. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Information in these records is obtained directly from individual participants, and from physicians, research investigators and other collaborating persons, and from medical records and clinical research observations at hospitals, HHS agencies, universities, medical schools, research institutions, commercial institutions, state agencies, and collaborating Federal agencies.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0152**

**SYSTEM NAME:**

Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Records included in this system are collected by contractors and are located in hospitals and clinics; research centers; educational institutions; commercial; local, State and Federal government agencies; and in National Institute of Dental Research (NIDR) facilities. Inactive records may be stored at Federal Records Centers. A list of locations and contracts is available upon request from the System Manager.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Voluntary participants in epidemiological and biometric studies sponsored by NIDR, including adults and minors, both males and females, with known or suspected diseases or disorders of the teeth and supporting structures, as well as normal or nonsuspect individuals in control or study groups for purposes of comparison.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

This system consists of medical and dental records and information resulting from personal interviews, questionnaires, or direct observation. The system may also include current

addresses of study participants, radiographs, records on biological specimens (e.g., teeth, plaque, etc.), study models, computerized epidemiological data and correspondence.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Sections 301, 401, 405 and 453 of the Public Health Service Act (42 U.S.C. 241, 281, 284, 285h). These sections establish the National Institute of Dental Research and authorize the conduct and support of dental and oral research and related activities.

**PURPOSE(S):**

This system is used to: (1) Support research on diseases and disorders of the oral cavity (teeth and their supporting structures); their causes and treatment; the incidence and prevalence of these diseases and disorders; and familial, demographic and behavioral factors related to their causes and treatment; (2) provide data for program review, evaluation, planning, and administrative accountability.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USE:**

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff for the purpose of analyzing data and preparing scientific reports and articles in order to accomplish the research purpose for which the records are collected. The recipients are required to maintain Privacy Act safeguards with regards to such records.

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

3. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose, (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to, (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the

purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

4. The Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to maintain Privacy Act safeguards with respect to records.

5. Disclosure may be made to a congressional office from the record to an individual in response to an inquiry from the congressional office made at the request of the individual.

6. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee, for example, in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Data may be stored in file folders, magnetic tapes or disks, punched cards, or bound notebooks.

**RETRIEVABILITY:**

Information is retrieved by name and/or a participant identification number.

**SAFEGUARDS:**

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. *Authorized users:* Employees who maintain records in this system are instructed to grant regular access only to contractor personnel; consultants to the contractor; the NIDR project officer; and NIDR employees whose duties require the use of such information. Access to the data controlled by the Project Director, the NIDR Project Officer, and/or the System Manager.

2. *Physical safeguards:* Records are stored in locked files or secured areas. Computer terminals are in secured areas.

3. *Procedural safeguards:* Names and other identifying particulars are deleted when data from original records is encoded for analysis. Encoded data is indexed by code numbers. Tables linking these code numbers with actual identifiers are maintained separately. Code numbers and identifiers are linked only if there is a specific need. Data stored in computers is accessed through the use of keywords known only to the principal investigators or authorized personnel. These keywords are changed frequently.

The particular safeguards implemented in each project will be developed in accordance with Chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS.hf: 45-13, and Part 6, "ADP Systems Security", of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Chief, Contract Management Section, Extramural Program, National Institute of Dental Research, Natcher Building, Room 4AN-44B, 45 Center Drive MSC 6402, Bethesda, MD 20892-6402

**NOTIFICATION PROCEDURE:**

Write to:  
Privacy Act Coordinator, National Institute of Dental Research, 31 Center Drive MSC 2290, Building 31, Room 2C-35, Bethesda, MD 20892-2290  
and provide the following information in writing:

1. Full name at time of participation in the study.
2. Name and description of the study.
3. Location and approximate dates of participation.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of, or access to, a medical or dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, the medical record of a child or incompetent person shall designate a family physician or other health professional (other than a family member) to whom the records, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURES:**

Contact the System Manager at the address above. The contestor must reasonably identify the record, specify in writing the information being contested, and state the corrective action sought, and the reason(s) for the corrective action, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Information contained in these records is obtained directly from individual participants and from medical/dental and clinical research observations.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0153**

**SYSTEM NAME:**

Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HSS/NIH/NICHD.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Records included in this system in this system are located in hospitals and clinics, research centers, educational institutions, commercial organizations, local and State agencies, and other Executive Branch agencies of the Federal Government under contract to the National Institute of Child Health and Human Development (NICHD), and in NICHD facilities in Bethesda, Maryland. Inactive records may be stored at Federal Records Centers. A list of specific locations and contractors is available upon request from the System Manager, whose address is listed below.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Participants in these studies include adults and children (a) who are presently or have been treated by the NICHD, (b) whose physical, genetic, social, economic, environmental, behavioral or nutritional conditions or habits are being studied by the NICHD, or (c) normal volunteers who have agreed to provide control data for purposes of comparison.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

This system consists of a variety of clinical, medical, and statistical information collected in biomedical and behavioral research studies, such as medical histories, vital statistics, personal interviews, questionnaires, current addresses of study participants, radiographs, records on biological specimens, study models, and correspondence from or about participants in these studies.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 301, Research and Investigation, and section 441, National Institute of Child Health and Human Development, of the Public Health

Service Act as amended (42 U.S.C. sections 241, 298d).

**PURPOSE(S):**

This system is used: (1) For program review, evaluation, planning, and administrative management for research on child health and human development; (2) to monitor the incidence, prevalence or development of the disease, condition, behavior, or health status under investigation; (3) to determine the relation of various factors (e.g., social, economic, environmental, physical, and medical) to the occurrence of the disease, condition, development, behavior, or health status under investigation; (4) to identify abnormal disease, condition, or health status and inform the Centers for Disease Control (CDC) or the Food and Drug Administration (FDA) of the existence of such conditions. CDC uses this information in fulfilling its congressionally mandated responsibility for the monitoring of disease and prevention of epidemics. FDA use this information in carrying out its congressional mandate for controlling certain potentially harmful products.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff for the purposes of analyzing data and preparing scientific reports and articles in order to accomplish the research purpose for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

3. The Department contemplates that it may contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to comply with the requirements of the Privacy Act with respect to such records.

4. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

5. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or

policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

6. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

7. In the event of litigation where the defendant is: (a) The Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with

the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Data may be stored in file folders, microfilm, magnetic tapes or disks, punched cards, or bound notebooks.

**RETRIEVABILITY:**

Information is retrieved by name and/or a participant identification number.

**SAFEGUARDS:**

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. *Authorized users:* Employees who maintain records in this system are instructed to grant regular access only to contractor personnel; consultants to the contractor; the NICHD project officer; and NICHD employees whose duties require the use of such information. One time and special access to the data is controlled by the System Manager, the NICHD Project Officer, and the Contract and/or Project Director.

2. *Physical safeguards:* Records are stored in locked files or secured areas. Computer terminals are in secured areas.

3. *Procedural safeguards:* Names and other identifying particulars are deleted when data from original records is encoded for analysis. Encoded data is indexed by code numbers. Tables linking these code numbers with actual identifiers are maintained separately. Code numbers and identifiers are linked only if there is a specific need, such as alerting the volunteer subjects to any findings in the study that might affect their health. Data stored in computers is accessed through the use of passwords/keywords known only to the principal investigators or authorized personnel. These passwords/keywords are changed frequently.

The particular safeguards implemented in each project will be developed in accordance with Chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS hf: 45-13; Part 6, "ADP Systems Security," of the HHS ADP Systems Manual, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are trained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Chief, Contracts Management Branch, NICHD, Executive Building, Room 7A07, 6100 Executive Blvd., North Bethesda, MD 20892-7510

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to:

NICHD Privacy Act Coordinator, Executive Building, Room 4A01B, 6100 Executive Blvd., North Bethesda, MD 20892-7510

and provide the following information in writing:

1. Full name and address at time of participation in the study.
2. Name or description of the study.
3. Location and approximate dates of participation.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of, or access to, a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, the medical record of a child or incompetent person shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify his or her relationship to the child or incompetent person as well as his or her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedure above. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURES:**

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Information contained in these records is obtained directly from individual participants, medical and clinical research observations, and other federal agencies.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0154**

**SYSTEM NAME:**

Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and (2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

National Institutes of Health, Executive Plaza North, Room 343K, 6130 Executive Blvd. MSC 7350, Bethesda, MD 20892-7350

and

National Institutes of Health, Building 12, 9000 Rockville Pike, Bethesda, MD 20892

and

National Institutes of Health, Building 1 Room 260, 9000 Rockville Pike, Bethesda, MD 20892

and at hospitals, medical schools, universities, research institutions, commercial organizations, collaborating State and Federal Government agencies, and Federal Records Centers. Write to system manager at the address below for the address of current locations.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

NCI: Adults and children in the following categories: Patients with cancer; persons for whom cancer risk can potentially be lowered; and persons without signs or symptoms who may be identified through screening and detection methods as having cancer or

being at increased risk of developing cancer. For certain types of epidemiologic studies, e.g., case-control studies, NCI may also collect, for purposes of comparison, records on other persons. These comparison groups could include normal individuals (e.g., family members or neighborhood controls), or other patient groups (e.g., hospital controls) who do not have cancer or are not at a particularly high risk of developing cancer. Health care and educators who provide services and training for all such persons above. WHI: Women for whom risk of cancer and/or other chronic disease may potentially be lowered. Women without signs or symptoms of chronic disease who may be identified through screening and detection methods as being at risk for serious chronic ailments. WHI may also collect, for purposes of comparison, longitudinal records on other women for whom no added disease risk has been identified.

#### CATEGORIES OF RECORDS IN THE SYSTEM:

Information identifying participants (such as name, address, Social Security Number), medical records, progress reports, correspondence, epidemiologic data, and records on biological specimens (e.g., blood, tumors, urine, etc).

#### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

NCI: Sections 301, Research and Investigation, 405 Appointment and Authority of the Directors of the National Research Institutes, and Title IV, Part C, Subpart 1—National Cancer Institute, of the Public Health Service (PHS) Act (42 U.S.C. 241, 284 and 285–285a–5). WHI: 42 U.S.C. 241 and section 402, Appointment and Authority of Director of NIH, of the PHS (42 U.S.C. 282).

#### PURPOSE(S):

Records in this system will be used, (1) to evaluate cancer and other chronic disease control programs, such as prevention, screening, detection, diagnosis, treatment, rehabilitation, and continuing care; (2) to identify characteristics of persons who may be particularly susceptible to environmental or occupational factors for substances which cause or prevent cancer and/or other chronic diseases; (3) to determine risk factors or substances which cause or prevent cancer and/or other chronic diseases, and the ways in which they do so; (4) to evaluate statistical and epidemiological methodologies for risk factor assessment, clinical trials, cancer control studies, and the study of the natural history of cancers and/or other

chronic diseases; (5) to plan for, administer, and review research activities as described in the above purposes; (6) information from this system may be reported to the Food and Drug Administration (FDA) as a condition for approval of clinical investigations of new drugs, or to report adverse effects of drugs so that FDA can make informed decisions on authorizing use of such drugs.

#### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purposes for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessments, medical audits or utilization review.

3. The Department contemplates that it may contract with a private firm for the purposes of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to comply with the requirements of the Privacy Act with respect to such records.

4. A record be disclosed for a research purpose, when the Department: (a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written

authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

5. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

6. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example, in defending a claim against the Public Health Service based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

#### POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

##### STORAGE:

File folders, microfilm, charts, graphs, computer tapes, disks, and punch cards.

##### RETRIEVABILITY:

By name, Social Security Number when supplied voluntarily or contained in existing records used in projects under this system, or other identifying number.

##### SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. *Authorized users.* NCI and WHI employees who maintain records in this

system are instructed to grant regular access only to physicians, scientists, and support staff of the National Cancer Institute and Women's Health Initiative, respectively, or their contractors, grantees or collaborators who need such information in order to contribute to the research or administrative purposes of the system. The system managers specifically authorize one-time and special access by others on a need-to-know basis consistent with the purposes and routine uses of the system.

2. *Physical safeguards.* Records are kept in limited access areas. Offices and records storage locations are locked during off-duty hours. Input data for computer files is coded to avoid individual identification. Where possible, information on individual identities is kept separate from data used for analysis.

3. *Procedural safeguards.* Access to manual files is granted only to authorized personnel, as described above. Access to computer files is controlled through security codes known only to authorized users. Names and other details necessary to identify individuals are not included in data files used for analysis. These files are indexed by code numbers. Code numbers and complete identifiers are linked only if there is a specific need, such as for data verification.

Contractors, grantees or collaborators who maintain records in this system are instructed to make no further disclosure of the records except as authorized by the system manager and permitted by the Privacy Act. Privacy Act requirements are specifically included in contracts and in agreements with grantees or collaborators participating in research activities supported by this system. HHS project director, contract officers and project officers oversee compliance with these requirements.

The particular safeguards implemented at each site are developed in accordance with Chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS.hf: 45-13, and Part 6, "ADP Systems Security", of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

#### RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records"

(HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

#### SYSTEM MANAGER AND ADDRESS:

Associate Director, Surveillance Program, DCPC, National Cancer Institute, Executive Plaza North, Room 343K, 6130 Executive Blvd, MSC 7350, Bethesda, MD 20892-7350 and

Director, Women's Health Initiative, Office of the Director, National Institutes of Health, Building 1, Room 260, 9000 Rockville Pike, Bethesda, MD 20892

#### NOTIFICATION PROCEDURE:

To determine if a file exists, write to the appropriate system manager and provide the following information:

a. System name: "Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and (2) Women's Health Initiative Studies, HHS/NIH/OD."

b. Complete name at time of participation;

c. Facility and home address at the time of participation;

d. In some cases, where records are retrieved by an identifying number, such as the Social Security Number or Hospital Identification Number, it may be necessary to provide that number. In some cases, to ensure proper identification it may be necessary to provide date(s) of participation (if known), birth date, disease type (if known), and study name and location (if known).

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a maximum fine of five thousand dollars.

Individuals seeking notification of or access to medical records should designate a representative (including address) who may be a physician, other health professional, or other responsible individual, who would be willing to review the record and inform the subject individual of its contents, at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or

other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

#### RECORD ACCESS PROCEDURES:

Write to the appropriate system manager and provide the same information as requested under the notification procedure above. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

#### CONTESTING RECORD PROCEDURES:

Write to the appropriate system manager, identify the record, and specify the information contested. State the corrective action sought and your reasons for requesting the correction, and provide supporting information to show that the record is inaccurate, incomplete, irrelevant, untimely, or unnecessary. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

#### RECORD SOURCE CATEGORIES:

HHS agencies, institutions under contract to the U.S. Government, such as universities, medical schools, hospitals, research institutions, commercial institutions, state agencies, other U.S. Government agencies, patients and normal volunteers, physicians, research investigators and other collaborating personnel.

#### SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

#### 02-25-0156

#### SYSTEM NAME:

Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD.

#### SECURITY CLASSIFICATION:

None.

#### SYSTEM LOCATION:

This system of records is an umbrella system comprising separate sets of records located either in the organizations responsible for conducting evaluations or at the sites of programs or activities under evaluation. Locations include Public Health (PHS) facilities, or facilities of contractors of the PHS. Write to the appropriate System Manager below for a list of current locations.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals covered by this system are those who provide information or opinions that are useful in evaluating programs or activities of the PHS, other persons who have participated in or benefitted from PHS programs or activities; or other persons included in evaluation studies for purposes of comparison. Such individuals may include (1) participants in research studies; (2) applicants for and recipients of grants, fellowships, traineeships or other awards; (3) employees, experts and consultants; (4) members of advisory committees; (5) other researchers, health care professionals, or individuals who have or are at risk of developing diseases or conditions studied by PHS; (6) persons who provide feedback about the value or usefulness of information they receive about PHS programs, activities or research results; (7) persons who have received Doctorate level degrees from U.S. institutions; (8) persons who have worked or studied at U.S. institutions that receive(d) institutional support from PHS.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

This umbrella system of records covers a varying number of separate sets of records used in different evaluation studies. The categories of records in each set depend on the type of program being evaluated and the specific purpose of the evaluation. In general, the records contain two types of information: (1) Information identifying subject individuals, and (2) information which enables PHS to evaluate its programs and services.

(1) Identifying information usually consists of a name and address, but it might also include a patient identification number, grant number, Social Security Number, or other identifying number as appropriate to the particular group included in an evaluation study.

(2) Information used for evaluation varies according to the program evaluated. Categories of evaluative information include personal data and medical data on participants in clinical and research programs; personal data, publications, professional achievements and career history of researchers; and opinions and other information received directly from individuals in evaluation surveys and studies of PHS programs.

The system does not include any master list, index or other central means of identifying all individuals whose records are included in the various sets of records covered by the system.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Authority for this system comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 2891-1 and 44 U.S.C. 3101), and section 301 and 493 of the Public Health Service Act.

**PURPOSE(S):**

This system supports evaluation of the policies, programs, organization, methods, materials, activities or services used by PHS in fulfilling its legislated mandate for (1) conduct and support of biomedical research into the causes, prevention and cure of diseases; (2) support for training of research investigators; (3) communication of biomedical information.

This system is not used to make any determination affecting the rights, benefits or privileges of any individual.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to HHS contractors and collaborating researchers, organizations, and State and local officials for the purpose of conducting evaluation studies or collecting, aggregating, processing or analyzing records used in evaluation studies. The recipients are required to protect the confidentiality of such records.

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessments, medical audits or utilization review.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. The Department may disclose information from this system of records to the Department of Justice, to court or other tribunal, or to another party before such tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the

Department of Justice, the tribunal, or the other party is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:****STORAGE:**

Data may be stored in file folders, bound notebooks, or computer-accessible media (e.g., magnetic tapes or discs).

**RETRIEVABILITY:**

Information is retrieved by name and/or participant identification number within each evaluation study. There is no central collection of records in this system, and no central means of identifying individuals whose records are included in the separate sets of records that are maintained for particular evaluation studies.

**SAFEGUARDS:**

A variety of safeguards are implemented for the various sets of records in this system according to the sensitivity of the data each set contains. Information already in the public domain, such as titles and dates of publications, is not restricted. However, sensitive information, such as personal or medical history or individually identified opinions, is protected according to its level of sensitivity. Records derived from other systems of records will be safeguarded at a level at least as stringent as that required in the original systems. Minimal safeguards for the protection of information which is not available to the general public included the following:

1. *Authorized users:* Regular access to information in a given set of records is limited to PHS or to contractor employees who are conducting, reviewing or contributing to a specific evaluation study. Other access is granted only on a case-by-case basis, consistent with the restrictions required by the Privacy Act (e.g., when disclosure is required by the Freedom of Information Act), as authorized by the system manager or designated responsible official.

2. *Physical safeguards:* Records are stored in closed or locked containers, in areas which are not accessible to unauthorized users, and in facilities which are locked when not in use. Records collected in each evaluation project are maintained separately from

those of other projects. Sensitive records are not left exposed to unauthorized persons at any time. Sensitive data in machine-readable form may be encrypted.

3. *Procedural safeguards:* Access to records is controlled by responsible employees and is granted only to authorized individuals whose identities are properly verified. Data stored in mainframe computers is accessed only through the use of keywords known only to authorized personnel. When personal computers are used, magnetic media (e.g. diskettes) are protected as under Physical Safeguards. When data is stored within a personal computer (i.e., on a "hard disk"), the machine itself is treated as though it were a record, or records, under Physical Safeguards. Contracts for operation of this system of records require protection of the records in accordance with these safeguards; PHS project and contracting officers monitor contractor compliance.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

#### RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 1100-C-2. Refer to the NIH Manual Chapter for specific disposition instructions.

#### SYSTEM MANAGER(S) AND ADDRESS:

See Appendix 1.

Policy coordination for this system is provided by:

Associate Director, Office of Strategic Planning and Evaluation, Office of Science Policy and Technology Transfer, National Institutes of Health, 6006 Executive Boulevard, Suite 312, Rockville, MD 20892

#### NOTIFICATION PROCEDURE:

To determine if a record exists, write to the official of the organization responsible for the evaluation, as listed in Appendix 2. If you are not certain which component of PHS was responsible for the evaluation study, or if you believe there are records about

you in several components of PHS, write to:

NIH Privacy Act Officer, Building 31, Room 1B25, 9000 Rockville Pike, Bethesda, MD 20892.

Requesters must provide the following information:

1. Full name, and name(s) used while studying or employed;
2. Name and location of the evaluation study or other PHS program in which the requester participated or the institution at which the requester was a student or employee, if applicable;
3. Approximate dates of participation, matriculation or employment, if applicable.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, other health professional, or other responsible individual, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

#### RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

#### CONTESTING RECORD PROCEDURES:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to

information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

#### RECORD SOURCE CATEGORIES:

Information contained in these records is obtained directly from individual participants; from systems of records 09-25-0036, "Grants: IMPAC (Grants/Contract Information), HHS/NIH/DRG;" 09-25-0112, "Grants: Research, Research Training, Fellowship and Construction Applications and Awards, HHS/NIH/OD"; NSF-6, "Doctorate Record File", NSF-43, "Doctorate Work History File" (previously entitled NSF-43, "Roster and Survey of Doctorate Holders in The United States" and other records maintained by the operating programs of NIH; the National Academy of Sciences, professional associations such as the AAMC and ADA, and other contractors; grantees or collaborating researchers; or publicly available sources such as bibliographies.

#### SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

#### Appendix 1: System Managers

Associate Director, Office of Strategic Planning and Evaluation, Office of Science Policy and Technology Transfer, National Institutes of Health, 6006 Executive Boulevard, Suite 312, Rockville, MD 20892  
 National Institutes of Health, Office of the Director, Director, Division of Personnel Management, Building 1, Room B1-60, 9000 Rockville Pike, Bethesda, MD 20892  
 National Heart, Lung, and Blood Institute (NHLBI), NHLBI Minority Coordinate, OD, OPPE, Building 31, Room 5A03/5A06, 31 Center Drive, MSC 2482, Bethesda, MD 20892-2482  
 National Library of Medicine (NLM), Associate Director for Health Information Programs Development, Building 38, Room 2S20, Bethesda, MD 20894  
 National Eye Institute (NEI), Associate Director for Science Policy and Legislation, Building 31, Room 6A25, Bethesda, MD 20892  
 National Cancer Institute (NCI), Public Health Educator, OCC, NCI, National Institutes of Health Building 31, Room 4B43, Bethesda, MD 20892  
 National Institute on Aging (NIA), Chief, Office of Planning, Analysis, Technical Information and Evaluation, Federal Building, Room 6A09, 7550 Wisconsin Avenue, Bethesda, MD 20892  
 National Institute of Allergy and Infectious Diseases (NIAID), Chief, Evaluation and Reporting Section, Policy Analysis and Legislation Branch, Office of Administration Management, Building 31, Room 7A-16, Bethesda, MD 20892  
 National Institute of Child Health and Human Development (NICHD), Chief, Office of Science Policy and Analysis, Building 31, Room 2A10, Bethesda, MD 20892

National Institute on Deafness and Other Communications Disorders, Chief, Program Planning and Health Reports Branch, Building 31, room 3C35, 9000 Rockville Pike, Bethesda, MD 20892

National Institute of Dental Research (NIDR), Director, Office of Planning Evaluation, and Communications, Building 31, Room 2C34, 31 Center Drive MSC 2290, Bethesda, MD 20892-2290

National Institute of Environmental Health Sciences (NIEHS) Programs, Analyst, Office of Program Planning and Evaluation, P.O. Box 12233, Research Triangle Park, NC 27709

National Institute of General Medical Sciences (NIGMS), Chief, Office of Program Analysis and Evaluation, Natcher Building, Room 3AS49, 9000 Rockville Pike, Bethesda, MD 20892

Fogarty International Center (FIC), National Institutes of Health, Assistant Director for Planning, Evaluation and Public Affairs, Building 31, Room B2C32, Bethesda, MD 20892

Division of Research Grants (DRG), Assistant Director for Special Projects, Westwood Building, Room 457, 5333 Westbard Avenue, Bethesda, MD 20892

National Center for Research Resources (NCRR), Evaluation Officer, Office of Science Policy, Westwood Building, Room 8A03, Bethesda, MD 20892

National Institute of Nursing Research (NINR), Chief, Office of Planning, Analysis and Evaluation, Building 31, Room 5B09, Bethesda, MD 20892

Office of Research Integrity, Policy Analyst, Division of Policy and Education, U.S. Public Health Service, 5515 Security Lane, Suite 700, Rockwell-II Building, Rockville, MD 20852

#### Appendix 2: Notification and Access Officials

NIH, Office of the Director, Associate Director for Science, Policy and Legislation, Building 1, Room 137, 9000 Rockville Pike, Bethesda, MD 20892

National Institutes Health, Office of the Director, Director, Division of Personnel Management, Building 1, Room B1-60, 9000 Rockville Pike, Bethesda, MD 20892

National Heart, Lung, and Blood Institute (NHLBI), Privacy Act Coordinator, Building 31, Room 5A29, Bethesda, MD 20892

National Library of Medicine (NLM), Assistant Director for Planning and Evaluation, Building 38, Room 2S18, Bethesda, MD 20894

National Eye Institute (NEI), Executive Officer, Building 31, Room 6A25, Bethesda, MD 20892

Fogarty International Center (FIC), National Institutes of Health, Assistant Director for Planning, Evaluation and Public Affairs, Building 31, Room B2C32, Bethesda, MD 20892

Division of Research Grants (DRG), Assistant Director for Special Projects, Westwood Building, Room 457, 5333 Westbard Avenue, Bethesda, MD 20892

National Center of Research Resources (NCRR), Evaluation Officer, Office of Science Policy, NIH, Westwood Building, Room 8A03, Bethesda, MD 20892

National Cancer Institute, Privacy Act Coordinator, National Institutes of Health, Building 31, Room 10A30, Bethesda, MD 20892

#### 02-25-0156

##### SYSTEM NAME:

Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the National Institutes of Health, HHS/NIH/OD.

##### SECURITY CLASSIFICATION:

None.

##### SYSTEM LOCATION:

This system of records is an umbrella system comprising separate sets of records located either in the organizations responsible for conducting evaluations or at the sites of programs or activities under evaluation. Locations include National Institutes of Health (NIH) facilities in Bethesda, Maryland, or facilities of contractors of the NIH. Write to the appropriate System Manager below for a list of current locations.

##### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by this system are those who provide information or opinions that are useful in evaluating programs or activities of the NIH, other persons who have participated in or benefitted from NIH programs or activities; or other persons included in evaluation studies for purposes of comparison. Such individuals may include (1) participants in research studies; (2) applicants for and recipients of grants, fellowships, traineeships or other awards; (3) employees, experts and consultants; (4) members of advisory committees; (5) other researchers, health care professionals, or individuals who have or are at risk of developing diseases or conditions studied by NIH; (6) persons who provide feedback about the value or usefulness of information they receive about NIH programs, activities or research results; (7) persons who have received Doctorate level degrees from U.S. institutions; (8) persons who have worked or studied at U.S. institutions that receive (d) institutional support from NIH.

##### CATEGORIES OF RECORDS IN THE SYSTEM:

This umbrella system of records covers a varying number of separate sets of records used in different evaluation studies. The categories of records in each set depend on the type of program being evaluated and the specific purpose of the evaluation. In general, the records contain two types of information: (1) information identifying

subject individuals, and (2) information which enables NIH to evaluate its programs and services.

(1) Identifying information usually consists of a name and address, but it might also include a patient identification number, grant number, Social Security Number, or other identifying number as appropriate to the particular group included in an evaluation study.

(2) Information used for evaluation varies according to the program evaluated. Categories of evaluative information include personal data and medical data on participants in clinical and research programs; personal data, publications, professional achievements and career history of researchers; and opinions and other information received directly from individuals in evaluation surveys and studies of NIH programs.

The system does not include any master list, index or other central means of identifying all individuals whose records are included in the various sets of records covered by the system.

##### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for this system comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 2891-1 and 44 U.S.C. 3101).

##### PURPOSE(S):

This system supports evaluation of the policies, programs, organization, methods, materials, activities or services used by NIH in fulfilling its legislated mandate for (1) conduct and support of biomedical research into the causes, prevention and cure of diseases; (2) support for training of research investigators; (3) communication of biomedical information.

This system is not used to make any determination affecting the rights, benefits or privileges of any individual.

##### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors and collaborating researchers, organizations, and State and local officials for the purpose of conducting evaluation studies or collecting, aggregating, processing or analyzing records used in evaluation studies. The recipients are required to protect the confidentiality of such records.

