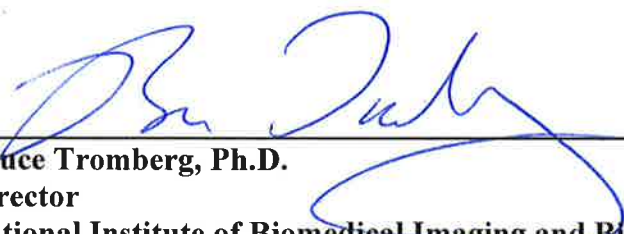


DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director

**2018 TRIENNIAL ADVISORY COUNCIL REPORT
CERTIFYING COMPLIANCE WITH THE
NIH POLICY ON INCLUSION GUIDELINES**



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NIBIB Report Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2016 – FY2018

I. Background/Overview

A. Mission statement of the National Institute of Biomedical Imaging and Bioengineering (NIBIB)

The mission of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) is to improve human health by leading the development and accelerating the application of biomedical imaging and bioengineering technologies. The Institute is committed to integrating the engineering and physical sciences with the life sciences to advance basic research and medical care, to improve health by leading the development and application of emerging and breakthrough biomedical technologies based in the physical and engineering sciences.

B. Description of NIBIB portfolio

Extramural Program

The NIBIB **portfolio**. The Institute funds both NIBIB-solicited and investigator-proposed research activities, enabling the best minds in academia, industry, and government to explore new approaches to health care solutions and to provide valuable insights into biology and medicine. The Institute also funds multidisciplinary research training through institutional training grants and individual fellowships, as well as in the context of individual research project grants. The Extramural Program supports research and research training that are conducted at colleges, universities, hospitals, and businesses across the United States and to a limited extent, internationally. The NIBIB has four operational Divisions from which the projects are administered: The **Division of Applied Science and Technology (DAST)**, the **Division of Discovery Science and Technology (DDST)**, the **Division of Health Information Technology (DHIT)**, and the **Division of Interdisciplinary Training (DIDT)**. The Program Areas are generally administered by a Division as indicated in the list below, although some projects in a Program Area might be administered by a different Division or jointly, depending on the science/technology in the

project.

Given that the focus of the NIBIB research is technology development, NIBIB does not support projects at the Phase III clinical trial stage. Rather, as a project matures its support comes from one of the organ-, system-, or disease-specific institutes and centers (ICs).

NIBIB Extramural Program Divisions

Division of Applied Science & Technology (DAST)

- Bio-Electromagnetic Technologies
- Image-Guided Interventions
- Magnetic Resonance Imaging
- Molecular Probes and Imaging Agents
- Nuclear Medicine
- Optical Imaging and Spectroscopy
- Ultrasound: Diagnostic and Interventional
- X-ray, Electron and Ion Beam

Division of Discovery Science & Technology (DDST)

- Biomaterials and Biomolecular Constructs
- Biosensors and Physiological Detectors
- Engineered Cells
- Engineered Tissues
- Mathematical Modeling, Simulation, and Analysis
- Point of Care Technologies - Diagnostics
- Surgical Tools
- Synthetic Biology for Technology Development
- Technologies for Immunoengineering
- Technologies for Tissue Chips
- Therapeutic Medical Devices

Division of Health Informatics Technologies (DHIT)

- Biomedical Informatics
- Connected Health - Mobile Health and Telehealth
- Image Processing, Visual Perception and Display
- Artificial Intelligence, Machine Learning, and Deep Learning
- Point of Care Technologies - Diagnostics

Division of Interdisciplinary Training (DIDT)

- Undergraduate & Graduate
- Predoctoral
- Postdoctoral
- Junior Investigator
- Clinician-Scientist
- Diversity
- Conference Support

Intramural Program

The Intramural Research Program plays a key role in fulfilling the Institute's mission by advancing knowledge in imaging and bioengineering research using a combination of basic, translational, and clinical science and supporting training activities. All NIBIB intramural laboratories are located on the NIH campus.

