

FDA will be assuring the availability of well-characterized and uniform reference materials for the comparative evaluation of new materials and devices. Evaluation of biological performance data based on comparison to previously-used and successful products will be both facilitated and improved.

Program Description

1. Selection of Materials—Candidate materials for SRM development will be selected by mutual agreement between FDA and NIST. The goal is to provide more realistic calibration standards for the determination of physical, chemical, electrical, and biological characteristics and/or properties of biomaterials. Criteria for selection will include magnitude of the current or potential utilization of the material in biomedical applications, documented or reasonably foreseeable variability in response from “off-the-shelf” materials, criticality of the medical application, cost of developing and potential market for the SRM, and others mutually agreeable to both parties. At the time of selection, the properties and characteristics to be controlled and measured will be identified for each candidate SRM, as will be the proposed unit size for distribution.

1.a An initial listing of candidate materials proposed at the time of the initial agreement is given in Appendix A. Materials 1 & 2 were developed as a collaborative research initiative between FDA and the American Dental Association (ADA) at both the FDA and NIST laboratories. Material 1 has been provided to NIST for consideration as an SRM. Material 2 which is currently being synthesized will be provided on or about September 1993. No development work has been done on materials 3–8.

2. Production of Materials—SRMs will be developed by any of several laboratories, including NIST, FDA, NIH, commercial materials suppliers, device manufacturers, academic institutions, and others. A Material Safety Data Sheet (MSDS) will be required from the supplier of all component materials and precursor/catalyst/ancillary materials

used in the production of SRMs developed under this MOU.

3. Certification—NIST will determine and specify what testing must be performed and be the sole reviewer of the adequacy of data used in the qualification of SRMs developed under this MOU. NIST reserves the right to refuse distribution of materials if the data are inadequate. All SRMs developed under this program will be supplied with NIST certification for the properties/characteristics deemed critical to the application.

4. Packaging—NIST will determine for each SRM the appropriate source of packaging, either in-house or contract. Contract packagers will seal the entire shipment in appropriate packages for shipment to NIST.

5. Replenishment—NIST agrees to assume the responsibility for replenishment of stocks for SRMs for which the market is at a level that is financially beneficial to the Standard Reference Materials Program.

6. Program Funding—FDA does not commit to providing any funding or equipment to NIST or any selected SRM producer, or to providing any laboratory effort in the development, characterization, or production of SRMs being developed under this program.

Costs and Pricing

1. Initially, FDA will provide 900 grams of hydroxyapatite (material 1, Appendix A) and 1000 grams of β-Tricalcium Phosphate (material 2, Appendix A) to NIST for use as an SRM. No compensation to FDA is required for this initial supply of material. Monies collected from the sale of the SRMs, which is over and above the cost to produce, characterize and package the materials will be used for additional SRM development.

2. NIST will have final authority over all matters pertaining to pricing policy and for setting the price of individual SRMs.

General

1. SRMs developed in whole or in part by FDA prior to or under this MOU, which remain unsold and are deemed by NIST, to be technologically obsolete or otherwise no

longer acceptable as SRMs, may be removed from the NIST inventory without liability for reimbursement to FDA by NIST. If FDA desires such products returned to FDA, NIST will do so at FDA’s expense after removal of SRM certification.

2. The official representatives of the respective organizations will be:

FDA: Director Division of Mechanics and Materials Science Office of Science and Technology Center for Devices and Radiological Health

NIST: Chief Standard Reference Materials Program Office of Measurement Services

Effective Dates

1. This MOU will become effective 30 days after being signed by the appropriate authorities at both NIST and FDA. It will remain in effect until terminated.

2. Either NIST or FDA may unilaterally terminate this MOU by providing the other party written notice. It will become ineffective 60 days after such notice is delivered.

Approval/Acceptance

Signed:
D. Bruce Burlington, M.D.
Director, FDA/CDRH
Date: November 19, 1993

Approved:
Peter L.M. Heydemann, PhD.
Director, NIST/Technology Services
Date: January 14, 1994

Concur:
Thomas E. Gills
Chief, NIST/SRMP
Date: January 14, 1994

Appendix A

Purpose:

Development of a series of Calcium-Phosphorous based SRMs for use in determining the composition of mixtures of calcium phosphate based biomaterials or biomaterial coatings.