2. Disclosure may be made to organizations deemed qualified by the

Secretary to carry out quality assessments, medical audits or utilization review.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. The Department may disclose information from this system or records to the Department of Justice, to court or other tribunal, or to another party before such tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the tribunal, or the other party is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Data may be stored in file folders, bound notebooks, or computer-accessible media (e.g., magnetic tapes or discs).

**RETRIEVABILITY:**

Information is retrieved by name and/or participant identification number within each evaluation study. There is no central collection of records in this system, and no central means of identifying individuals whose records are included in the separate sets of records that are maintained for particular evaluation studies.

**SAFEGUARDS:**

A variety of safeguards are implemented for the various sets of records in this system according to the sensitivity of the data each set contains. Information already in the public domain, such as titles and dates of publications, is not restricted. However, sensitive information, such as personal or medical history or individually identified opinions, is protected according to its level of sensitivity. Records derived from other systems of records will be safeguarded at a level at

least as stringent as that required in the original systems. Minimal safeguards for the protection of information which is not available to the general public include the following:

1. *Authorized users:* Regular access to information in a given set of records is limited to NIH or to contractor employees who are conducting, reviewing or contributing to a specific evaluation study. Other access is granted only on a case-by-case basis, consistent with the restrictions required by the Privacy Act (e.g., when disclosure is required by the Freedom of Information Act), as authorized by the system manager or designated responsible official.

2. *Physical safeguards:* Records are stored in closed or locked containers, in areas which are not accessible to unauthorized users, and in facilities which are locked when not in use. Records collected in each evaluation project are maintained separately from those of other projects. Sensitive records are not left exposed to unauthorized persons at any time. Sensitive data in machine-readable form may be encrypted.

3. *Procedural safeguards:* Access to records is controlled by responsible employees and is granted only to authorized individuals whose identities are properly verified. Data stored in mainframe computers is accessed only through the use of keywords known only to authorized personnel. When personal computers are used, magnetic media (e.g. diskettes) are protected as under Physical Safeguards. When data is stored within a personal computer (i.e., on a "hard disk"), the machine itself is treated as though it were a record, or records, under Physical Safeguards. Contracts for operation of this system of records require protection of the records in accordance with these safeguards; NIH project and contracting officers monitor contractor compliance.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—

"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 1100-C-2. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER(S) AND ADDRESS:**

See Appendix 1.  
Policy coordination for this system is provided by:  
Associate Director, Office of Strategic Planning and Evaluation, Office of Science Policy and Technology Transfer, National Institutes of Health, 6006 Executive Boulevard, Suite 312, Rockville, MD 20892.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the official of the organization responsible for the evaluation, as listed in Appendix 2. If you are not certain which component of NIH was responsible for the evaluation study, or if you believe there are records about you in several components of NIH, write to:

NIH Privacy Act Officer, Building 31, Room 1B25, 9000 Rockville Pike, Bethesda, MD 20892.

Requesters must provide the following information:

1. Full name, and name(s) used while studying or employed;
2. Name and location of the evaluation study or other NIH program in which the requester participated or the institution at which the requester was a student or employee, if applicable;
3. Approximate dates of participation, matriculation or employment, if applicable.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, other health professional, or other responsible individual, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or

other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

#### RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

#### CONTESTING RECORD PROCEDURES:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

#### RECORD SOURCE CATEGORIES:

Information contained in these records is obtained directly from individual participants; from systems of records 09-25-0036, "Grants: IMPAC (Grants/Contract Information), HHS/NIH/DRG;" 09-25-0112, "Grants: Research, Research Training, Fellowship and Construction Applications and Awards, HHS/NIH/OD"; NSF-6, "Doctorate Record File", NSF-43, "Doctorate Work History File" (previously entitled NSF-43, "Roster and Survey of Doctorate Holders in the United States" and other records maintained by the operating programs of NIH: the National Academy of Sciences, professional associations such as the AAMC and ADA, and other contractors; grantees or collaborating researchers; or publicly available sources such as bibliographies.

#### SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

#### Appendix 1: System Managers

Associate Director, Office of Strategic Planning and Evaluation, Office of Science Policy and Technology Transfer, National Institutes of Health, 6006 Executive Boulevard, Suite 312, Rockville, MD 20892  
National Institutes of Health, Office of the Director, Director, Division of Personnel Management, Building 1, Room B1-60, 9000 Rockville Pike, Bethesda, MD 20892  
National Heart, Lung, and Blood Institute (NHLBI), NHLBI Minority Coordinator, Building 31, Room 5A07, Bethesda, MD 20892

National Library of Medicine (NLM), Associate Director for Health Information Programs Development, Building 38, Room 2S28, Bethesda, MD 20894

National Eye Institute (NEI), Associate Director for Science Policy and Legislation, Building 31, Room 6A25, Bethesda, MD 20892

National Cancer Institute (NCI), Public Health Educator, OCC, NCI, National Institutes of Health Building 31, Room 4B43, Bethesda, MD 20892

National Institute on Aging (NIA), Chief, Office of Planning, Analysis, Technical Information and Evaluation, Federal Building, Room 6A09, 7550 Wisconsin Avenue, Bethesda, MD 20892

National Institute of Allergy and Infectious Diseases (NIAID), Acting Director, Office of Policy Analysis and Technology Transfer, Building 31, Room 7A-52, Bethesda, MD 20892

National Institute of Child Health and Human Development (NICHD), Chief, Office of Science Policy and Analysis, Building 31, Room 2A10, Bethesda, MD 20892

National Institute on Deafness and Other Communication Disorders, Chief, Program Planning and Health Reports Branch, Building 31, Room 3C36, 9000 Rockville Pike, Bethesda, MD 20892

National Institute of Dental Research (NIDR), Chief, Office of Planning Evaluation, and Communications, Building 31, Room 2C35, Bethesda, MD 20892

National Institute of Environmental Health Sciences (NIEHS) Program, Analyst, Office of Program Planning and Evaluation, P.O. Box 12233, Research Triangle Park, N.C. 27709

National Institute of General Medical Sciences (NIGMS), Chief, Office of Program Analysis, Westwood Building, Room 934, 5333 Westbard Avenue, Bethesda, MD 20892

Fogarty International Center (FIC), National Institutes of Health, Assistant Director for Planning, Evaluation and Public Affairs, Building 31, Room B2C32, Bethesda, MD 20892

National Center for Research Resources (NCRR), Evaluation Officer, Office of Science Policy, Westwood Building, Room 8A03, Bethesda, MD 20892

National Institute of Nursing Research (NINR), Chief, Office of Planning, Analysis and Evaluation, Building 31, Room 5B09, Bethesda, MD 20892

#### Appendix 2: Notification and Access Officials

NIH, Office of the Director, Associate Director for Science, Policy and Legislation, Building 1, Room 137, 9000 Rockville Pike, Bethesda, MD 20892

National Institutes of Health, Office of the Director, Director, Division of Personnel Management, Building 1, Room B1-60, 9000 Rockville Pike, Bethesda, MD 20892

National Heart, Lung, and Blood Institute (NHLBI), Privacy Act Coordinator, Building 31 Room 5A29, Bethesda, MD 20892

National Library of Medicine (NLM), Associate Director for Health Information

Programs Development, Building 38, Room 2S28, Bethesda, MD 20894

National Eye Institute (NEI), Executive Officer, Building 31, Room 6A25, Bethesda, MD 20892

Fogarty International Center (FIC), National Institutes of Health, Assistant Director for Planning, Evaluation and Public Affairs, Building 31, Room B2C32, Bethesda, MD 20892

Division of Research Grants (DRG), Assistant Director for Special Projects, Westwood Building, Room 457, 5333 Westbard Avenue, Bethesda, MD 20892

National Center for Research Resources (NCRR), Evaluation Officer, Office of Science Policy, NIH, Westwood Building, Room 8A03, Bethesda, MD 20892

National Cancer Institute, Privacy Act Coordinator, National Institutes of Health, Building 31, Room 10A30, Bethesda, MD 20892

#### 09-25-0161

#### SYSTEM NAME:

Administration: NIH Consultant File, HHS/NIH/DRG.

#### SECURITY CLASSIFICATION:

None.

#### SYSTEM LOCATION:

This system of records is an umbrella system comprising separate sets of records located in each of the NIH organizational components or facilities of contractors of the NIH.

Division of Computer Research and Technology, Data Management Branch, Building 12A, Room 4041B, National Institutes of Health, Bethesda, Maryland 20892

Write to the appropriate system manager listed in Appendix I for a list of current locations.

#### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Consultants who provide the evaluation of extramural grants and cooperative agreement applications and research contract proposals, including the NIH Reviewers' Reserve and/or advise on policy. Consultants who participate in NIH conferences, workshops, evaluation projects and/or provide technical assistance at site locations arranged by contractors.

#### CATEGORIES OF RECORDS IN THE SYSTEM:

Names, addresses, Social Security numbers, resumes, curriculum vitae (C.V.s), areas of expertise, gender, minority status, business status. AREA-eligible status, publications, travel records, and payment records for consultants.

#### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 301 of the Public Health Service Act, describing the general

powers and duties of the Public Health Service relating to research and investigation, and section 402 of the Public Health Service Act, describing the appointment and authority of the Director of the National Institutes of Health, (42 U.S.C. 241, 282 and 290 aa).

**PURPOSE(S):**

This umbrella system comprises separate sets of records located in each of the NIH organizational components or facilities of contractors of the NIH. These records are used: (1) To identify and select experts and consultants for program reviews and evaluations; (2) To identify and select experts and consultants for the review of special grant and cooperative agreement applications and research contract proposals and (3) To obtain and pay consultants who participate in NIH conferences, workshops, evaluation projects and/or provide technical assistance at site locations arranged by contractors, and (4) To provide necessary reports related to payment to the Internal Revenue Service.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.
2. Disclosure may be made to the Department of Justice or to a court or other tribunal from this system of records, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected.
3. Disclosure may be made to contractors to process or refine the records. Contracted services may include transcription, collection, computer input, and other records processing.
4. Information in this system of records is used routinely to prepare W-2 and 1099 Forms to submit to the Internal Revenue Service and applicable

State and local governments those items to be included as income to an individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records may be stored in file folders, computer tapes and disks, microfiche, and microfilm.

**RETRIEVABILITY:**

Records are retrieved by name, expertise, gender, minority status, business status, AREA-eligible status and experimental system used.

**SAFEGUARDS:**

1. *Authorized users:* Data on computer files is accessed by keyword known only to authorized users who are PHS or contractor employees involved in managing a review or program advisory committee, conducting a review of extramural grant applications, cooperative agreement applications, or research contract proposals, performing an evaluation study or managing the consultant file. Access to information is thus limited to those with a need to know.

2. *Physical safeguards:* Room where records are stored are locked when not in use. During regular business hours rooms are unlocked but are controlled by on-site personnel.

3. *Procedural safeguards:* Names and other identifying particulars are deleted when data from original records are encoded for analysis. Data stored in computers is accessed through the use of keywords known only to authorized users. Contractors who maintain records in this system are instructed to make no further disclosure of the records except as authorized by the system manager and permitted by the Privacy Act.

This system of records will be protected according to the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual,

Appendix B-361), item 1100-G. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER(S) AND ADDRESS:**

The policy coordinator for this system is also the system manager listed for the Division of Research Grants.

Chief, Biological and Physiological Sciences Review Section, Referral and Review Branch, Division of Research Grants, Westwood Building, Room 417, 5333 Westbard Avenue, Bethesda, Maryland 20892

and

See Appendix I

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the appropriate system manager as listed in Appendix I.

The Requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requestor is whom he or she claims to be. The request should include: (a) Full name, and (b) appropriate dates of participation.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requestors should also reasonably specify the record contents being sought. Individuals may also request listing of accountable disclosures that have been made of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Contact the official under notification procedures above, reasonably identify the record, specify the information to be contested, and state the corrective action sought with supporting information. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Subject individual.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**Appendix I: System Managers**

Office of the Director (OD), Extramural Programs Management Officer, Building 31, Room 5B31, Bethesda, MD 20892  
National Center for Research Resources (NCRR), Director, Office of Review, Westwood Building, Room 8A16, Bethesda, MD 20892

National Cancer Institute (NCI), Chief, Review Logistics Branch, Executive Plaza North, Room 636, Bethesda, MD 20892  
National Eye Institute (NEI), Review and Special Projects Officer, Executive Plaza South, Room 350, Bethesda, MD 20892  
National Heart, Lung, and Blood Institute (NHLBI), Chief, Review Branch, Westwood

Building, Room 557A, 5333 Westbard Avenue, Bethesda, MD 20892

National Institute on Aging (NIA), Chief, Scientific Review Office, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892

National Institute of Allergy and Infectious Diseases (NIAID), Director, Scientific Review Program, Division of Extramural Activities, Solar Bldg., Room 3C-16, 6003 Executive Blvd., Bethesda, MD 20892

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Chief, Grants Review Branch, Natcher Building, Room 5AS-25U, Bethesda, MD 20892

National Institute of Child Health and Human Development (NICHD), Director, Division of Scientific Review, 6100 Executive Boulevard, Room 5E03H, Bethesda, MD 20892

National Institute on Deafness and Other Communication Disorders (NIDCD), Chief, Scientific Review Branch, Executive Plaza South, Room 400B, 620 Executive Boulevard, Rockville, MD 20852

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Chief, Review Branch, Natcher Building, Room 6AS-37F, Bethesda, MD 20892

National Institute of Dental Research (NIDR), Chief, Scientific Review Section, POB, Natcher Building, Room 4AN-38D, 45 Center Drive MSC 6402, Bethesda, MD 20892-6402

National Institute of Environmental Health Sciences (NIEHS), Chief, Scientific Review Branch, Division of Extramural Research and Training, P.O. Box 12233, Research Triangle Park, NC 27709

National Institute of General Medical Sciences (NIGMS), Chief, Office of Scientific Review, Natcher Building, Room 1AS-13F, Bethesda, MD 20892

National Institute of Neurological Disorders and Stroke (NINDS), Chief, Scientific Review Branch, Federal Building, Room 9C10A, Bethesda, MD 20892

National Institute of Nursing Research (NINR), Chief, Office of Review, Natcher Building, Room 3AN24 MSC 6302, Bethesda, MD 20892-6302

National Library of Medicine (NLM), Chief, Biomedical Information Support Branch, Building 38A, Room 5S522, Bethesda, MD 20894

National Center for Human Genome Research (NCHGR), Chief, Office of Scientific Review, Building 38A, Room 604, Bethesda, MD 20892