Advanced Imaging and Microscopy (AIM) Resource

The Advanced Imaging & Microscopy Resource is a trans-NIH shared resource that houses, operates, disseminates, and improves non-commercial, prototype optical imaging systems developed at the NIH. The facilities at AIM are available for use by the entire NIH intramural research community.

Laboratory of Cellular Imaging and Macromolecular Biophysics (LCIMB):

The LCIMB develops new approaches for determining the organization, structure and interactions of organelles and macromolecular assemblies both in the context of cells and tissues, as well as in isolation from cells. The LCIMB includes the Cellular and Supramolecular Structure and Function Section, the Dynamics of Macromolecular Assembly Section, Nanoinstrumentation and Force Spectroscopy Section.

Laboratory of Molecular Imaging and Nanomedicine (LOMIN):

The LOMIN specializes in synthesizing molecular imaging probes, single-photon emission computed tomography, magnetic resonance imaging, optical, contrast enhanced ultrasound, photoacoustic imaging, as well as multimodality imaging. The LOMIN includes the Biological Molecular Imaging Section, and the Theranostic Nanomedicine Section

Molecular Tracer and Imaging Core Facility

This core facility provides chemical and radiochemical synthesis capabilities and molecular imaging resources for small animal preclinical research for the NIBIB intramural research program.

Section on Quantitative Medical Imaging

The Section on Quantitative Medical Imaging develops methods to derive biomarkers from data acquired by non-invasive imaging techniques.

Section on Biophotonics

The Section on Biophotonics develops probes and techniques for use in diffraction limited and sub-diffraction limited fluorescence imaging of cells and tissues.

Section on High Resolution Optical Imaging (HROI):

The Section on HROI develops novel technologies for studying biological processes at unprecedented speed and resolution, such as improving the performance of 3D optical imaging microscopes, particularly with respect to resolution, depth, speed and phototoxicity.

Trans-NIH Shared Resource on Biomedical Engineering and Physical Science (BEPS):

BEPS Shared Resource consists of the following Units: Electron Microscopy, Infrared Imaging and Thermometry, Micro Analytical Immunochemistry, Microfabrication and Microfluidics, Quantitative Methods for Macromolecular Interactions, and Scanning Probe Microscopy.

C. A Brief History of NIBIB

A detailed history of NIBIB is available at:

<https://www.nibib.nih.gov/about-nibib/history>

On December 29, 2000, President Clinton signed the NIBIB Establishment Act as Public Law 106-580. Approximately 15 months later, NIBIB received its first congressional appropriation and began to operate fully. The first full budget appropriation in FY2003 was \$278 million, the NIBIB budget has grown to \$378 million in FY2018. NIBIB exists to facilitate the development of and accelerate the application of innovative biomedical technologies to improve health care. The NIBIB domain is broad, encompassing research conducted at the nexus of biology, physics, engineering, mathematics, chemistry, and computer science.

II. Strategies for Ensuring Compliance

A. Peer Review

- The implementation of inclusion guidelines involves the participation of review, program, policy, and grants management staff. Inclusion is first addressed by peer review. Reviewers on NIBIB peer review panels are given specific guidance on reviewing inclusion on the basis of sex/gender, race, ethnicity, and age when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion by sex/gender, race, and ethnicity. For NIH-defined Phase III clinical trials, enrollment goals are further assessed for plans to conduct analyses of intervention effects among sex/gender, racial, and ethnic groups. Unacceptable inclusion plans are reflected in the priority score of the application and documented in the minutes of the review session. Initial review groups make recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. If issues are raised in review, and an application is tagged for funding, the program and/or grants management staff notify principal investigators, who are required to address these issues prior to funding. Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received and approved.

B. Program Monitoring and Grants Management Oversight

- Prior to an award, program officials/program directors are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate. The NIBIB Inclusion Enrollment Officer (NIEO) in the NIBIB Office of Program Evaluation and Strategic Partnerships (OPESP) assists the Program staff in monitoring actual enrollment progress throughout the year and in annual progress reports. For NIH-defined Phase III clinical trials, program officials/program directors monitor the requirement for sex/gender and race/ethnicity analyses in applications and annual progress reports. The NIEO consults with the PIs when necessary. Grants management staff ensure that appropriate terms

and conditions of award are included in the Notice of Award, and that this information is appropriately documented in the official grant file.

