DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

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Sandra Gabriel
Senior Health Physicist, Medical Branch
Division of Nuclear Materials Safety
United States Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Subject: NRC Licenses 19-00296-10 and 19-09760-02 03031714

Dear Ms. Gabriel:

This letter responds to your September 8, 2005, letter to me as the Radiation Safety Officer for the National Institutes of Health's (NIH) campus in Bethesda, Maryland, and your June 9, 2005, letter to Dr. Barry Hoffer, the Director of the National Institute on Drug Abuse's (NIDA) Intramural Research Program in Baltimore, Maryland. Although NIDA has a separate license with the Nuclear Regulatory Commission, NIDA is a component of the NIH. In both your letters, you asked the NIH to provide revised Certifications of Financial Assurance (CFA) and revised Statements of Intent (SOI) from a duly authorized NIH official for both the Bethesda and Baltimore licensed facilities.

Following the receipt of your letter NIH's Division of Radiation Safety contracted with a consultant, Radiation Safety Academy, Inc. (RSA), to develop a revised Decommissioning Funding Cost Estimate for License 19-00296-10 covered facilities, including the future NIAID IRF in Frederick and also covering the USAG Waste Water Treatment Plant at that location. Data from the Final Site Surveys conducted during the past two years by RSA (three FSS's) were used to provide a realistic cost. The revised estimate is $5.653 million. The NIDA SOI is based on the 10 CFR 30.35(d) level of $1.125 million.

The revised CFAs and SOIs are enclosed. The CFA and SOI for both licenses have been signed by Ms. Colleen Barros, the NIH's Deputy Director for Management (DDM). The DDM directs and coordinates all NIH-wide administration and management matters, including the NIH's budget and financial operations, as well as the NIH's radiation safety program. The DDM is the NIH official who prepares requests for NIH appropriations, as needed, for the President's budget.

Please contact me at (301) 496-2254 if you would like to discuss this matter further.

Sincerely yours,

Robert A. Zoon

Robert A. Zoon, M.E., M.S.
Director, Division of Radiation Safety
Radiation Safety Officer, NIH

Enclosures

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Statement of Intent
for
License 19-09760-02

As Deputy Director for Management (DDM), I am the Chief Financial Officer (CFO) of the National Institutes of Health. In my capacity as the DDM and CFO, I am the NIH official authorized and responsible for preparing requests for NIH appropriations from the United States Congress, as needed, for the President's budget, including funds for decommissioning activities associated with operations authorized by U.S. Nuclear Regulatory Commission Material License No. 19-09760-02. This authority is established by section 402 of the Public Health Service Act, 42 U.S.C. 282, and the official Organization Functional Statement for the NIH Office of Management. Within this authority, I intend to request that funds be made available, if and when necessary, in the amount of $1,125,000 to decommission the National Institute of Drug Abuse facilities at its 5500 Nathan Shock Drive and 333 Cassell Drive, Baltimore, Maryland locations. I intend to request and obtain these funds sufficiently in advance of decommissioning to prevent a delay of required activities.

A copy of section 402 of the Public Health Service Act and a copy of the referenced Functional Statement are attached as evidence that I am authorized to represent the National Institutes of Health in this transaction.

Colleen Barros
Deputy Director for Management, NIH

Attachment

NONNEGOTIABLE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

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CERTIFICATION OF FINANCIAL ASSURANCE

Principal: Colleen Barros, Deputy Director for Management
Chief Financial Officer, NIH,
1 Center Drive, Bethesda, MD 20892

For: The National Institute on Drug Abuse
5500 Nathan Shock Drive
Baltimore, MD 21224

NRC License Number: 19-09760-02

I certify that the National Institutes of Health is licensed to possess types and forms of radioactive material as follows:

Byproduct, source, and/or special nuclear material	**Chemical and/or physical form**	**Maximum amount that licensee may possess at any one time under this license**
As specified in 10 CFR 33.100, Schedule A (Type B Broad License)	Any	See Condition 12 below
Cesium 137	Sealed source (3M Model No. 4F6S)	15 milliCuries
Iodine 125	As radioactive waste	100 milliCuries

Condition 12:

A. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column I. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

B. Notwithstanding Paragraph A immediately above, and 10 CFR 33.100, Schedule A, Column I, the applicable quantities for the following radionuclides are reduced to:

Carbon 14	1 Curie
Krypton 85	1 Curie
Silver 110m	10 milliCuries
Iodine 129	1 milliCurie
Any byproduct material other than alpha emitting byproduct material not listed in 10 CFR 33.100, Schedule A	1 milliCurie

C. Notwithstanding Paragraph A above, and 10 CFR 33.100, Schedule A, the applicable quantity for the following radionuclide is:

Phosphorus 33	1 Curie

I also certify that we have provided a statement of intent to obtain, if and when needed, the sum of $1,125,000 for the purpose of decommissioning as prescribed by 10 CFR Part 30.

