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

provided, including , but not limited to, consultation (which may include consultation carried out by the IRB itself) with representatives of the communities from which the subjects will be drawn;

(iv) The research could not practicably be carried out without the waiver; and

(v) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Background

The NIH, through its National Institute of Neurological Disorders and Stroke, has funded a research project entitled, ''National Acute Brain Injury Study: Hypothermia,'' which is a study of the treatment with hypothermia of severe head injury. This important and necessary research needs to be carried out in human subjects who, because of their injuries, are not conscious and cannot, therefore, consent to their participation. In some instances, but not always, consent from a legally authorized representative can be sought and obtained. Nevertheless, the unavailability of such representatives in many cases is impeding the progress of the research to such an extent, that the NIH determined that the research cannot go forward in the context of the current Department of Health and Human Services (HHS) regulations for the protection of human subjects (45 CFR Part 46) unless certain informed consent requirements of those regulations are waived by the Secretary, HHS in accord with the waiver provisions provided at 45 CFR 46.101(i). A request for consideration of such a waiver was received from the Institutional Review Board, University of Texas Health Science Center, Houston, on July 12, 1995.

Current HHS regulations permit IRBs acting in accord with an Assurance of Compliance with 45 CFR Part 46, to waive the requirement for obtaining informed consent under the following stringently applied conditions found at 45 CFR 46.116(d).

The IRB must find and document that:

- The research involves no more than minimal risk to the subjects;
- The waiver * * * will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver * * *; and,
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

However, the waiver of informed consent requirements now being authorized under § 46.101(i) could not previously have been approved by an IRB, acting independently of the § 46.101(i) waiver, because the risk involved in this emergency treatment activity is greater than minimal and therefore the ''minimal risk'' requirement for the exercise of an IRB waiver of informed consent could not be met.

NIH notes that testimonies to this effect, in regard to similar research activities, were delivered to (i) the Subcommittee on Regulation, Business Opportunities, and Technology, Committee on Small Business, U.S. House of Representatives (Washington, DC, May 23, 1994); (ii) the Coalition Conference of Acute Resuscitation Researchers (Washington, DC, October 25, 1994); (iii) the meeting of Applied Research Ethics National Association (Boston, MA, October 30, 1994); (iv) the meeting of Public Responsibility in Medicine & Research (Boston, MA, November 1, 1994); and (v) the Food and Drug Administration/National Institutes of Health Public Forum on Informed Consent in Clinical Research Conducted in Emergency Circumstances (Rockville, MD, January 9–10, 1995).

Therefore, the issue for decision by the Secretary was whether this particular research activity, involving greater than minimal risk to the subjects, should be permitted to go forward in the absence of legally effective informed consent. The decision is that under certain strictly limited circumstances such permission is appropriate.

Periodic Review

A periodic review of the implementation by IRBs of this waiver will be conducted by OPRR to determine its adequacy in meeting its intended need or if adjustments to the waiver might be necessary and appropriate.

Dated: July 19, 1995.

Philip R. Lee,

Assistant Secretary for Health.

[FR Doc. 95–18334 Filed 7–25–95; 8:45 am]

BILLING CODE 4140–01–M

Office of Refugee Resettlement

Refugee Resettlement Program; Availability of Formula Allocation Funding for FY 1995 Targeted Assistance Grants for Services to Refugees in Local Areas of High Need

AGENCY: Office of Refugee Resettlement (ORR), ACF, HHS.

ACTION: Final notice of availability of formula allocation funding for FY 1995 targeted assistance grants to States for services to refugees [1] in local areas of high need.

SUMMARY: This notice announces the availability of funds and award procedures for FY 1995 targeted assistance grants for services to refugees under the Refugee Resettlement Program (RRP). These grants are for service provision in localities with large refugee populations, high refugee concentrations, and high use of public assistance, and where specific needs exist for supplementation of currently available resources. The formula has been updated to take into account FY 1994 arrivals.

A notice of proposed allocation of targeted assistance funds was published for public comment in the **Federal Register** on April 17, 1995 (60 FR 19270).

FOR FURTHER INFORMATION CONTACT: Toyo Biddle (202) 401–9250.

APPLICATION DEADLINE: The deadline for applications from States for grants under this notice is on August 25, 1995.

Applications from States for grants under this notice must be received on time. An application will be considered to be received on time under either of the following two circumstances: The application is postmarked indicating it was sent via the U.S. Postal Service or by private commercial carrier not later than the closing date specified in the final notice or the application is hand-delivered on or before the closing date to the Office of Refugee Resettlement, 370 L'Enfant Promenade, SW., 6th Floor, Washington, DC 20447. Hand-delivered applications will be accepted during the normal working hours of 8:00 a.m. to 4:30 p.m., Monday through Friday (excluding Federal legal holidays) up to 4:30 p.m. of the closing date.

To be considered complete, an application package must include a

[1] In addition to persons who meet all requirements of 45 CFR 400.43, ''Requirements for documentation of refugee status,'' eligibility for targeted assistance includes Cuban and Haitian entrants, certain Amerasians from Vietnam who are admitted to the U.S. as immigrants, and certain Amerasians from Vietnam who are U.S. citizens. (See section II of this notice on ''Authorization.'') The term ''refugee'', used in this notice for convenience, is intended to encompass such additional persons who are eligible to participate in refugee program services, including the targeted assistance program.

Refugees admitted to the U.S. under admissions numbers set aside for private-sector-initiative admissions are not eligible to be served under the targeted assistance program (or under other programs supported by Federal refugee funds) during their period of coverage under their sponsoring agency's agreement with the Department of State—usually two years from their date of arrival, or until they obtain permanent resident alien status, whichever comes first.