National Institute of Mental Health, Associate Director for Program Coordination, Division of Extramural Activities, Parklawn Building, Room 9C-15, 5600 Fishers Lane, Rockville, MD 20857

National Institute on Alcohol Abuse and Alcoholism, Committee Management Officer, Willco Building, Suite 504, 6000 Executive Blvd MSC 7003, Bethesda, MD 20892-7003

National Institute on Alcohol Abuse and Alcoholism, Deputy Director, Office of Scientific Affairs, Willco Building, Suite 409, 6000 Executive Blvd. MSC 7003, Bethesda, MD 20892-7003

National Institute on Drug Abuse, Office of Extramural Program Review, Parklawn

Building, Room 10-42, 5600 Fishers Lane, Rockville, MD 20857

**09-25-0165****SYSTEM NAME:**

National Institutes of Health Loan Repayment Program, HHS/NIH/OD.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Loan Repayment Program (LRP), Office of the Director, National Institutes of Health, Federal Building, Room 102, 7550 Wisconsin Avenue, Bethesda, Maryland 20892-9015

Division of Computer Research and Technology (DCRT), National Institutes of Health, Building 12A, Room 4037, 9000 Rockville Pike, Bethesda, Maryland 20892

Operations Accounting Branch, Division of Financial Management (DFM), National Institutes of Health, Building 31, Room B1B55, 9000 Rockville Pike, Bethesda, Maryland 20892

See Appendix I for a listing of other NIH offices responsible for administration of the Loan Repayment Program. Write to the System Manager at the address below for the address of any Federal Records Center where records from this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who have applied for, who have been approved to receive, who are receiving, and who have received funds under the NIH LRP; and individuals who are interested in participation in the NIH LRP.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Name, address, Social Security number; service pay-back obligations, standard school budgets, educational loan data including deferment and repayment/delinquent/default status information; employment data; professional and credentialing history of licensed health professionals including schools of attendance; personal, professional, and demographic background information; employment status verification (which includes certifications and verifications of continuing participation in AIDS research); Federal, State and local tax information, including copies of tax returns.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 487A (42 U.S.C. 288-1) of the PHS Act, as amended, authorizes the NIH to implement a program of educational loan repayment for qualified health professionals who agree

to conduct, as employees of NIH, AIDS research (the NIH AIDS Research LRP). The provisions of section 338B of the PHS Act (42 U.S.C. 2541-1), as amended, governing the NHSC loan repayment program, are incorporated except as inconsistent. Section 487E (42 U.S.C. 288-5) of the PHS Act authorizes the NIH to establish and implement a program of educational loan repayment for qualified health professionals who agree to conduct, as employees of the NIH, clinical research (the NIH Clinical Research LRP). Eligibility for the Clinical Research LRP is restricted to individuals who are from disadvantaged backgrounds. The provisions of section 338C and 338E of the PHS Act (42 U.S.C. 2541-1), as amended, governing the NHSC loan repayment program, are incorporated except as inconsistent. The Internal Revenue Code at 26 U.S.C. 6109 requires the provision of the SSN for the receipt of loan repayment funds under the NIH LRP.

**PURPOSE(S):**

(1) To identify and select applicants for the NIH LRP; (2) To monitor loan repayment activities, such as payment tracking, deferment of service obligation, and default; and (3) To assist NIH officials in the collection of overdue debts owed under the NIH LRP. Records may be transferred to system No. 09-15-0045, "Health Resources and Services Administration Loan Repayment/Debt Management Records System, HHS/HRSA/OA," for debt collection purposes when NIH officials are unable to collect overdue debts owed under the NIH LRP.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USE:**

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. Disclosure may be made to the Department of Justice or to a court or other tribunal from this system of records, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States of any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice,

court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected.

3. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute, or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred to the appropriate agency, whether Federal, State, or local, charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

4. NIH may disclose records to Department contractors and subcontractors for the purpose of collecting, compiling, aggregating, analyzing, or refining records in the system. Contractors maintain, and are also required to ensure that subcontractors maintain, Privacy Act safeguards with respect to such records.

5. NIH may disclose information from this system of records to private parties such as present and former employers, references listed on applications and associated forms, other references and educational institutions. The purpose of such disclosures is to evaluate an individual's professional accomplishments, performance, and educational background, and to determine if an applicant is suitable for participation in the NIH LRP.

6. NIH may disclose information from this system of records to a consumer reporting agency (credit bureau) to obtain a commercial credit report to assess and verify the ability of an individual to repay debts owed to the Federal Government. Disclosures are limited to the individual's name, address, Social Security number and other information necessary to identify him/her; the funding being sought or amount and status of the debt; and the program under which the applicant or claim is being processed.

7. NIH may disclose from this system of records a delinquent debtor's or a defaulting participant's name, address, Social Security number, and other information necessary to identify him/her; the amount, status, and history of the claim, and the agency or program under which the claim arose, as follows:

a. To another Federal agency so that agency can effect a salary offset for debts owed by Federal employees; if the claim

arose under the Social Security Act, the employee must have agreed in writing to the salary offset.

b. To another Federal agency so that agency can effect an unauthorized administrative offset; i.e., withhold money, other than federal salaries, payable to or held on behalf of the individual.

c. To the Treasury Department, Internal Revenue Service (IRS), to request an individual's current mailing address to locate him/her for purposes of either collecting or compromising a debt, or to have a commercial credit report prepared.

8. NIH may disclose information from this system of records to another agency that has asked the Department to effect a salary or administrative offset to help collect a debt owed to the United States. Disclosure is limited to the individual's name, address, Social Security number, and other information necessary to identify the individual to information about the money payable to or held for the individual, and other information concerning the offset.

9. NIH may disclose to the Treasury Department, Internal Revenue Service (IRS), information about an individual applying for loan repayment under any loan repayment program authorized by the Public Health Service Act to find out whether the applicant has a delinquent tax account. This disclosure is for the sole purpose of determining the applicant's creditworthiness and is limited to the individual's name, address, Social Security number, other information necessary to identify him/her, and the program for which the information is being obtained.

10. NIH may report to the Treasury Department, Internal Revenue Service (IRS), as taxable income, the written-off amount of a debt owed by an individual to the Federal Government when a debt becomes partly or wholly uncollectible, either because the time period for collection under the statute of limitations has expired, or because the Government agrees with the individual to forgive or compromise the debt.

11. NIH may disclose to debt collection agents, other Federal agencies, and other third parties who are authorized to collect a Federal debt, information necessary to identify a delinquent debtor or a defaulting participant. Disclosure will be limited to the individual's name, address, Social Security number, and other information necessary to identify him/her; the amount, status, and history of the claim, and the agency or program under which the claim arose.

12. NIH may disclose information from this system of records to any third

party that may have information about a delinquent debtor's or a defaulting participant's current address, such as a U.S. post office, a State motor vehicle administration, a professional organization, an alumni association, etc., for the purpose of obtaining the individual's current address. This disclosure will be strictly limited to information necessary to identify the individual, without any reference to the reason for the agency's need for obtaining the current address.

13. NIH may disclose information from this system of records to other Federal agencies that also provide loan repayment at the request of these Federal agencies in conjunction with a matching program conducted by these Federal agencies to detect or curtail fraud and abuse in Federal loan repayment programs, and to collect delinquent loans or benefit payments owed to the Federal Government.

14. NIH may disclose from this system of records to the Department of Treasury, Internal Revenue Service (IRS): (1) A delinquent debtor's or a defaulting participant's name, address, Social Security number, and other information necessary to identify the individual; (2) the amount of the debt; and (3) the program under which the debt arose, so that IRS can offset against the debt any income tax refunds which may be due to the individual.

15. NIH may disclose information provided by a lender to other Federal agencies, debt collection agents, and other third parties who are authorized to collect a Federal debt. The purpose of this disclosure is to identify an individual who is delinquent in loan or benefit payments owed to the Federal Government.

#### DISCLOSURE TO CONSUMER REPORTING AGENCIES:

*Disclosures pursuant to 5 U.S.C. 552a(b)(12):* Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). The purposes of these disclosures are: (1) To provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records, and (2) to enable NIH to improve the quality of loan repayment decisions by taking into account the financial reliability of applicants, including obtaining a commercial credit report to assess and verify the ability of an individual to repay debts owed to the Federal Government. Disclosure of records will be limited to the individual's name, Social Security

number, and other information necessary to establish the identity of the individual, the amount, status, and history of the claim, and the agency or program under which the claim arose.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are maintained in file folders, computer tape, discs, and file cards.

**RETRIEVABILITY:**

Records are retrieved by name, Social Security number, or other identifying numbers.

**SAFEGUARDS:**

1. *Authorized users:* Data on computer files is accessed by keyword known only to authorized users who are NIH employees responsible for implementing the NIH LRP. Access to information is thus limited to those with a need to know.

2. *Physical safeguards:* Rooms where records are stored are locked when not in use. During regular business hours rooms are unlocked but are controlled by on-site personnel. Security guards perform random checks on the physical security of the data.

3. *Procedural and technical safeguards:* A password is required to access the terminal and a data set name controls the release of data to only authorized users. All users of personal information in connection with the performance of their jobs (see Authorized Users, above) protect information from public view and from unauthorized personnel entering an unsupervised office.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, the Department's Automated Information System Security Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 2300-537-1. Participant case files are transferred to a Federal Records Center one year after closeout and destroyed five years later. Closeout is the process by which it is

determined that all applicable administrative actions and loan repayments have been completed by the LRP and service obligations have been completed by the participant. Applicant case files are destroyed three years after disapproval or withdrawal of their application. Official appeal and litigation case files are destroyed six years after the calendar year in which the case is closed. Other copies of these files are destroyed two years after the calendar year in which the case is closed.

**SYSTEM MANAGER AND ADDRESS:**

Director, NIH Loan Repayment Program, Office of the Director, National Institutes of Health, Federal Building, Room 102, 7550 Wisconsin Avenue, Bethesda, Maryland 20892-9015.

**NOTIFICATION PROCEDURES:**

To determine if a record exists, write to the System Manager listed above. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be. The request should include: (a) Full name, and (b) appropriate dates of participation. The requester must also understand that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine. Requesters appearing in person must provide a valid driver's license or passport, including photo, and at least one other form of identification.

**RECORD ACCESS PROCEDURES:**

Write to the System Manager specified above to attain access to records and provide the same information as is required under the Notification Procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request an accounting of disclosure of their records, if any.

**CONTESTING RECORD PROCEDURES:**

Contact the System Manager specified above and reasonably identify the record, specify the information to be contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Subject individual; participating lending institutions; educational institutions attended; other Federal agencies; consumer reporting agencies/ credit bureaus; and third parties that provide references concerning the subject individual.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**Appendix I: System Locations**

Loan Repayment Program, National Institutes of Health, Federal Building, Room 102, 7550 Wisconsin Avenue, Bethesda, MD 20892-9015

Division of Computer Research and Technology, National Institutes of Health, Building 12A, Room 4018, 9000 Rockville Pike, Bethesda, MD 20892

Operations Accounting Branch, Division of Financial Management, National Institutes of Health, Building 31, Room B1B55, 9000 Rockville Pike, Bethesda, MD 20892

Division of Cancer Treatment, National Cancer Institute, National Institutes of Health, Building 31, Room 3A44, 9000 Rockville Pike, Bethesda, MD 20892

Division of Cancer Etiology, National Cancer Institute, National Institutes of Health, Building 31, Room 11A11, 9000 Rockville Pike, Bethesda, MD 20892

Division of Cancer Biology, Diagnosis, and Centers, National Cancer Institute, National Institutes of Health, Building 31, Room 3A05, 9000 Rockville Pike, Bethesda, MD 20892

National Heart, Lung, and Blood Institute, National Institutes of Health, Building 10, Room 7N220, 9000 Rockville Pike, Bethesda, MD 10892

National Institute of Dental Research, National Institutes of Health, Building 31, Room 2C23, 9000 Rockville Pike, Bethesda, MD 20892

National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Building 10, Room 9N222, 9000 Rockville Pike, Bethesda, MD 20892

National Institute of Neurological Disorders and Stroke, National Institutes of Health, Building 10, Room 5N220, 9000 Rockville Pike, Bethesda, MD 20892

National Institute of Allergy and Infectious Diseases, National Institutes of Health, Building 31, Room 7A05, 9000 Rockville Pike, Bethesda, MD 20892

Pharmacological Sciences Program, National Institute of General Medical Sciences, National Institutes of Health, Building 45, Room 2AS, 9000 Rockville Pike, Bethesda, MD 20892

National Institute of Child Health and Human Development, National Institutes of Health, Building 31, Room 2A25, 9000 Rockville Pike, Bethesda, MD 20892

National Eye Institute, National Institutes of Health, Building 10, Room 10N202, 9000 Rockville Pike, Bethesda, MD 20892

National Institute of Environmental Health Sciences, National Institutes of Health, South Campus, Building 101, Room B-248, 111 Alexander Drive, Research Triangle Park, NC 27709

Gerontology Research Center, National Institute on Aging, National Institutes of Health, 4940 Eastern Avenue, Baltimore, MD 21224

National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, Building 31, Room 4C13, 9000 Rockville Pike, Bethesda, MD 20892

National Institute of Deafness and Communication Disorders, National Institutes of Health, Building 31, Room 3C02, 9000 Rockville Pike, Bethesda, MD 20892

National Institute for Nursing Research, National Institutes of Health, Building 31, Room 5B06, 9000 Rockville Pike, Bethesda, MD 20892

National Center for Research Resources, National Institutes of Health, Building 31, Room 3B36, 9000 Rockville Pike, Bethesda, MD 20892

Clinical Center, National Institutes of Health, Building 10, Room 1N312, 9000 Rockville Pike, Bethesda, MD 20892

National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Parklawn Building, Room 16C05, 5600 Fishers Lane, Rockville, MD 20857

National Institute on Drug Abuse, National Institute of Health, Parklawn Building, Room 10A38, 5600 Fishers Lane, Rockville, MD 20857

National Institute of Mental Health, National Institutes of Health, Parklawn Building, Room 1599, 56 Fishers Lane, Rockville, MD 20857

Clinical Center Nursing Recruiting Office, National Institutes of Health, Building 10, Room 2C206, 9000 Rockville Pike, Bethesda, MD 20892

#### 09-25-0166

##### SYSTEM NAME:

Administration: Radiation and Occupational Safety and Health Management Information Systems, HHS/NIH/ORS.

##### SECURITY CLASSIFICATION:

None.