C. Intramural

- All intramural clinical research studies require investigators to provide plans for the appropriate inclusion of women and minorities and/or a justification whenever representation is limited or absent, as part of their NIH protocol reviews. Intramural IRBs review intramural research protocols for compliance with inclusion guidelines and conduct annual monitoring. With each annual review and renewal, the investigator documents the number, gender, race, and ethnicity of those who were recruited during the past year; any issues with recruitment are addressed at the annual review by the investigator and reviewed by the pertinent IRB. The Clinical Center's Office of Protocol Services (OPS) coordinates annual reporting of demographic participant data to the Office of Extramural Research (OER) and the Office of Research on Women's Health. The NIEO, through arrangement with the NIBIB Scientific Director, is available to assist the Intramural investigators with any issues they might encounter with inclusion.

D. NIBIB Inclusion Training Approaches

- NIBIB Program Officials/Program Directors and Scientific Review Officers attended the May 11, 2018 training, Ensuring Inclusion in NIH Clinical Research: Policies and Procedures for Grants and Contracts. Staff can access the archive of this training on the NIH staff intranet as needed.
- The NIBIB Inclusion Enrollment Officer (NIEO) in the NIBIB Office of Program Evaluation and Strategic Partnerships (OPEPSP) is an internal resource to train and advise NIBIB staff on inclusion. The NIEO serves on the Sex as a Biological Variable (SABV) working group of the Office of Research on Women's Health (ORWH), is on the ORWH Strategic Plan Working Group, and is the NIBIB alternate for the Coordinating Committee on Research for Women's Health (CCRWH).

III. Analysis and Interpretation of Data

- A. NIBIB aggregate inclusion data tables:
- Table 2-1. Total Inclusion Data Records for NIH-Defined Extramural and Intramural Clinical Research
 - Table 4-1-1-C. Enrollment for All NIH-Defined Clinical Research by Race
 - Table 5-1-1-C. Enrollment for All NIH-Defined Clinical Research, by Sex/Gender, Race, and Ethnicity
- B. The appended tables show enrollment data for fiscal years (FY) 2016 through 2018.
- C. Given NIBIB projects are generally involved in technology development and not large clinical trials, the number of projects actively recruiting human subjects is usually low, as indicated by the data for FY2016. The large increases in enrollment in 2017 and 2018 were due to the deployment of a mobile health research platform using mobile and internet technology. The high proportion of unreported data (Tables 4-1-1-C and 5-1-1-C) is because the participants using this mobile research platform are not required to enter their sex, race, and ethnicity information to participate in the study.
- D. NIBIB did not support any NIH-defined Phase III clinical trials.
- E. Inclusion enrollment data by Research Condition and Disease Categorization (RCDC) category for FY 2018 is available at <https://report.nih.gov/RISR/>.

IV. Additional information

- A. Policy changes related to the 21st Century Cures Act
- The 21st Century Cures Act, enacted December 13, 2016, included several new requirements related to inclusion of participants in clinical research. As a result, NIH updated its policy on the Inclusion of Women and Minorities as Subjects in Clinical Research on November 28, 2017, to require studies that are both NIH-defined Phase III clinical trials and applicable clinical trials to report the results of analyses by sex/gender and/or race/ethnicity to ClinicalTrials.gov. This requirement is effective for competing grant awards on or after December 13, 2017, as well as contract solicitations and intramural studies initiated after this date. Additionally, NIH revised its Inclusion of Children Policy on December 19, 2017. The revised policy, now called the NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects, applies to individuals of all ages and requires reporting of participant age at enrollment in annual progress reports. The policy is effective for applications

submitted on or after January 25, 2019, and contract solicitations and intramural studies initiated after this date. The 21st Century Cures Act amended the frequency of the Report of the NIH Director on the inclusion of women and minorities from biennial to triennial. Thus, this first triennial report provides information on inclusion of participants in NIH clinical research from FY 2016 – 2018. Section IV of the Report of the Advisory Committee on Research on Women's Health includes IC reports on monitoring adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research for FY 2015 and 2016.

