

and effectiveness of these devices are unproven.

65-11 BLADDER STIMULATORS (PACEMAKERS)—NOT COVERED
Pelvic floor stimulators, whether

inserted into the vaginal canal or rectum or implanted in the pelvic area, used as a treatment for urinary incontinence either as a bladder pacer

or a retraining mechanism are not covered for the reason that the safety and effectiveness of these devices are unproven.

ADDENDUM V.—REGULATION DOCUMENTS PUBLISHED IN THE FEDERAL REGISTER

Publication date	FR vol. 60 page	CFR part	File code	Regulation title	End of comment period	Effective date
01/03/95	46-54	410,414	BPD-789-CN	Medicare Program; Refinements to Geographic Adjustment Factor Values, Revisions to Payment Policies, Adjustments to the Relative Value Units (RVUs) Under the Physician Fee Schedule for Calendar Year 1995, and the 5-Year Refinement of RVUs.	01/01/95
01/03/95	130-132	HSQ-224-N	CLIA Program: Approval of the Joint Commission on Accreditation of Healthcare Organizations As An Accrediting Organization.	01/03/95
01/03/95	132-141	BPO-129-N	Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions—Third Quarter 1994.	01/03/95
1/09/95	2325-2330 ..	400, 405, 410, 484, 485, 486, 498, ..	BPD-798-FC	Medicare Program; Providers and Suppliers of Specialized Services: Technical Amendments.	03/10/95	02/08/95
01/13/95	3250-3253	MB-089-N	Medicaid Program; Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1995.	01/13/95
01/17/95	3405-3410	BPD-778-FN	Medicare Program; Special Payment Limits for Home Blood Glucose Monitors.	02/16/95
01/23/95	4418-4423	ORD-070-N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: November and December 1994.	01/23/95
01/26/95	5185-5204	BPD-776-FNC	Medicare Program; Additions To and Deletions From the Current List of Covered Surgical Procedures for Ambulatory Surgical Centers.	03/27/95	02/27/95
02/02/95	6537-6547	BPD-812-NC	Medicare Program; Criteria for Medicare Coverage of Lung Transplants.	04/03/95	02/02/95
02/08/95	7514	482	BPD-826-N	Medicare Program; Hospice Wage Index	02/08/95
02/09/95	7774-7780	HSQ-223-N	CLIA Program: Approval of the College of American Pathologists.	02/09/95
02/14/95	8389-8406	BPD-793-NC	Medicare Program; Schedule of Limits on Home Health Agency Costs Per Visit.	04/17/95	07/01/94
02/16/95	8951-8955 ..	410	BPD-424-F	Medicare Program; Medicare Coverage of Prescription Drugs Used in Immunosuppressive Therapy.	01/01/95
02/24/95	10395-10396	OPL-004-N	Medicare Program; Meeting of the Practicing Physicians Advisory Council.	02/24/95
03/02/95	11632-11633 ..	485, 486	BPD-798-CN	Medicare Program; Providers and Suppliers of Specialized Services-Technical Amendments; Corrections.	02/08/95
03/13/95	13441	BPD-833-N	Medicare Program; Hospice Wage Index	03/13/95
03/16/95	14223-14224 ..	410	BPD-724-F	Medicare Program; Medicare Coverage of Screening Mammography; Correction.	10/01/94
03/30/95	16481-16486	ORD-073-N	New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: January 1995.

*GN—General Notice; PN—Proposed Notice; FN—Final Notice; P—Notice of Proposed Rulemaking (NPRM); F—Final Rule; FC—Final Rule with Comment Period; CN—Correction Notice; SN—Suspension Notice; WN—Withdrawal Notice; NR—Notice of HCFA Ruling

[FR Doc. 95-18333 Filed 7-25-95; 8:45 am]
BILLING CODE 4120-01-P

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.
ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has made final findings of scientific misconduct in the following case:
John J. Tomasula, Mount Sinai Medical Center: On June 29, 1995, ORI found that John J. Tomasula, formerly of the Mount Sinai Medical Center in New York, committed scientific misconduct by falsifying research involving

guanabenz treatment of spinal cord injured cats reported in a Public Health Service (PHS) grant application. Additionally, ORI found that Mr. Tomasula had falsified his credentials on three PHS grant applications in which he claimed to have a Ph.D. degree from Northwestern University when, in fact, he had obtained a mail-order

degree from Northwestern College of Allied Sciences in Oklahoma, an unaccredited, now-defunct "institution."