##### SYSTEM LOCATION:

Radiation Safety Branch (RSB), Division of Safety, Office of Research Services, NIH, Building 21, Room 134, 9000 Rockville Pike, Bethesda, MD 20892.

Occupational Safety and Health Branch (OSHB), Division of Safety, National Institutes of Health, Building 13, Room 3K04, 9000 Rockville Pike, Bethesda, Maryland 20892.

Write to appropriate System Manager at the address below for the address of contractor locations, including the address of any Federal Records Center where records from this system may be stored.

##### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Radiation Safety Branch (RSB): NIH employees using radioactive materials

or radiation producing machinery, contractor employees who provide service to the Radiation Safety Branch and any other individuals who could potentially be exposed to radiation or radioactivity as a result of NIH operations and who, therefore, must be monitored in accordance with applicable regulations.

Occupational Safety and Health Branch (OSHB): Individuals (including NIH employees and NIH service contract employees) who use or come into contact with potentially hazardous biological or chemical materials, and participants of occupational safety and health monitoring/surveillance programs.

##### CATEGORIES OF RECORDS IN THE SYSTEM:

Employee name, title, organizational affiliation, birth date, Social Security number (optional), work address, work telephone number, name of supervisor, and other necessary employment information; radiation/occupational safety and health training information; medical and technical information pertaining to safety and health related initiatives; research protocols and other related documents used to monitor and track radiation exposure and exposure to potentially hazardous biological or chemical materials; radiation materials usage data; and incident data.

##### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, regarding the general powers and duties of the Public Health Service relating to research and investigation; 5 U.S.C. 7902 regarding agency safety programs; and 42 U.S.C. 2201, regarding general duties of the Nuclear Regulatory Commission including the setting of standards to cover the possession and use of nuclear materials in order to protect health.

##### PURPOSE(S):

1. To provide adequate administrative controls to assure compliance with internal NIH policies, and applicable regulations of the Occupational Safety and Health Administration (OSHA), Department of Labor, and other Federal and/or State agencies which may establish health and safety requirements or standards. Ensure legal compliance with requirements of Nuclear Regulatory Commission to maintain internal and external radiation exposure data.

2. To identify, evaluate and monitor use or contact (including incident follow-up) with:

- a. Radiation (exposure maintained at lowest levels reasonable)
- b. Biological and/or chemical (potentially hazardous materials).

3. To monitor, track, and assess the use of personal protective equipment in the work place to ensure availability, effectiveness and proper maintenance.

4. To address emergent safety and health issues or concerns.

##### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USE:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. Disclosure may be made to the Department of Justice or to a court or other tribunal from this system of records, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States of any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected.

3. Disclosure may be made to contractors for the purpose of processing or refining the records. Contracted services may include monitoring, testing, sampling, surveying, evaluating, transcription, collation, computer input, and other records processing. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

4. Disclosure may be made to: (a) Officials of the United States Nuclear Regulatory Commission which, by Federal regulation, licenses, inspects and enforces the regulations governing the use of radioactive materials; and (b) OSHA, which provides oversight to ensure that safe and healthful work conditions are maintained for employees. Disclosure will also be permitted to other Federal and/or State agencies which may establish health and safety requirements or standards.

5. Radiation exposure and/or training and experience history may be transferred to new employer.

6. A record may be disclosed for a research purpose, when the Department:

(A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are maintained in file cabinets or in computer databases maintained by the RSB and OSHB. Records may be stored in file folders, binders, magnetic tapes, magnetic disks, optical disks and/or other types of data storage devices.

**RETRIEVABILITY:**

Records are retrieved by name, Social Security number, office address, or unique RSB or OSHB assigned identification number.

**SAFEGUARDS:**

1. *Authorized users:* Employees who maintain this system are instructed to grant regular access only to RSB/OSHB staff, authorized contractor personnel, U.S. Nuclear Regulatory Commission Inspectors, Radiation Safety Committee Members, Biosafety Committee

members, and other appropriate NIH administrative and management personnel with a need to know. Access to information is thus limited to those with a need to know.

2. *Physical safeguards:* Rooms where records are stored are locked when not in use. During regular business hours, rooms are unlocked but are controlled by on-site personnel. Individually identifiable records are kept in locked file cabinets or rooms under the direct control of the Project Director.

3. *Procedural safeguards:* Names and other identifying particulars are deleted when data from original records are encoded for analysis. Data stored in computers is accessed through the use of keywords known only to authorized users. All users of personal information in connection with the performance of their jobs (see Authorized Users, above) will protect information from public view and from unauthorized personnel entering an unsupervised office. The computer terminals are in secured areas and keywords needed to access data files will be changed frequently.

4. *Additional RSB technical safeguards:* Computerized records are accessible only through a series of code or keyword commands available from and under direct control of the Project Director or his/her delegated representatives. The computer records are secured by a multiple level security system which is capable of controlling access to the individual data field level. Persons having access to the computer database can be restricted to a confined application which only permits a narrow "view" of the data. Data on computer files is accessed by keyword known only to authorized users who are NIH or contractor employees involved in work for the program.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, supplementary Chapter PHS hf: 45-13, the Department's Automated Information Systems Security Program Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361): Item 1300-B which applies to Division of Safety records. Refer to the NIH Manual Chapter for specific disposition instructions. Radiation exposure records are retained

under item 1300-B-10, which does not allow disposal at this time.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Data and Analytical Services Section, Radiation Safety Branch, DS, ORS, Building 21, Room 104, 9000 Rockville Pike, Bethesda, Maryland 20892.

Chief, Occupational Safety and Health Branch, Division of Safety, National Institutes of Health, Building 13, Room 3K04, 9000 Rockville Pike, Bethesda, Maryland 20892.

**NOTIFICATION PROCEDURES:**

To determine if a record exists, write to the appropriate system manager as listed above.

The requestor must also verify his or her identity by providing either a notarization of the request or a written certification that the requestor is whom he or she claims to be. The request should include: (a) Full name, and (b) appropriate dates of participation.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requestors should also reasonably specify the record contents being sought. Individuals may also request an accounting of disclosure of their records, if any.

**CONTESTING RECORD PROCEDURE:**

Contact the appropriate System Manager specified above and reasonably identify the record, specify the information to be contested, and state the corrective action sought with supporting documentation. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Information is obtained from the subject individual, previous employers and educational institutions, contractors, safety and health monitoring/surveillance records, employee interviews, site visits, or other relevant NIH organizational components.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0168**

**SYSTEM NAME:**

Invention, patent and licensing documents submitted to the Public Health Service by its employees, grantees, fellowship recipients and contractors, HHS/PHS/NIH/OTT.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Office of Technology Transfer,  
National Institutes of Health, 6011  
Executive Boulevard, Third Floor,  
Rockville, MD 20852.

Division of Financial Management  
(DFM), Operations Accounting Branch,  
National Institutes of Health, Building  
31, Room B1B55, 9000 Rockville Pike,  
Bethesda, Maryland 20892.

Division of Extramural Reports, Office  
of Extramural Research, National  
Institutes of Health, Building 31, Room  
5B41, 31 Center Drive, Bethesda,  
Maryland 20892-2184.

Public Health Service (PHS)  
Technology Development Coordinators  
and PHS Contract Attorneys retain files  
supplemental to the records maintained  
by the Office of Technology Transfer.  
Write to the system manager at the  
address below for office locations.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

PHS employees, grantees, fellowship recipients and contractors who have reported inventions, applied for patents, have been granted patents, and/or are receiving royalties from patents.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Inventor name, address, Social Security number (required if inventor is receiving royalties, otherwise optional), title and description of the invention, Employee Invention Report (EIR) number, prior art related to the invention, evaluation of the commercial potential of the invention, prospective licensees' intended development of the invention, associated patent prosecution and licensing documents and royalty payment information.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

45 CFR parts 6 (Inventions and Patents (General)), 7 (Employee Inventions) and 8 (Inventions Resulting from Research Grants, Fellowship Awards, and Contracts for Research), describing Departmental standards for assessing, reporting, and maintaining rights, including patent rights, in inventions of Departmental employees, grantees, fellowship recipients, and contractors, or inventions made through other resources and activities of the Department; Exec. Order No. 9865, as amended, 35 U.S.C. 266 note, "Patent protection abroad of inventions resulting from research financed by the Government," describing the Government-wide policy for obtaining foreign patent protection for inventions resulting from research conducted or financed by the Government; and Exec. Order No. 10096, as amended, 35 U.S.C. 266 note, "Uniform Government Patent

Policy for Inventions by Government Employees," describing Government-wide policy pertaining to inventions made by Government employees.

**PURPOSE(S):**

Records in this system are used to: (1) Obtain patent protection of inventions submitted by PHS employees; (2) monitor the development of inventions made by grantees, fellowship recipients and contractors and protect the government rights to patents made with NIH support; (3) grant licenses to patents obtained through the invention reports; and (4) provide royalty payments to PHS inventors.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USE:**

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. Disclosure may be made to the Department of Justice or to a court or other tribunal from this system of records, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected. Disclosure may also be made to the Department of Justice to obtain legal advice concerning issues raised by the records in this system.

3. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred to the appropriate agency, whether Federal, State, or local, charged with enforcing or implementing the statute or rule,

regulation or order issued pursuant thereto.

4. NIH may disclose records to Department contractors and subcontractors for the purpose of collecting, compiling, aggregating, analyzing, or refining records in the system. Contractors maintain, and are also required to ensure that subcontractors maintain, Privacy Act safeguards with respect to such records.

5. NIH may disclose information from this system of records for the purpose of obtaining patent protection for PHS inventions and licenses for these patents to: (a) Scientific personnel, both in this agency and other Government agencies, and in non-Governmental organizations such as universities, who possess the expertise to understand the invention and evaluate its importance as a scientific advance; (b) contract patent counsel and their employees and foreign contract personnel retained by the Department for patent searching and prosecution in both the United States and foreign patent offices; (c) all other Government agencies whom PHS contacts regarding the possible use, interest in, or ownership rights in PHS inventions; (d) prospective licensees or technology finders who may further make the invention available to the public through sale or use; (e) parties, such as supervisors of inventors, whom PHS contacts to determine ownership rights, and those parties contacting PHS to determine the Government's ownership; and (f) the United States and foreign patent offices involved in the filing of PHS patent applications.

6. NIH will report to the Treasury Department, Internal Revenue Service (IRS), as taxable income, the amount of royalty payment paid to PHS inventors.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:****STORAGE:**

The records will be stored in file folders, computer tapes and computer discs.

**RETRIEVABILITY:**

Records are retrieved by name of the inventor, EIR number, or keywords relating to the nature of the invention.

**SAFEGUARDS:**

1. *Authorized users:* Data on computer files is accessed by keyword known only to authorized users who are NIH or contractor employees involved in patenting and licensing of PHS inventions. Access to information is thus limited to those with a need to know.

2. *Physical safeguards:* records are stored in a locked room or in locking

file cabinets in file folders. During normal business hours, OTT Patent Branch and Licensing Branch on-site personnel regulate availability of the files. During evening and weekend hours the offices are locked and the building is closed.

**3. Procedural and technical safeguards:** Data stored in computers will be accessed through the use of keywords known only to the authorized users. A password is required to access the data base. All users of personal information in connection with the performance of their jobs (see Authorized Users, above) protect information, including confidential business information submitted by potential licensees, from public view and from unauthorized personnel entering an unsupervised office.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, the Department's Automated Information System Security Program Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management manual, Appendix B-361), item 1100-L, which allows records to be kept for a maximum of twenty (20) years. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Chief, Technology Management Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Third Floor, Rockville, Maryland 20852.

Division of Extramural Reports, Office of Extramural Research, National Institutes of Health, Building 31, Room 5B41, 31 Center Drive, Bethesda, MD 20892-2184.

**NOTIFICATION PROCEDURES:**

To determine if a record exists, write to the System Manager listed above. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an

individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine. The request should include: (a) Full name, and (b) appropriate identifying information on the nature of the invention.

**RECORD ACCESS PROCEDURES:**

Write to the System Manager specified above to attain access to records and provide the same information as is required under the Notification Procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request an accounting of disclosure of their records, if any.

**CONTESTING RECORD PROCEDURES:**

Contact the System manager specified above and reasonably identify the record, specify the information to be contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

**RECORD SOURCE CATEGORIES:**

Inventors and other collaborating persons, grantees, fellowship recipients and contractors; other Federal agencies; scientific experts from non-Government organizations; contract patent counsel and their employees and foreign contract personnel; Unites States and foreign patent offices; prospective licensees; and third parties whom PHS contacts to determine individual invention ownership or Government ownership.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0170**

**SYSTEM NAME:**

Diabetes Data System, HHS/NIH/NIDDK.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

A list of all contractor/subcontractor locations is available upon request for the System Manager (see address below).

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who participated in the Diabetes Prevention Trial—Type 1

Diabetes (DPT-1); the Diabetes Prevention Trial—Type 2 Diabetes (DPT-2); the Epidemiology of Diabetes Interventions and Complications Study (EDIC); the International Pancreas and Islet Transplant Registry (IPITR), and family members of these participants.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Participant names, addresses, phone numbers; Social Security numbers (voluntary), phone numbers, driver's license numbers, employer information, spouse names, study identification numbers, educational background, occupational history, names of medical provider, medical record identification numbers, health and medical record data collected during these trials and follow-up studies; the names, addresses and phone numbers of acquaintances and relatives to assist in follow-up; a family tree (or pedigree) and information pertaining to DCCT stored biologic specimens (including blood, urine and genetic materials).

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 301(a) of the Public Health Service (PHS) Act (42 U.S.C. 241(a)), describing the general powers and duties of the Public Health Service relating to research and investigation, and section 426 of the PHS Act (42 U.S.C. 285c) describing the purpose of the National Institute of Diabetes and Digestive and Kidney Diseases to conduct research with respect to, among other areas, diabetes mellitus.

**PURPOSE(S):**

These records are used to: (1) Conduct research on diabetes mellitus in order to understand the disease and find better treatments and/or an eventual cure; (2) conduct follow-up studies (projected follow-up of 7-10 years) on the morbidity and mortality experiences of study participants; and (3) provide relevant demographic, health and medical record data on participants to biomedical researchers authorized to use information and stored biologic materials.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USE:**

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to

affect directly the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Department of Justice has agreed to represent such employee, for example, in defending a claim against the Public Health Service, based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

3. NIH may disclose records to Department contractors and subcontractors for the purpose of collecting, compiling, aggregating, analyzing, or refining records in the system. Contractors maintain, and are also required to ensure that subcontractors maintain, Privacy Act safeguards with respect to such records.

4. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit,

or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

5. Information from this system may be disclosed to Federal agencies, State agencies (including the Motor Vehicle Administration and State vital statistics offices, private agencies, and other third parties (such as current or prior employers, acquaintances, relatives), in order to obtain information on morbidity and mortality experiences and to locate individuals for the follow-up studies. Social Security numbers may be disclosed: (1) To the National Center for Health Statistics to ascertain vital status through the National Death Index; (2) to the Health Care Financing Agency to ascertain morbidities; and (3) to the Social Security Administration to ascertain disabilities and/or location of participants. Social Security numbers may also be given to other Federal agencies, and State and local agencies for purposes of locating individuals for participation in follow-up studies.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records may be stored in file folders and computer tapes and diskettes, microfiche, and file cards.

**RETRIEVABILITY:**

Records are retrieved by name, Social Security number, or other identifying numbers, keywords, and parameters of individual patient health or medical record data.

**SAFEGUARDS:**

1. *Authorized users:* Data on computer files is accessed by keyword known only to authorized users who are NIH or contractor employees who have a need for the data in performance of their duties as determined by the system manager. Researchers authorized to conduct research on biologic specimens will have access to the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual. Access to information is thus limited to those with a need to know.

2. *Physical safeguards:* Records and data tapes are stored in locked files in secured areas with restricted access. During regular business hours rooms are unlocked but are controlled by on-site personnel. Terminal access is controlled by user ID and keywords; off-site data backup is maintained in a separate building; fire protection is maintained

by an on-site fire extinguisher system and fire alarm system present in the computer room.

3. *Procedural and technical safeguards:* Names and other identifying particulars are deleted when data from original records are encoded for analysis. Data stored in computers is accessed through the use of keywords known only to authorized users. A password is required to access the terminal and a data set name controls the release of data to only authorized users. All users of personal information in connection with the performance of their jobs (see Authorized Users, above) protect information from public view and from unauthorized personnel entering an unsupervised office. Contractors and subcontractors who maintain records in this system are instructed to make no further disclosure of the records except as authorized by the System manager and permitted by the Privacy Act. Privacy Act requirements are specifically included in contracts and in agreements with grantees or collaborators participating in research activities supported by the system. HHS project directors, contract officers, and project officers oversee compliance with these requirements.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and the Department's Automated Information System Security Program Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-G-3(b), which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

**SYSTEM MANAGER AND ADDRESS:**

Chief, Diabetes Research Section, DPB, DDEM, National Institutes of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Westwood Building, Room 622, 5333 Westbard Avenue, Bethesda, MD 20892.

**NOTIFICATION PROCEDURES:**

To determine if a record exists, write to the System Manager listed above. The

requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine. The request should include: (a) Full name, and (b) appropriate dates of participation.

Individuals who request notification of or access to a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's/incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify their relationship to the child/incompetent person as well as his/her own identity.

#### RECORD ACCESS PROCEDURES:

Write to the System Manager specified above to attain access to records and provide the same information as is required under the Notification Procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request an accounting of disclosure of their records, if any.

#### CONTESTING RECORD PROCEDURES:

Contact the System Manager specified above and reasonably identify the record, specify the information to be contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

#### RECORD SOURCE CATEGORIES:

Subject individual; patient health and medical record data; data generated from the DCCT; Federal, State and local agencies (including the Social Security Administration), and if the person is deceased, from the National Death Index, and/or family members and other knowledgeable third persons.

#### SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

#### 09-25-0202

#### SYSTEM NAME:

Patient Records on PHS Beneficiaries (1935-1974) and Civilly Committed Drug Abusers (1967-1976) Treated at the PHS Hospitals in Fort Worth, Texas, or Lexington, Kentucky, HHS/NIH/NIDA.

#### SECURITY CLASSIFICATION:

None.

#### SYSTEM LOCATION:

National Institute on Drug Abuse, Intramural Research Program, Johns Hopkins Bayview Medical Center, P.O. Box 5180, Baltimore, Maryland 21224.

Federal Records Center, 1557 St. Joseph Avenue, East Point, Georgia 30344.

Washington National Records Center, 4205 Suitland Road, Washington, DC 20409.

National Business Activities, 8200 Preston Court, Suite One, Jessup, Maryland 20794.

#### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Civilly committed narcotic addicts (1967-1976) and adult PHS beneficiaries (1935-1974) treated at either the PHS hospital in Fort Worth, Texas, or Lexington, Kentucky.

#### CATEGORIES OF RECORDS IN THE SYSTEM:

Administrative records, such as treatment admission and release dates, name and address, and other demographic data; medical records, such as, but not limited to, medical history information, drug abuse/use data as well as treatment information, any laboratory tests, etc.

#### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Narcotic Addict Rehabilitation Act of 1966, and Narcotic Addict Rehabilitation Amendments of 1971, Titles I and III (42 U.S.C. 3411 et seq. and 28 U.S.C. 2901 et seq.), and Public Health Service Act, Sections 321-326, 341 (a) and (c) (42 U.S.C. 248-253, 257 (a) and (c)).

#### PURPOSE(S):

The records were collected originally to monitor the individual's progress while being treated at either of two PHS hospitals and to ensure continuity of that care. These systems are now inactive. The records are used to respond to requests from subject individuals (or his/her designated representative) to (1) establish eligibility for certain Federal benefits for the

individual or his/her dependent(s), and (2) provide information to subsequent health care providers at the request of the individual regarding medical treatment received to ensure continuity of care.

#### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

None.

#### POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

##### STORAGE:

Records at National Institute on Drug Abuse (NIDA) are on microfilm and contain only part of the admission and discharge information. The microfilm is stored in a file cabinet in a locked room. Records sent to Federal Records Center are stored in GSA-approved storage containers.

##### RETRIEVABILITY:

The administrative records and microfilm are filed by patient name. The medical records are filed either by patient name or by patient's hospital number with a cross-reference list at NIDA matching number to name.

##### SAFEGUARDS:

- Authorized users:* Only the System Manager and designated staff.
- Physical safeguards:* The microfilm is in a room which has limited access, or stored at a security coded warehouse. The room is located in a building with a 24-hour security patrol/television surveillance system. Sign in and out procedures are used at all times. The warehouse has security access, records can only be retrieved by the System Manager or designated staff using a confidential code number. The warehouse is patrolled on a 24-hour basis with television surveillance.
- Procedural safeguards:* Only the System Manager and his/her staff have access to the microfilm information and have been trained in accordance with the Privacy Act.
- Implementation guidelines:* DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 of the General Administration Manual.

##### RETENTION AND DISPOSAL:

All administrative and medical records have been retired to a Federal Records Center. The records collected under the Narcotic Addict Rehabilitation Act of 1966 will be destroyed when they are 25 years old, which will be in 2001 because the last patient was released from treatment in 1976. The PHS beneficiaries' records will be destroyed at the same time. The

records will be shredded in 2003 upon written request from the System Manager.

**SYSTEM MANAGER(S) AND ADDRESS:**

Medical Records Officer, National Institute on Drug Abuse, Intramural Research Program, Johns Hopkins Bayview Medical Center, Box 5180, Baltimore, Maryland 21224.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. An individual may learn if a record exists about himself or herself upon written request with a notarized signature. The request should include, if known: Patient hospital record number, full name or any alias used, patient's address during treatment, birth date, veteran status (if applicable) and approximate dates in treatment, and Social Security Number.

An individual who requests notification of a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the individual of its content at the representative's discretion.

**RECORD ACCESS PROCEDURES:**

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

**RECORD SOURCE CATEGORIES:**

Patients; patients' drug treatment program counselors; court records; hospital personnel.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

09-25-0203

**SYSTEM NAME:**

National Institute on Drug Abuse, Intramural Research Program, Federal Prisoner and Non-Prisoner Research Files, HHS/NIH/NIDA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

National Institute on Drug Abuse, Intramural Research Program, P.O. Box 5180, Baltimore, Maryland 21224.

Maryland Medical Laboratories, Inc., Pathology Building, 1901 Silver Spring Road, Baltimore, Maryland 21227.

Federal Records Center, 1557 St. Joseph Avenue, East Point, Georgia 30344.

Washington National Records Center, 4205 Suitland Road, Washington, DC 20409.

NOVA, Johns Hopkins Bayview Medical Center, Building C, 4940 Eastern Avenue, Baltimore, Maryland 21224.

National Business Activities, 8200 Preston Court, Suite One, Jessup, Maryland 20794.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Volunteers, adult males (from 1968 to present), adult females (beginning in 1985) and adolescents (ages 13-18, beginning in 1983) and children (neonate to 12 beginning in 1989). Clinical research projects conducted at the Addiction Research Center (ARC). This system also includes records on adult Federal prisoners involved in research projects at ARC when located at Lexington, Kentucky, from 1968-1976, and some records from system 09-30-0020 to be used for statistical research only.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

The categories of records involved are administrative, medical and research records.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, section 301(a) (42 U.S.C. 241(a)); sections 341(a) and 344(d) (42 U.S.C. 257(a) and 260(d)); section 503 and 515 (42 U.S.C. 290aa-2 and 290cc). These sections authorize the conduct of research in all areas of drug abuse.

**PURPOSE(S):**

(1) To collect and maintain a data base for research activities at ARC, and (2) to enable Federal drug abuse researchers to evaluate and monitor the subjects' health during participation in a research project. The areas of research include, but are not limited to, biomedical, clinical, behavioral, pharmacological, psychiatric, psychosocial, epidemiological, etiological, statistical, treatment and prevention of narcotic addiction and drug abuse.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. The National Institute on Drug Abuse (NIDA) uses a contractor to recruit volunteers and to screen these individuals for their acceptability to participate in specific research projects, and limits the contractor's access to the records to these procedures. NIDA also uses a contractor to perform routine medical laboratory tests on blood and urine samples. These routine tests verify that the subject is in good health. Both contractors disclose records from this system only to NIDA and are required to maintain Privacy Act safeguards with respect to such records.

2. (a) PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

(b) PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has, notified such sexual or needle-sharing partner(s).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:****STORAGE:**

Data may be stored in file folders or on computer disks, magnetic tapes, or microfilm.

**RETRIEVABILITY:**

Administrative and medical records are indexed and retrieved by the subject's name and identification code number. Research records are indexed and retrieved by the subject's name and identification code number.

**SAFEGUARDS:**

1. *Authorized areas:* Only authorized ARC staff (Principal Investigator and his/her research team) are allowed access to these files. The contractor staff has access to the files during the recruitment/screening process.

2. *Physical safeguards:* Files and file rooms are locked after business hours. Building has electronic controlled entry at all times with a 24-hour guard/television surveillance system. The computer terminals are in a further secured area.

3. *Procedural safeguards:* All users of personal information in connection with the performance of their jobs protect information from unauthorized personnel. Access codes to the research records are available only to the Principal Investigator and his/her research team. Access to the records is strictly limited to those staff members trained in accordance with the Privacy Act. The contractor staff members are required to secure the information in accordance with the Privacy Act. ARC Project Officer and contracting officials will monitor contractor compliance.

4. *Implementation guidelines:* DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 of the General Administration Manual; and Chapter 6-05, "Risk Management," under Part 6 in the Department's ADP Systems Security Manual.

In addition, because much of the data collected in these research projects are sensitive and confidential, special safeguards have been established. Certificates of confidentiality have been issued under Protection of Identity—Research Subjects Regulations (42 CFR part 2a) to those projects initiated since February 1980. This authorization enables persons engaged in research on mental health, including research on the use and effect of psychoactive drugs, to protect the privacy of research subjects by withholding their names or other identifying characteristics from all persons not connected with the conduct of the research. Persons so authorized may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify such individuals. In addition, these records are subject to 42 CFR part 2, the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (42 CFR 2.56), which state: "Where the content of patient records has been disclosed pursuant to these regulations for the purpose of conducting scientific research \* \* \* information contained therein which would directly or indirectly identify any patient may not be disclosed by the recipient thereof

either voluntarily or in response to any legal process whether Federal or State."

**RETENTION AND DISPOSAL:**

Records will be disposed of in accordance with the NIH Records Control Schedule, i.e., when the records are 10 years old or no longer required for administrative or research purposes. The records on individuals who do not qualify for a specific research project are kept for one year by the contractor who then destroys them by shredding.

**SYSTEM MANAGER(S) AND ADDRESSES:**

Medical Records Officer, NIDA, Intramural Research Program, Johns Hopkins Bayview Medical Center—Building C, P.O. Box 5180, Baltimore, Maryland 21224.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. Provide a notarized signature as proof of identity. This can be waived if the request is made through official federal, state, or local channels. The request should include the patient's register number and/or the number of years of incarceration (for prisoner subjects), full name at time of participation in the research project, date(s) of research participation, and title of research project or name of drug being studied. An individual who requests notification of a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or legal guardian who requests notification of an adolescent's record shall designate a family physician or other health professional (other than a family member) of the Addiction Research Center staff to whom the record, if any, will be sent. The parent or legal guardian must verify in writing the relationship to the adolescent as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought. An individual may also request an accounting of disclosures that have been made of his/her records, if any.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, and state the corrective action sought and reasons for requesting

the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

**RECORD SOURCE CATEGORIES:**

The individual; observations and medical recordings (such as blood pressure, dosage of compound administered, etc.) made by the Principal Investigator and his/her research team; system of records number 09-30-0020; drug treatment programs; Bureau of Prisons; case workers; psychiatrists; research laboratories; and pharmacies and hospitals. Many of these records are confidential and privileged communication is guaranteed under section 344(d) of the PHS Act.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0205****SYSTEM NAME:**

Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/NIDA and HHS/NIH/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Records are located at the research facilities which collect or provide research data for this system under contract to the agency. Contractors may include, but are not limited to, research centers, clinics, hospitals, universities, research foundations, national associations, and coordinating centers. Records may also be located at the research facilities of the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA); and the National Institute of Mental Health (NIMH). A current list of sites is available by writing to the appropriate System Manager at the address below.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who are the subjects of research in epidemiologic, clinical, methodologic, and longitudinal research studies and surveys of mental health and alcohol and drug use/abuse and mental, alcohol, and/or drug abuse disorders. These individuals are selected as representative of the general adult and/or child population or of special groups. Special groups include, but are not limited to, normal individuals serving as controls; clients referred for or receiving medical, mental

health, and alcohol and/or drug abuse related treatment and prevention services; providers of services; demographic sub-groups as applicable, such as age, sex, ethnicity, race, occupation, geographic location; and groups exposed to hypothesized risks, such as relatives of individuals who have experienced mental health and/or alcohol, and/or drug abuse disorders, life stresses, or have previous history of mental, alcohol, and/or drug abuse related illness.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

The system contains data about the individual as relevant to a particular research study. Examples include, but are not limited to, items about the health/mental health and/or alcohol or drug consumption patterns of the individual; demographic data; social security numbers (voluntary); past and present life experiences; personality characteristics; social functioning; utilization of health/mental health, alcohol, and/or drug abuse services; family history; physiological measures; and characteristics and activities of health/mental health; alcohol abuse, and/or drug abuse care providers.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, sections 301 and 405 (42 U.S.C. 241, and 284, General Research and Investigation Authorities); Public Health Service Act, sections 301, 302, 303 and Title V, Parts A and B (42 U.S.C. 241, 242, 242(a).