Colleen Barros 12/15/05

Colleen Barros Date

Office of Management of the NIH

Home

Statement

Org Chart

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DDM Facts

Links

Functional Statement

Office of Management - HNAM (1) Advises the NIH Director and staff on all phases of NIH-wide administration and management; (2) provides leadership and direction to all aspects of management; and (3) oversees the management of functions in the areas of budget and financial management, personnel management, management policy, management assessment, program integrity, contract, procurement, and logistics management, engineering services, safety, space and facility management, support services, and security operations.

TITLE 42 > CHAPTER 6A > SUBCHAPTER III > Part A > § 282

§ 282. Director of National Institutes of Health

Release date: 2005-02-25

(a) Appointment

The National Institutes of Health shall be headed by the Director of the National Institutes of Health (hereafter in this subchapter referred to as the "Director of NIH") who shall be appointed by the President by and with the advice and consent of the Senate. The Director of NIH shall perform functions as provided under subsection (b) of this section and as the Secretary may otherwise prescribe.

(b) Duties and authority

In carrying out the purposes of section 241 of this title, the Secretary, acting through the Director of NIH—

(1) shall be responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;

(2) shall coordinate and oversee the operation of the national research institutes and administrative entities within the National Institutes of Health;

(3) shall assure that research at or supported by the National Institutes of Health is subject to review in accordance with section 289a of this title;

(4) for the national research institutes and administrative entities within the National Institutes of Health—

(A) may acquire, construct, improve, repair, operate, and maintain, at the site of such institutes and entities, laboratories, and other research facilities, other facilities, equipment, and other real or personal property, and

(B) may acquire, without regard to section 8141 of title 40, by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed ten years;

(5) may secure resources for research conducted by or through the National Institutes of Health;

(6) may, without regard to the provisions of title 5 governing appointments in the competitive

service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific peer review groups and scientific program advisory committees as are needed to carry out the requirements of this subchapter and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups;

(7) may secure for the National Institutes of Health consultation services and advice of persons from the United States or abroad;

(8) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(9) may, for purposes of study, admit and treat at facilities of the National Institutes of Health individuals not otherwise eligible for such treatment;

(10) may accept voluntary and uncompensated services;

(11) may perform such other administrative functions as the Secretary determines are needed to effectively carry out this subchapter;

(12) after consultation with the Director of the Office of Research on Women's Health, shall ensure that resources of the National Institutes of Health are sufficiently allocated for projects of research on women's health that are identified under section 287d (b) of this title;

(13) may conduct and support research training—

(A) for which fellowship support is not provided under section 288 of this title; and

(B) which does not consist of residency training of physicians or other health professionals; and

(14) may appoint physicians, dentists, and other health care professionals, subject to the provisions of title 5 relating to appointments and classifications in the competitive service, and may compensate such professionals subject to the provisions of chapter 74 of title 38.

The Federal Advisory Committee Act shall not apply to the duration of a peer review group appointed under paragraph (6). The members of such a group shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of such group. Not more than one-fourth of the members of any such group shall be officers or employees of the United States.

(c) Availability of substances and organisms for research

The Director of NIH may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(d) Services of experts or consultants; number; payment of expenses, conditions, recovery

(1) The Director of NIH may obtain (in accordance with section 3109 of title 5, but without regard to the limitation in such section on the period of service) the services of not more than 220 experts or consultants, with scientific or other professional qualifications, for the National Institutes of Health.

(2)

(A) Except as provided in subparagraph (B), experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, for their travel to and from their place of service and for other expenses associated with their assignment.

(B) Expenses specified in subparagraph (A) shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(e) Dissemination of research information

The Director of NIH shall—

(1) advise the agencies of the National Institutes of Health on medical applications of research;

(2) coordinate, review, and facilitate the systematic identification and evaluation of, clinically relevant information from research conducted by or through the national research institutes;

(3) promote the effective transfer of the information described in paragraph (2) to the health care community and to entities that require such information;

(4) monitor the effectiveness of the activities described in paragraph (3); and

(5) ensure that, after January 1, 1994, all new or revised health education and promotion materials developed or funded by the National Institutes of Health and intended for the general public are in a form that does not exceed a level of functional literacy, as defined in the National Literacy Act of 1991 (Public Law 102-73).