Mr. Tomasula has entered into a Voluntary Exclusion Agreement with ORI in which he has accepted ORI's finding and has agreed to exclude himself voluntarily, for the three (3) year period beginning June 29, 1995, from:

(1) applying for or receiving any Federal grant or contract funds; and,
(2) serving in any advisory capacity to the PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

No scientific publications were required to be corrected as part of this Agreement.

FOR FURTHER INFORMATION CONTACT: Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852.

Lyle W. Bivens,

Director, Office of Research Integrity.

[FR Doc. 95-18347 Filed 7-25-95; 8:45 am]

BILLING CODE 4110-60-P

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has made final findings of scientific misconduct in the following case:

Jose R. Sotolongo, Jr., M.D., Mount Sinai Medical Center: On July 3, 1995, ORI found that Jose R. Sotolongo, Jr., M.D., formerly of Mount Sinai Medical Center in New York, committed scientific misconduct by falsifying research involving guanabenz treatment of spinal cord injured cats presented in a Public Health Service (PHS) grant application.

Dr. Sotolongo has entered into a Voluntary Exclusion Agreement with ORI in which he has accepted ORI's finding and has agreed to exclude himself voluntarily, for the three (3) year period beginning July 3, 1995, from:

(1) Applying for or receiving any Federal grant or contract funds; and,
(2) Serving in any advisory capacity to the PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

The above voluntary exclusion, however, shall not apply to Dr. Sotolongo's future training or practice of clinical medicine as a licensed

practitioner unless that practice involves research or research training.

No scientific publications were required to be corrected as part of this Agreement.

FOR FURTHER INFORMATION CONTACT: Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852.

Lyle W. Bivens,

Director, Office of Research Integrity.

[FR Doc. 95-18348 Filed 7-25-95; 8:45 am]

BILLING CODE 4110-60-P

National Institutes of Health

Division of Research Grants; Notice of a Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meeting:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Behavioral and Neurosciences.

Date: July 27, 1995.

Time: 9:00 a.m.

Place: Holiday Inn, Chevy Chase, MD.

Contact Person: Dr. Keith Murray, Scientific Review Admin., 6701 Rockledge Drive, Room 5194, Bethesda, MD 20892, (301) 435-1256.

The meeting will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the grant review cycle.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 20, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95-18284 Filed 7-25-95; 8:45 am]

BILLING CODE 4140-01-M

Public Health Service

Action Related to Emergency Research Activity

AGENCY: Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The Public Health Service is announcing an action related to the applicability of the Title 45 CFR Part 46 (protection of human subjects) requirement for obtaining and documenting informed consent for a specific research activity. The purpose of this action is to invoke 45 CFR 46.101(i) related to an NIH funded research project: "National Acute Brain Injury Study: Hypothermia." This important and necessary research needs to be carried out in human subjects who require emergency therapy and for whom, because of the subjects' medical condition and the unavailability of legally authorized representatives of the subjects, no legally effective informed consent can be obtained.

FOR FURTHER INFORMATION CONTACT: F. William Dommel, Jr., J.D., Senior Policy Advisor, Office for Protection from Research Risks, 6100 Executive Boulevard, Suite 3B01J, National Institutes of Health, MSC 7507, Rockville, MD 20892-7507. Telephone (301) 496-7005 ext. 203 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Waiver

Pursuant to Section 46.101(i) of Title 45 of the Code of Federal Regulations, the Secretary of Health and Human Services, has waived the general requirements for informed consent at 45 CFR 46.116 and 46.117 for the specific research activity known as the "National Acute Brain Injury Study: Hypothermia" and funded by the National Institutes of Health (NIH) grant number R01 NS 32786 under the following strictly limited circumstances:

In the course of the conduct of the research funded under NIH grant number R01 NS 32786, human research subjects may be included without seeking informed consent as otherwise required by 45 CFR 46.116 and 46.117 if the proposed research involves the study of activities which would be carried out on persons who are in need of emergency treatment and the IRB(s) responsible for the review, approval, and continuing review of the research approve(s) that research without requiring that legally effective informed consent be obtained and the IRB(s) find(s), document(s), and report(s) to the Office for Protection from Research Risks (OPRR), NIH, that the research is approved in the absence of a requirement for obtaining informed consent for the following reasons:

- (i) The opportunity for the subjects to participate in the research is in the health interest of the subjects;
- (ii) The waiver of consent will not adversely affect the rights and welfare of the subjects;
- (iii) Additional appropriate protections of the rights and welfare of the subjects will be