Table 2-1: Metrics Based on Inclusion Data Records (IERS)

Total Inclusion Data Records (IERS) for NIH-Defined Extramural and Intramural Clinical Research Reported Between FY2016 and FY2018

Fiscal Year	Total IERS	IERS Without Enrollment		IERS With Enrollment		US Site IERS		Non-US Site IERS		Female Only IERS		IERS Excluding Male-only and Female-only*	
2016	129		22		107		104		3		3		11
2017	131		25		106		105		1		1		9
2018	164		50		114		111		3		3		10

*Inclusion Data Records (IERS) excluding male-only and female-only include unknown sex/gender, and combination of unknown and any

Table 4-1-1-C: Enrollment by Race
 Total Enrollment of All NIND-Defined Clinical Research

Fiscal Year	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black American	% Black American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2016	22,478	129	10,465	46.6	337	1.5	863	3.8	7,616	33.9	32	0.1	10,174	45.3	799	3.6	2,657	11.8
2017	109,992	131	17,630	16.0	295	0.3	4,952	4.5	3,413	3.1	98	0.1	61,069	55.5	2,953	2.7	37,214	33.8
2018	198,509	164	30,203	15.2	521	0.3	8,657	4.4	5,238	2.6	170	0.1	104,956	52.9	5,177	2.6	73,790	37.2

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 5-1-1-C: Total Enrollment: All NIH-Defined Clinical Research Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity

Year	Sex Gender	Minority		% Minority	Total Enrollment	% Total	Hispanic Latino		% Not Hispanic		% Unknown Not Reported	
		Alaska Native	Indian				Hispanic Latino	% Not Hispanic	Hispanic Latino	% Not Reported		
2016	Female	7,125	52.6	13,539	60.2	11,561	85.4	648	4.8	1,330	9.8	
2016	Male	3,319	37.9	8,765	39.0	7,057	80.5	487	5.6	1,221	13.9	
2016	Unknown	21	12.1	174	0.8	39	22.4	17	9.8	118	67.8	
2017	Female	9,031	21.5	42,067	38.2	36,854	87.6	3,265	7.8	1,948	4.6	
2017	Male	8,574	23.4	36,669	33.3	30,807	84.0	3,753	10.2	2,109	5.8	
2017	Unknown	25	0.1	31,256	28.4	67	0.2	20	0.1	31,169	99.7	
2018	Female	13,087	21.9	59,784	30.1	53,342	89.2	5,121	8.6	1,321	2.2	
2018	Male	17,104	24.0	71,271	35.9	62,103	87.1	7,437	10.4	1,731	2.4	
2018	Unknown	12	0.0	67,454	34.0	39	0.1	4	0.0	67,411	99.9	

Year	Sex Gender	% American Indian		% Asian	% Black African American		% Native Hawaiian Pacific Islander		% More Than One Race		% Unknown Not Reported		
		Alaska Native	Indian		American	African American	Pacific Islander	Hawaiian	White	% White	White	% Not Reported	
2016	Female	244	1.8	397	2.9	5,480	40.5	13	0.1	5,547	41.0	1,324	9.8
2016	Male	93	1.1	464	5.3	2,134	24.3	19	0.2	4,589	52.4	2,203	13.7
2016	Unknown	0	0.0	2	1.1	2	1.1	0	0.0	38	21.8	2	1.1
2017	Female	173	0.4	1,812	4.3	2,496	5.9	59	0.1	32,882	78.2	2,795	6.6
2017	Male	120	0.3	3,138	8.6	914	2.5	39	0.1	28,115	76.7	3,241	8.8
2017	Unknown	0	0.0	2	0.0	3	0.0	0	0.0	72	0.2	31,178	99.8
2018	Female	290	0.5	2,558	4.3	3,268	5.5	86	0.1	48,186	80.6	2,530	4.2
2018	Male	231	0.3	6,096	8.6	1,968	2.8	84	0.1	56,734	79.6	3,850	5.4
2018	Unknown	0	0.0	3	0.0	2	0.0	0	0.0	36	0.1	67,410	99.9

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