**PURPOSE(S):**

The purpose of the system of records is to collect and maintain databases for research activities. Analyses of these data involve groups of individuals with given characteristics and do not refer to special individuals. The generation of information and statistical analyses will ultimately lead to a better description and understanding of mental, alcohol, and/or drug abuse disorders, their diagnosis, treatment and prevention, and the promotion of good physical and mental health.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. A record may be disclosed for a research purpose, when the Department: (a) As determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 290 (dd-3), 42 U.S.C. 241 and 405, 42 CFR part 2, and

where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 242a and 42 CFR part 2a; (b) as determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (c) has required the recipient to— (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except—(A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law; and (d) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

2. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from a congressional office made at the written request of that individual.

3. In the event of litigation, where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee; the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., disclosure may be made to the

Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of the individual's participation in activities of a Federal Government supported research project).

4. The Department contemplates that it will contract with a private firm for the purpose of collecting, analyzing, aggregating, or otherwise refining records in this system. Relevant records will be disclosed to such contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records may be stored on index cards, file folders, computer tapes and disks, microfiche, microfilm, and audio and video tapes. Normally, the factual data, with study code numbers, are stored on computer tape or disk, while the key to personal identifiers is stored separately, without factual data, in paper files.

**RETRIEVABILITY:**

During data collection stages and followup, if any, retrieval by personal identifier (e.g., name, social security number) (in some studies), or medical record number), is necessary. During the data analysis stage, data are normally retrieved by the variables of interest (e.g., diagnosis, age, occupation).

**SAFEGUARDS:**

1. *Authorized users:* Access to identifiers and to link files is strictly limited to the authorized personnel whose duties require such access. Procedures for determining authorized access to identified data are established as appropriate for each location. Personnel, including contractor personnel, who may be so authorized include those directly involved in data collection and in the design of research studies, e.g., interviewers and interviewer supervisors; project managers; statisticians involved in designing sampling plans.

2. *Physical safeguards:* Records are stored in locked rooms, locked file cabinets, and/or secured computer facilities. Personal identifiers and link files are separated as much as possible and stored in locked files. Computer data access is limited through the use of key words known only to authorized personnel.

3. *Procedural safeguards:* Collection and maintenance of data is consistent

with legislation and regulations in the protection of human subjects, informed consent, confidentiality, and confidentiality specific to drug and alcohol abuse patients where these apply. When an Institute Division or a contractor provides anonymous data to research scientists for analysis, study numbers which can be matched to personal identifiers will be eliminated, scrambled, or replaced by the agency or contractor with random numbers which cannot be matched. Contractors who maintain records in this system are instructed to make no further disclosure of the records. Privacy Act requirements are specifically included in contracts for survey and research activities related to this system. The HHS project directors, contract officers, and project officers oversee compliance with these requirements.

4. *Implementation guidelines:* DHHS Chapter 45- and supplementary Chapter PHS.hf: 45-13 of the General Administration Manual and Part 6, "ADP System Security" of the HHS ADP Systems Security Manual.

#### RETENTION AND DISPOSAL:

Personal identifiers are retained only as long as they are needed for the purposes of the current research project, and for followup studies generated by the present study. Removal or disposal of identifiers is done according to the storage medium (e.g., erase computer tape, shred or burn index cards, etc.). A staff person designated by the System Manager will oversee and will describe and confirm the disposal in writing.

#### SYSTEM MANAGER(S) AND ADDRESS:

Privacy Act Coordinator, National Institute of Mental Health, Room 7C-22, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Deputy Director, Division of Biometry and Epidemiology, National Institute on Alcohol Abuse and Alcoholism, Willco Building, Suite 514, 6000 Executive Blvd. MSC 7003, Bethesda, MD 20892-7003.

Deputy Director, Division of Clinical and Prevention Research, National Institute on Alcohol Abuse and Alcoholism, Willco Building, Suite 505, 6000 Executive Blvd. MSC 7003, Bethesda, MD 20892-7003.

Privacy Act Coordinator, National Institute on Drug Abuse, Room 10A-42, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

#### NOTIFICATION PROCEDURE:

To determine if a record exists, write to the appropriate System Manager at the address above. Provide individual's name; current address; date of birth;

date, place and nature of participation in specific research study; name of individual or organization administering the research study (if known); name or description of the research study (if known); address at the time of participation; and a notarized statement by two witnesses attesting to the individual's identity.

#### RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

An individual who requests notification of, or access to, a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

#### CONTESTING RECORD PROCEDURE:

Contact the appropriate official at the address specified under System Manager(s) above and reasonably identify the record, specify the information being contested, and state corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

#### RECORD SOURCE CATEGORIES:

The system contains information obtained directly from the subject individual by interview (face-to-face or telephone), by written questionnaire, or by other tests, recording devices or observations, consistent with legislation and regulation regarding informed consent and protection of human subjects. Information is also obtained from other sources, such as health, mental health, alcohol, and/or drug abuse care providers; relatives; guardians; and clinical medical research records.

#### SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0207

#### SYSTEM NAME:

Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse and on Treatment Medications, HHS/NIH/NIDA.

#### SECURITY CLASSIFICATION:

None.

#### SYSTEM LOCATION:

University of California, San Francisco, Langley Porter Psychiatric Institute, San Francisco, California 94143.

#### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Normal, healthy adults who voluntarily participate in studies on the pharmacokinetics and pharmacodynamics of psychoactive drugs at Langley Porter Psychiatric Institute, during the period September 1987 through June, 1997.

#### CATEGORIES OF RECORDS IN THE SYSTEM:

Research records on each subject-participant contain the following information: Name; clinician's records including medical history, laboratory test results, physical examinations, psychological profile, and drug use profile; drug study data including records of drugs administered, exposures to radioactivity, and drug reactions; and date of study in which the subject participated.

#### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, sections 301(a), 503 and 405 (42 U.S.C. 241 and 284).

#### PURPOSE(S):

The primary purpose of this system is to support research on the pharmacokinetics and pharmacodynamics of drugs of abuse as well as treatment drugs. The term "pharmacokinetics" refers to the manner in which the human body processes a drug. "Pharmacodynamics" refers to the manner in which the drug affects the human body.

The clinical investigator used data of a medical nature that is contained in the system to make determinations regarding drug dosages and/or radiochemical exposures appropriate to the individual human subject-participants, in order to preserve and protect the health of each. The system also provides baseline data for studying the drug effects.

The Food and Drug Administration (FDA) also may use the records in routine inspections FDA conducts in accordance with its responsibilities to

develop standards on the composition, quality, safety, and efficacy of drugs administered to humans, and to monitor experimental usage of drugs.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. We may disclose to a congressional office the record of an individual in response to a verified inquiry from the congressional office made at the written request of the individual.

2. NIH contractors, use the records in this system to accomplish the research purpose for which the records are collected. The contractors are required to maintain Privacy Act safeguards with respect to such records.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

The contractor maintains the records on paper in file folders.

**RETRIEVABILITY:**

The contractor indexes and retrieves the records by the subject-participant's name.

**SAFEGUARDS:**

1. *Authorized users:* Only the contract Project Director and his/her research team and the Federal Project Officer and his/her support staff have access to these records.

2. *Physical safeguards:* The contractor keeps all records in a locked metal file cabinet in premises with limited accessibility. Only the clinical investigator (Project Director) has the key to the locked files.

3. *Procedural safeguards:* Only the contract staff have access to the files. Persons other than subject participants who request individually identifiable data from a record, must provide written consent from the subject participant permitting the requested disclosure. The only exception would be for disclosure to persons or organizations permitted by the Privacy Act, Section 3(B) to obtain personally identifiable data.

4. *Implementation guidelines:* DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 of the General Administration Manual. In addition, the contract staff complies with contractor's (University of California, San Francisco) standard procedures for safeguarding data.

**RETENTION AND DISPOSAL:**

The records will be kept no later than June 2002 (5 years after the anticipated completion of the studies). At that time, the NIDA project officer will authorize in writing the clinical investigators to

destroy the records by shredding or burning.

**SYSTEM MANAGER(S) AND ADDRESS:**

Project Officer, Pharmacokinetic Studies on Drugs of Abuse, Medications Development Division, National Institute on Drug Abuse, National Institutes of Health, Room 11A55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the system manager listed above.

Provide the following information: Subject-participant's full name and a letter of request (or permission, if the requester is not the subject-participant) with notarized signature of the individual who is the subject of the record, approximate date(s) of experiment(s) in which the individual participated, and drug name (if known). In addition, an individual who requests notification of, or access to, a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its content at the representative's discretion.

**RECORD ACCESS PROCEDURES:**

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

**CONTESTING RECORD PROCEDURES:**

Contact the System Manager at the address above and reasonably identify the record, specify the information to be contested, the corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

**RECORD SOURCE CATEGORIES:**

The subject-participants and the contractor personnel conducting the research studies.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

09-25-0208

**SYSTEM NAME:**

Drug Abuse Treatment Outcome Study (DATOS), HHS/NIH/NIDA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Research Triangle Institute, Center for Social Research and Policy Analysis,

Research Triangle Park, North Carolina 27709.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Voluntary adult clients of federally funded treatment programs, including Treatment Alternative Street Crime (TASC) Programs of the Department of Justice, who requested to be included in TOPS from 1979 through 1986. New data collected from voluntary adults/ adolescent clients of public and private funded-treatment programs beginning in 1991 and will continue through 1995.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

The categories are: Demographic data, treatment outcome data, treatment process data, client locator information, and personal identifiers (name and assigned numerical identifier).

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, sections 301 and 405 (42 U.S.C. 241 and 284).

**PURPOSE(S):**

The purpose of the system is to compile information on drug abusers in drug abuse treatment programs in order to derive information on the treatment environments and abusers' behaviors and characteristics subsequent to treatment. Researchers and drug abuse service providers may use the aggregate data to address issues and generate hypotheses to understand better the interactions among the client and community.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Within the restrictions set forth in HHS regulations concerning the confidentiality of drug abuse patient records (42 CFR 2.56), we may disclose a record for a research purpose, when the Department: (a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (b) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring, (c) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless

the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except: (A) In emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law; (d) has secured a written statement attesting to the recipient's understanding of, and willingness to, abide by these provisions.

2. The Research Triangle Institute, an NIH contractor, uses the records in this system to accomplish the research purpose for which the records are collected. In the event of followup studies or continuation studies because the contract has been terminated for convenience by the Government, we may disclose records in this system to a subsequent NIH contractor. We would require the new contractor to maintain Privacy Act safeguards with respect to such records.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Interview forms, magnetic tapes, and disks.

**RETRIEVABILITY:**

Records are indexed and retrieved by unique alpha numerical identifier. In order to relate the data collected to specific individuals, one must use the link file discussed under Safeguards.

**SAFEGUARDS:**

1. *Authorized users:* Contractor personnel, the agency project officer, and agency employees whose duties require the use of the information in the system.

2. *Physical safeguards:* The data management task leader, the project leader, or the project director provide technical supervision of all data collection and processing activities. Individually identified forms are stored in a secure, vault-like room provided for this purpose. Authorized personnel have access to the room by one locked door with controlled entry, i.e., only on the written authority of the professional staff member in charge. Computerized

records are kept in a vault area with limited accession.

3. *Procedural safeguards:* Because some of the data collected in this study, such as data on drug use, are sensitive and confidential, special safeguards have been established. A Certificate of Confidentiality has been issued under 42 CFR part 2a. This authorization enables persons engaged in research on mental health, including research on the use and effect of psychoactive drugs, to protect the privacy of research subjects by withholding the names or other identifying characteristics from all persons not connected with the conduct of the research. Persons so authorized may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, to identify such individuals. In addition, these records are subject to 42 CFR part 2, the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (42 CFR 2.56), which state: "Where the content of patient records has been disclosed pursuant to (these regulations) for the purpose of conducting scientific research \* \* \* information contained therein which would directly or indirectly identify any patient may not be disclosed by the recipient thereof either voluntarily or in response to any legal process whether Federal or State."

Another safeguard is that the forms containing subject identification information for client followup and data matching purposes do not include any reference to the purpose of the study. Identification and location information is kept separate from any information that would suggest that the respondent has been in a drug treatment program.

Information on completed forms is entered immediately on the computer. Completed forms and computerized data are released only to authorized persons. Only aggregate data are provided and used in the preparation of necessary and appropriate reports.

A link file system is used. This system has three components: (1) Personal information, (2) data base information, and (3) the link file, which contains identifying number pairs which can be used to match data with individuals. The advantage of this system is that the data base can be used directly for report generation, etc., without the use of decrypting subroutines or access to the personal information or matching link files.

In addition, the computer center being utilized has developed an extensive security system to protect computer account codes and data. This system is described in a publication that is

available from the System Manager upon request.

We do not anticipate any disclosure of individually identifiable information to other persons or organizations within the Department of Health and Human Services. Nor does the contractor provide individually identification information to the Department of Justice, with which NIDA has a cooperative agreement for this study.

4. *Implementation guidelines:* We used the National Bureau of Standards guidelines and Part 6, HHS ADP Systems Security Manual, "ADP System Security" in developing the computer safeguard procedures. Safeguards for nonautomated records are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 of the General Administration Manual. In addition, project staff complies with the contractor's (Research Triangle Institute) standard procedures for safeguarding data.

The contractor provides only aggregate information to NIDA.