(f) Associate Director for Prevention; functions

There shall be in the National Institutes of Health an Associate Director for Prevention. The Director of NIH shall delegate to the Associate Director for Prevention the functions of the Director relating to the promotion of the disease prevention research programs of the national research institutes and the coordination of such programs among the national research institutes and between the national research institutes and other public and private entities, including elementary, secondary, and post-secondary schools. The Associate Director shall—

(1) annually review the efficacy of existing policies and techniques used by the national research institutes to disseminate the results of disease prevention and behavioral research programs; and

(2) recommend, coordinate, and oversee the modification or reconstruction of such policies and techniques to ensure maximum dissemination, using advanced technologies to the maximum extent practicable, of research results to such entities.

(g) Enhancing competitiveness of certain entities in obtaining research funds

(1)

(A) In the case of entities described in subparagraph (B), the Director of NIH, acting through the Director of the National Center for Research Resources, shall establish a program to enhance the competitiveness of such entities in obtaining funds from the national research institutes for conducting biomedical and behavioral research.

(B) The entities referred to in subparagraph (A) are entities that conduct biomedical and behavioral research and are located in a State in which the aggregate success rate for applications to the national research institutes for assistance for such research by the entities in the State has historically constituted a low success rate of obtaining such funds, relative to such aggregate rate for such entities in other States.

(C) With respect to enhancing competitiveness for purposes of subparagraph (A), the Director of NIH, in carrying out the program established under such subparagraph, may—

(i) provide technical assistance to the entities involved, including technical assistance in the preparation of applications for obtaining funds from the national research institutes;

(ii) assist the entities in developing a plan for biomedical or behavioral research proposals; and

(iii) assist the entities in implementing such plan.

(2) The Director of NIH shall establish a program of supporting projects of biomedical or behavioral research whose principal researchers are individuals who have not previously served as the principal researchers of such projects supported by the Director.

(h) Increased participation of women and disadvantaged individuals in biomedical and behavioral research

The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes of Health, shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research.

(i) Discretionary fund; uses; report to Congressional committees; authorization of appropriations

(1) There is established a fund, consisting of amounts appropriated under paragraph (3) and made available for the fund, for use by the Director of NIH to carry out the activities authorized in this chapter for the National Institutes of Health. The purposes for which such fund may be expended include—

(A) providing for research on matters that have not received significant funding relative to other matters, responding to new issues and scientific emergencies, and acting on research opportunities of high priority;

(B) supporting research that is not exclusively within the authority of any single agency of such Institutes; and

(C) purchasing or renting equipment and quarters for activities of such Institutes.

(2) Not later than February 10 of each fiscal year, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities undertaken and expenditures made under this section during the preceding fiscal year. The report may contain such comments of the Secretary regarding this section as the Secretary determines to be appropriate.

(3) For the purpose of carrying out this subsection, there are authorized to be appropriated $25,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996.

(j) Data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions

(1)

(A) The Secretary, acting through the Director of NIH, shall establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions (in this subsection referred to as the "data bank"). The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information.

(B) The Secretary shall establish the data bank after consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention.

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

(3) The data bank shall include the following:

(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to section 355 (i) of title 21, which provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria for participation in the clinical trials, a description of the location of trial sites, a point of contact for those wanting to enroll in the trial, and a description of whether, and through what procedure, the manufacturer or sponsor of the investigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children, and shall be in a form that can be readily understood by members of the public. Such information shall be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval of the protocol.

(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

(i) under a treatment investigational new drug application that has been submitted to the Secretary under section 360bbb (c) of title 21; or

(ii) as a Group C cancer drug (as defined by the National Cancer Institute).

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

(4) The data bank shall not include information relating to an investigation if the sponsor has

provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that such disclosure would not substantially interfere with such enrollment.

(5) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary. Fees collected under section 379h of title 21 shall not be used in carrying out this subsection.

(k) Day care for children of employees

(1) The Director of NIH may establish a program to provide day care services for the employees of the National Institutes of Health similar to those services provided by other Federal agencies (including the availability of day care service on a 24-hour-a-day basis).

(2) Any day care provider at the National Institutes of Health shall establish a sliding scale of fees that takes into consideration the income and needs of the employee.

(3) For purposes regarding the provision of day care services, the Director of NIH may enter into rental or lease purchase agreements.

(l) Interagency research on trauma

The Director of NIH shall carry out the program established in part F of subchapter X of this chapter (relating to interagency research on trauma).