Proposed Calcium Phosphate Reference Biomaterials

1. Ca ₃ (PO ₄) ₃ OH	Hydroxyapatite	Ca/P=1.67
2. Ca ₃ (PO ₄) ₂	Tricalcium Phosphate (β)	Ca/P=1.50
3. Ca ₃ (PO ₄) ₂	Tricalcium Phosphate (amorphous)	CA/P=1.50
4. Ca ₄ (PO ₄) ₂ O	Tetracalcium Phosphate	CA/P=2.0
5. Ca ₃ (PO ₄) ₂	Tricalcium Phosphate (α)	CA/P=1.50
6. Ca ₂ P ₂ O ₇	Calcium Pyrophosphate (α β γ)	CA/P=1.0
7. CaO	Calcium Oxide	NA
8. Ca ₁₀ (PO ₄) ₅ F ₂	Fluorapatite	CA/P=1.67

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[FDA–225–94–6000]

Memorandum of Understanding Between the Food and Drug Administration, the Uniformed Services University of the Health Sciences, and the National Naval Medical Center

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA, the Uniformed Services University of the Health Sciences, and the National Naval Medical Center. The purpose of the MOU is to establish an agreement in support of a clinical investigation program study entitled “Prevention of Photochemical Retinal Injuries During Extracapsular Cataract Surgery.”

DATES: The agreement became effective August 19, 1993.

FOR FURTHER INFORMATION CONTACT: Sandy Cordes, Center for Devices and Radiological Health (HFZ-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3516.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this memorandum of understanding.

Dated: May 2, 1995.

William B. Schultz,
Deputy Commission for Policy.

Memorandum of Understanding Between Uniformed Services University of the Health Sciences and Food and Drug Administration and the National Naval Medical Center, Bethesda, Maryland

I. General

A. The National Naval Medical Center, Bethesda, Maryland, herein referred to as the Naval Activity, has established this agreement for the purpose of conducting clinical investigation in support of education and training and patient care. This program requires collaboration with Uniformed Services University of the Health Sciences, Bethesda, Maryland and the Food and Drug Administration, Rockville, Maryland.

B. It is mutually beneficial to the Naval Activity and to the Uniformed Services University of the Health Sciences and the Food and Drug Administration to allow physicians, dentists, and other support personnel to participate in Navy patient care and research to enhance the quality of patient care and to contribute to their education and training. This agreement is in support of a Clinical Investigation Program study entitled "PREVENTION OF PHOTOCHEMICAL RETINAL INJURIES DURING EXTRACAPSULAR CATARACT SURGERY."

II. Understanding

A. Insofar as the Commander deems it appropriate and consonant with this command's basic mission, the Naval Activity will:

1. Provide that all research to be conducted at the Naval Activity will be reviewed and approved in accordance with applicable National Naval Medical Center, Health Sciences Education and Training Command, Chief, Bureau of Medicine and Surgery, Secretary of the Navy, and Department of Defense instructions.
2. Appoint personnel, as deemed appropriate, to participate in clinical

investigation in accordance with Federal Personnel Manual (FPM), chapter 213 (appendix C), chapter 53; FPM Supplement 990-1 (subchapter IV) and Navy Civilian Manpower Management Instruction (CMMI) 213 (appendix C).