**RETENTION AND DISPOSAL:**

The contractor destroys interview forms by shredding or burning immediately after contractor staff have completed and verified direct entry on magnetic tape or disk storage. The contractor will destroy individual identification and location data by shredding or burning, under the explicit written authorization of the System Manager, which is anticipated to be no longer than 5 years after the termination of the study unless the information is needed for research purposes. We will retain aggregate data tapes for research purposes. These tapes will not have any individually identifiable information. In accordance with the NIH Records Control Schedule, these tapes will be retained for 5 years after completion of the project (approximately 2000). At that time, the tapes will be retired to the Federal Records Center and destroyed when they are 10 years old or when they are no longer needed for research purposes.

**SYSTEM MANAGER(S) AND ADDRESS:**

Drug Abuse Treatment Outcome Study (DATOS), Project Officer, Services Research Branch, Division of Clinical and Services Research, National Institute on Drug Abuse, National Institutes of Health, Room 10A-30, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. An individual may learn if a

record exists about himself/herself upon written request, with notarized signature. The request should include, if known, name of the researcher, location of the research site, approximate date of data collection, any alias used, and subject identification number.

An individual who requests notification of a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or legal guardian who requests notification of an adolescent's record shall designate a family physician or other health professional (other than a family member) of the Division of Clinical Research staff to whom the record, if any, will be sent. The parent or legal guardian must verify in writing the relationship to the adolescent as well as his/her own identity.

#### RECORD ACCESS PROCEDURES:

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

Persons other than subject individuals, who request individually identifiable data from a record must provide written consent from the subject individual permitting the requested disclosure. The only exception (if not in conflict with confidentiality regulations) would be for disclosure to persons or organizations permitted by the Privacy Act, section 3(b), to obtain personally identifiable data.

#### CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, the corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

#### RECORD SOURCE CATEGORIES:

Research subjects, and staff in participating drug abuse treatment programs, written clinical evaluations, counselors, psychiatrists, psychotherapists, family members, research assistants, hospitals.

#### SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

#### 09-25-0209

##### SYSTEM NAME:

Subject-Participants in Drug Abuse Research Studies on Drug Dependence and in Research Supporting New Drug Applications, HHS/NIH/NIDA.

##### SECURITY CLASSIFICATION:

None.

##### SYSTEM LOCATION:

Veterans Administration Hospital, Cooperative Studies Program, Department of Veterans Medical Center, Perry Point, MD 21902.

Dixon and Williams Pharmaceutical, 5775 Hyde Park Circle, Jacksonville, Florida 32210.

Medications Development Division, Room 11A-55, and Division of Clinical Research, Room 10A-38, Parklawn Building, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, MD 20857.

Veterans Affairs Medical Center, 50 Irving Street, NW., Washington, DC 20422.

Veterans Affairs Medical Center, University and Woodland Avenues, Philadelphia, PA 19104.

Veterans Affairs Medical Center, Brentwood Division, Wilshire and Sawtell Boulevards, Los Angeles, CA 90073.

National Institute on Drug Abuse, Division of Intramural Research Programs, 4940 Eastern Avenue, Baltimore, MD 21224.

Write to the system manager at the address below for the address of any new locations where records from this system may be stored.

##### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Voluntary adult clients of federally funded and other drug abuse treatment programs who have requested to receive investigational new or marketed drugs, such as but not limited to, naltrexone, levo-alpha acetylmethadol (LAAM), or Buprenorphine as part of their treatment. Data collection for the earlier LAAM studies began in 1975 and continued through September 1979; additional LAAM studies began in 1992 and will continue through September 1997, naltrexone studies began in 1977 and continued through June 1984; and studies for other investigational new compounds (buprenorphine, gepirone, etc.) began in 1992 and may continue through September 1997.

##### CATEGORIES OF RECORDS IN THE SYSTEM:

Demographic data, treatment outcome data, treatment process data, client locator information, and personal identifiers (name and assigned numerical identifier).

##### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, sections 301, 464p, and 405 (42 U.S.C. 241, and 284).

##### PURPOSE(S):

1. To maintain information on the safety and effectiveness of drugs for treatment of drug dependence with or without abuse potential in various treatment environments and modalities and changes in the behavior and characteristics of drug abusers who received these substances as part of their treatment regimen.

2. To provide data required by the Food and Drug Administration (FDA) to support research on drug dependence and potential new drug applications for various drugs, and to treat drug dependence with or without abuse potential. A new drug application is a notice to FDA that a pharmaceutical company believes they have enough data to demonstrate the safety and efficacy of a substance to satisfy FDA for marketing the substance. FDA may also use the records in routine inspections that FDA conducts in accordance with its responsibilities to develop standards on the composition, quality, safety and efficacy of drugs administered to humans, and to monitor experimental usage of drugs.

3. To conduct research on the pharmacology, toxicology, and behavioral characteristics of drugs of abuse alone or in combination with proposed treatment drugs.

##### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

NIH contractor(s) use the records in the system in order to accomplish the research and development purposes for which the records were collected. In the event of a followup study or continuation study, the responsible project officer may disclose records in this system to a subsequent NIH contractor(s). Any new contractor(s) is and would be required to maintain Privacy Act safeguards with respect to such records and to comply with the confidentiality restrictions of 42 CFR part 2.

##### POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

##### STORAGE:

Interview and assessment forms, video tapes, magnetic tapes, disks and microfiche in boxes in closed cabinets in a locked room with limited accessibility.

**RETRIEVABILITY:**

The records are indexed and retrieved by subject-participant's name code (i.e., initials—not name) and unique numerical identifier. In order to relate the data collected to specific individuals, however, one must use the link file discussed under safeguards.

**SAFEGUARDS:**

1. *Authorized users:* For the naltrexone study, the System Manager or Federal Project Officer and only authorized contract staff have access to the records (computerized and hard copy files) in the system. The contractor provides only aggregate data in reports to NIDA, FDA, or the public. Only the NIDA personnel mentioned previously and selected authorized contract staff have access to the stored LAAM records.

A certificate of confidentiality has been issued to researchers conducting the naltrexone study under 42 CFR, Part 2, Protection of Identity—Research Subjects. This authorization enables persons engaged in research on mental health, including research on the use and effect of psychoactive drugs, to protect the privacy of research subjects by withholding the names or other identifying characteristics from all persons not connected with the conduct of the research. Persons so authorized may not be compelled in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals. The earlier LAAM study (from 1975 through 1979) was not conducted under a certificate of confidentiality. The 1992 LAAM studies were conducted under the protection afforded by a confidentiality certificate. These regulations do not prohibit voluntary disclosure by the researcher. However, the records of these studies also are subject to 42 CFR part 2, the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (42 CFR 2.56), which state: "Where the content of patient records has been disclosed. Pursuant to (these regulations) for the purpose of conducting scientific research \* \* \* information contained therein which would directly or indirectly identify any patient may not be disclosed by the recipient thereof either voluntarily or in response to any legal process whether Federal or State."

The contractor's institutional review board reviewed and approved the safeguards described above in accordance with 45 CFR Part 46 on the Protection of Human Subjects.

2. *Physical safeguards:* For the naltrexone records, the contractor(s) stored individually identified forms in a

locked room with controlled entry, i.e., only on written authority of the professional staff member in charge of data handling and processing). The contractor staff entered the collected information onto computer tape or disks as soon after contact with the subject-participant as possible, and stores the computerized records in a secured area with access limited as above.

For the LAAM, buprenorphine and other compound records, NIDA stores the individually identified forms in a lockable cabinet in a secure room. Only authorized NIDA personnel, i.e., Division of Clinical Research and Medications Development professional staff and their support staff (program assistant, clerk-typist, or secretary) have access to the room with controlled entry. The room is in a building which has a 24-hour guard/television surveillance system and has controlled entry (picture identification sign in and out procedures) before and after normal working hours.

Another safeguard for these studies is that the forms containing subject identification information do not include any reference to the purpose of the study. The identification information is separate from any information that would suggest that the respondent is or has been in a drug abuse treatment program. In addition, the computer center being utilized for naltrexone has developed an extensive security system to protect computer account codes and data.

3. *Procedural safeguards:* Access to the computerized records of the studies (naltrexone and other research) is protected by a computerized password routine which is changed periodically. In addition, the project staff complies with the contractor's standard procedures for safeguarding data. The link file system that identifies individuals with personal data has three components: (1) Identification information, (2) data base information, and (3) the link file, which contains identifying number pairs which match data with individuals. The advantage of this system is that one may use the baseline data directly for report generation, etc., without using the subroutines or accessing the personal information or link files.

4. *Implementation guidelines:* DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 of the General Administration Manual and Part 6, "ADP System Security" in the HHS ADP Systems Security Manual.

**RETENTION AND DISPOSAL:**

The naltrexone staff will destroy identifiable information by shredding or

burning when it is no longer needed for analysis or research purposes; then the tapes will be erased. NIDA will destroy individual identification and match-up information from other studies by shredding or burning 5 years after FDA completes the review and approves the new drug applications or when they are no longer needed for research purposes.

NIDA will retain the aggregate data tapes and/or paper records from studies for research purposes. These tapes will not have any individually identifiable information. In accordance with the FDA regulations governing new drug applications, the aggregate tapes will be retained for at least 2 years after FDA approves the new drug applications. At that time, the tapes will be retired to the Federal Records Center and destroyed when they are 5 years old or when they are no longer needed for research purposes.

**SYSTEM MANAGER(S) AND ADDRESS:**

Project Officer, Naltrexone Study, Division of Clinical Research, Room 10A-30, Parklawn Building, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, MD 20857.

Project Officer, LAAM and Other Research Records, Medications Development Division, Room 11A-55, Parklawn Building, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

An individual may determine if a record exists about himself/herself upon written request, with notarized signature if request is made by mail, or with suitable identification if request is made in person, to the appropriate system manager at the address above. The following information should be included, if known: Subject-participant's full name and a letter of request with notarized signature of the subject-participant of the record, any alias used, subject-participant's identification number, name of the researcher, name of clinic or research center, name of substance, and approximate date of study participation.

An individual who requests notification of a medical record must, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. An individual may also request

an accounting of disclosures of his/her record, if any.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above and reasonably identify the record, specify the information being contested, the corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

**RECORD SOURCE CATEGORIES:**

Research subject-participants, staff in the participating drug abuse treatment programs, written clinical evaluations, private physicians, counselors, psychiatrists, psychotherapists, family members, research assistants, and hospital records.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0212**

**SYSTEM NAME:**

Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Neuroscience Research Center at Saint Elizabeths Hospital, William A. White Building, Room 144, 2700 Martin Luther King, Jr., Avenue, SE., Washington, DC 20032, and at private organizations under contract. A list of specific sites is available from the System Manager.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Registered clinical research patients and some individuals not registered as patients but seen for diagnostic tests.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Inpatient and outpatient medical clinical records.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

The Public Health Service Act, section 301 (42 U.S.C. 241), "Research and Investigation," and Section 321 (42 U.S.C. 248), "Hospital."

**PURPOSE(S):**

(1) To provide a continuous history of the treatment afforded individual patients in the National Institute of Mental Health Neuroscience Research Center.

(2) To provide a data base for the clinical research conducted at the Neuroscience Research Center.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

2. Social work staff may give pertinent information to community agencies to assist patients for their families.

3. Referring physicians receive medical information for continuing patient care after discharge.

4. Information regarding diagnostic problems, or having unusual scientific value may be disclosed to appropriate medical research organizations or consultants in connection with treatment of patient or in order to accomplish the research purposes of this system. For example, tissue specimens may be sent to the Armed Forces Institute of Pathology; x-rays may be sent for the opinion of a radiologist with extensive experience in a particular kind of diagnostic radiology. The recipients are required to maintain Privacy Act safeguards with respect to these records.

5. Records may be disclosed to representative of the Joint Commission on Accreditation of Hospitals conducting inspections to ensure that the quality of the Neuroscience Research Center Program medical recordkeeping meets established standards.

6. Certain infectious diseases are reported to government jurisdictions as required by law.

7. Medical information may be disclosed to tumor registries for maintenance for health statistics.

8. The Department contemplates that it may contract with a private firm for transcribing, updating, copying or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to comply with the requirements of the Privacy Act with respect to such records.

9. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operation of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending a claim against the Public Health Service based upon an

individual's metal or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, disclosure may be made to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders and/or on microfiche, and on computer tapes. Files are stored in locked file cabinets or locked rooms.

**RETRIEVABILITY:**

The records are retrieved by hospital number and patient name.

**SAFEGUARDS:**

1. *Authorized users:* Employees maintaining records in this system are instructed to grant regular access only to physicians and dentists and other health care professionals officially participating in patient care and to contractors or to NIMH researchers specifically authorized by the system manager.

2. *Physical safeguard:* All record facilities are locked when system personnel are not present.

3. *Procedural safeguards:* Access to files is strictly controlled by the system manager. Records may be removed only by system personnel following receipt of a request signed by authorized user. Access to computerized records is controlled by the use of security codes known only to the authorizer user. Codes are user- and function-specific. Contractor compliance is assured through inclusion of Privacy Act requirements in contract clauses, and through monitoring by contract and project officers. Contractors who maintain records in this system are instructed to make no disclosure of the records except as authorized by the system manager.

4. *Implementation guidelines:* DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 of the General Administration Manual, and Part 6, "ADP System Security" in the HHS Information Resource Management Manual.

**RETENTION AND DISPOSAL:**

Records are retained for 20 years after last discharge or upon death of a patient and then transferred to the Washington National Records Center, where they are retained until 30 years after discharge or death.

**SYSTEM MANAGER(S) AND ADDRESS:**

Clinical Director, Neuroscience Research Center, Division of Intramural Research Programs, National Institute of Mental Health, Saint Elizabeths Hospital, Room 133, William A. White Building, 2700 Martin Luther King Jr., Avenue, SE., Washington, DC 20032.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System manager at the address above. An individual or a legally authorized representative may learn if a record exists about that individual upon written request with notarized signature. The request should include: (a) Full name or any alias used, (b) social security number, and (c) approximate time of participation in the hospital/project.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing a family

physician or health professional (other than a family member) to whom the record will be released. The representative must verify relationship to the individual as well as his/her own identity.

A parent or guardian who requests notification of, or access to, a child's/incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request an accounting of disclosures of their records, if any.

**CONTESTING RECORD PROCEDURES:**

Contact the System Manager at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, and state the corrective action sought and the reasons for correcting the information, along with supporting justification to show how the record is inaccurate, incomplete, or irrelevant.

**RECORD SOURCE CATEGORIES:**

Referring physicians, other medical facilities (with patient's consent), patients, relatives of patients.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

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