3. Ensure the credentialing of those physicians, dentists, and scientists, who would be participating in direct patient management.
 4. Require that all data accrued/generated at the Naval Activity becomes the property of the Department of the Navy. Upon execution of this Memorandum of Understanding, data may be exchanged between the participating institutions. Any materials compiled or published by the Naval Activity staff, relative to their clinical experience received at the Naval Activity, must clearly state that opinions or assertions contained herein are those of the writer and are not to be construed as official or reflecting the views and opinions of the Department of the Navy.
 5. Permit upon request the inspection of appropriate clinical facilities and other research areas by agencies charged with the responsibility for the accreditation of the institution and proper management of said protocols.
 6. Determine the efficacy of certain interventions to be effective in decreasing the incidence of photochemical retinal injuries during routine extracapsular cataract surgery.
 7. Recruit for study 960 NNMC cataract patients.
- B. Uniformed Services University of the Health Sciences will:
1. Provide the names of the physicians, dentists, and scientists who will participate in the research program entitled "Prevention of Photochemical Retinal Injuries During Extracapsular Cataract Surgery".
 2. Provide instruction, supervision, control, and evaluation of their participants in this research effort.
 3. Assist on the clinical trial planning, data management, statistical analysis and interpretations using computing equipment available at USUHS.
- C. Food and Drug Administration will:

1. Provide the names of the scientists who will participate in the research program entitled "Prevention of Photochemical Retinal Injuries During Extracapsular Cataract Surgery".
2. Provide instruction, supervision, control, and evaluation of their participants in this research effort.
3. Provide optical radiation metrology for the operating microscope, and perform scientific analysis of the data.

III. Liability

Inasmuch as National Naval Medical Center, Bethesda and the Food and Drug Administration and the Uniformed Services

University of the Health Sciences are instrumentalities of the United States, all claims arising hereunder will be handled in accordance with the Federal Tort Claims Act and all federal health care providers acting within the scope of this Memorandum of Understanding will be covered by the Gonzales Act and the Federal Employees Liability Reform and Tort Compensation Act.

IV.

All inventions conceived or reduced to practice under this Memorandum of Understanding by a government employee shall be reported to the Patent Counsel for each Agency of each government employee. Upon receipt of a disclosure, counsel shall confer, determine who shall prepare the application and decide, subject to review by higher authority, upon a division of royalties. This division shall fairly reflect relative contributions of each agency's employees, the risks and costs incurred, and the ability to proceed with testing and development, including licensing.

V. Reviews

- A. This agreement will continue in effect until the termination date as indicated on the DD Form 1144, or until it is canceled or terminated.
- B. This agreement will be reviewed annually on the anniversary date and may be modified, cancelled, or renegotiated upon 90 days notice by either party, or earlier by mutual consent. Changes in funding responsibility will be accomplished in accordance with the guidelines of NAVCOMPT Manual, paragraphs 075002 and 075022.

VI. Amendment

It is agreed that the changes to this Memorandum of Understanding, except for dates, must be forwarded to the Naval Health Sciences Education and Training Command, National Naval Medical Center, Bethesda, Maryland 20889-5022 in the form of an amendment signed by authorized agents of the institutions which hold final approval authority. If this Memorandum of Understanding is of the type that must have final approval by the Naval Health Science Education and Training Command, proposed changes are not to be effected without the written approval of the Naval Health Sciences Education and Training Command.

VII. Effective Period

The effective period of this memorandum of understanding shall be from 29 July 1992 to 28 July 1996 and may be renewed without change, except for dates, on a year to year basis upon mutual written agreement of all parties.

VIII. Termination

Termination may be effected by either participating institution upon written notice when deposited in the United States mail and directed to the party, notice being given at the address set forth below.

D. M. Lichtman
RADM, MC, USN

Commander

National Naval Medical Center

Bethesda, Maryland 20889-5000

Date August 19, 1993

(Original signature August 6, 1992)

D. Bruce Burlington, M.D.

Director

Center for Devices and Radiological Health

Food and Drug Administration

Rockville, Maryland 20857

Date August 19, 1993

[FR Doc. 95-11416 Filed 5-8-95; 8:45 am]

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Health Resources and Services Administration

Final Review Criteria for Cooperative Agreements for Basic/Core Area Health Education Centers Programs and Model State-Supported Area Health Education Centers Programs for Fiscal Year 1995

The Health Resources and Services Administration (HRSA) announces the final review criteria for fiscal year (FY) 1995 Cooperative Agreements for Basic/Core Area Health Education Centers (AHEC) Programs authorized under section 746(a)(1) and Model State-Supported Area Health Education Centers Programs authorized under section 746(a)(3), title VII of the Public Health Service Act, as amended by the Health Professions Education Extension Amendments of 1992, Public Law 102-408, dated October 13, 1992.

Purpose and Eligibility

In general, an area health education centers program shall be a cooperative program of one or more allopathic or osteopathic medical schools and one or more public or nonprofit private regional area health education centers.

Section 746(a)(1) of the PHS Act authorizes Federal assistance to schools of allopathic or osteopathic medicine which have cooperative arrangements with one or more public or nonprofit private area health education centers for the planning, development and operation of area health education centers programs.

To be eligible to receive support for an area health education centers cooperative agreement, the applicant must be a public or nonprofit private accredited school of allopathic or osteopathic medicine or consortium of

such schools, or the parent institution on behalf of such school(s).

Section 746(a)(3) authorizes Federal assistance to any school of allopathic or osteopathic medicine that is operating an area health education centers program and that is not receiving financial assistance under section 746(a)(1), title VII of the PHS Act.

The statutory authority for the Model State-Supported AHEC Program contains explicit language regarding activities and agreements between the medical and osteopathic schools which develop AHEC programs and the free-standing, community-based area health education centers which provide training sites and resources for the activities. To accomplish these specific tasks, a system of subcontracts is developed between the health professions schools and the independent AHEC centers in the communities. The principal objective of the legislation for the Model State-Supported AHEC Program is to encourage State coordination and support for AHEC activities.

Review Criteria

The program announcement, published in the **Federal Register** at 59 FR 67303 on December 29, 1994, proposed two additional review criteria for this program. No comments were received during the 30 day comment period. Therefore, the review criteria remain as proposed and are included as the last two criteria in the list below. These review criteria apply to the Basic/Core AHEC Programs, section 746(a)(1) and the Model State-Supported AHEC Programs, section 746(a)(3).

The review of applications will take into consideration the following criteria:

1. The degree to which the proposed project adequately provides for the program requirements set forth in sections 746(a)(1) and 746(a)(3);
2. The capability of the applicant to carry out the proposed project activities in a cost-efficient manner;
3. The extent of the need of the area to be served by the proposed area health education center;
4. The potential of the proposed AHEC program and participating centers to continue on a self-sustaining basis; and
5. The extent to which the proposed project adequately responds to AHEC Program performance measures and outcome indicators.

Additional Information

If additional programmatic information is needed, please contact: Louis Coccodrilli, M.P.H., Acting Chief, AHEC and Special Programs Branch,

Division of Medicine, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 9A-25, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443-6950, FAX: (301) 443-8890.

The Cooperative Agreement for Basic/Core Area Health Education Centers Programs is listed at 93.824 and the Model State-Supported Area Health Education Centers Programs is listed at 93.107 in the Catalog of Federal Domestic Assistance. These programs are not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100) or the Public Health System Reporting Requirements.

Dated: May 1, 1995.

Ciro V. Sumaya,
Administrator.

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Public Health Service

Statement of Organization, Functions, and Delegations of Authority; Office of the Assistant Secretary for Health

Part H, Public Health Service (PHS), Chapter HA (Office of the Assistant Secretary for Health), of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (DHHS) (42 FR 61318, December 2, 1977, as amended most recently at 60 FR 18846, April 13, 1995) is amended to reflect changes in the Office of Management and Budget, Office of the Assistant Secretary for Health.

Office of the Assistant Secretary for Health

Under *Chapter HA, Office of the Assistant Secretary for Health, Section HA-20, Functions*, after the title and statement for the *Office of Management and Budget (HAU), Administrative Services Center (HAU1)* at the end of the statement add:

Carries out the authorities of the PHS Claims Officer under the Federal Claims Collection Act, the Federal Tort Claims Act, and the Military Personnel and Civilian Employees' Claims Act.

Under the Division of Property Management (HAU17) at the end of the statement add:

Administers logistics activities of the PHS to assure a coordinated effort toward achieving the goals and objectives established by the Assistant Secretary for Health.