NIBIB Report Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2019- FY2021

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 Ill 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
- Bioanalytical Sensors
- 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)

- Mathematical Modeling, Simulation, and Analysis
- Biomaterial Interfaces
- Biorobotic Systems
- Synthetic Biological Systems
- Resource Centers for Bioengineering Technologies
- Small Businesses for Bioengineering Technologies

Division of Health Informatics Technologies (DHIT)

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

Division of Interdisciplinary Training (DIDT)

Career Stages

- Undergraduate
- Graduate/Clinical Training
- Postdoctoral Training/Clinical Residency
- Early Career Investigator
- Established Investigator

Grant Types

- Individual Fellowships
- Career Development Awards
- Career Transition Awards
- Institutional Grants
- Diversity Awards / Programs

Training-Related Programs

- Academic Research Enhancements (R15)
- Research Education Programs (R25)
- Supplements
- Loan Repayment Program
- Support for Conferences and Scientific Meetings (R13)

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.

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, and the Nanoinstrumentation and Force Spectroscopy Section.

Laboratory of Dynamics of Macromolecular Assembly (LDMA):
The LDMA develops biophysical methods to study protein interactions and the assembly of multi-protein complexes. Hallmarks of multi-protein complexes are multi-valent interactions and cooperativity. In the molecular machinery of cellular processes, these constitute ubiquitous mechanisms for the integration and transfer of information. Therefore, our focus is on the development of approaches for multi-component systems where several different macromolecular components interact to allow association and dissociation of different co-existing complexes in different states. We are interested in the characterization of the number of assembly states, their size, shape, and the interaction energetics. Complementary to crystallographic techniques, such solution interaction studies can provide information on the assembly principles of structurally polymorphic multi-protein complexes.

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

Laboratory of High Resolution Optical Imaging (LHROI):
The LHROI 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 toresolution, depth, speed and phototoxicity.

Section on Immunoengineering
The Section on Immunoengineering develops immune-active biomaterials for regenerative medicine through a bottom-up approach using mechanism-based immunology methods. The immune system is a critical mediator of tissue homeostasis and disease. Upon implantation of a biomaterial scaffold, an immune system response is activated, potentially with pathologic side effects including fibrosis or damaging inflammation. Furthermore, tissue growth and wound healing are modulated by immune responses. Through an understanding of how our immune system interacts with materials in the context of traumatic injury, combined with advances in biopolymers and cellular engineering, we will attempt to program immune responses to promote scaffold integration and tissue growth. Such information is critical for the advancement of next-generation materials used in non-integrating devices (i.e. pacemakers, drug delivery devices, cosmetic implants) as well as integrating medical devices (scaffolds for tissue repair).

Section on Mechanobiology
The focus of the Section on Mechanobiology is the development and use of advanced Atomic Force Microscopy (AFM) technologies for cellular and tissue mechanics investigation. We combine and apply diverse multidisciplinary knowledge to investigate the most pressing mechanobiology questions, including high spatio-temporal resolution AFM and confocal fluorescent microscopes, image analysis, and mathematical modeling.

The Section on Mechanobiology seeks to understand several important biological processes by applying physics and engineering principles, particularly: the molecular-mechanical regulation of the actomyosin cortex of melanoma cells; the solid tumor microenvironment for deciphering self-organization in cancer biology; and the anisotropic mechanical properties of developmental and mature inner ear sensory and non-sensory epithelial tissues using a novel noncontact AFM approach.

Additionally, the laboratory develops new AFM methodologies to study fast

multiparametric and multidimensional cellular and tissue processes, and advances the state-of-the-art AFM imaging methods for high spatio-temporal and quantitative nanomechanical mapping.

Laboratory on Quantitative Medical Imaging (LQMI)

The LQMI develops methods to derive biomarkers from data acquired by non-invasive imaging techniques.

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.

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.

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 $410 million in FY2021. 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. NIBIB does not currently and has not supported NIH-defined Phase III clinical trials. However, in the usual NIH protocol for NIH-defined Phase Ill 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 proposedstudy population with respect to the inclusion policies. If issues are raised in review and an application is to be funded, 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. ForNIH-defined Phase Ill 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 grantees 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 staff take inclusion training, the most recent of which occurred in April of 2020 and was videocast and made available for new staff. Addition training on secondary research and inclusion policies was made available in 2021 as an e-module. New staff can access the archives of these trainings 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 also serves on the Sex as a Biological Variable (SABV) working group of the Office of Research on Women's Health (ORWH) and is an alternate for NIBIB 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) 2019 through 2021.

C. Given NIBIB projects are generally involved in early-stage technology development and not clinical trials, the number of projects actively recruiting human subjects is usually low.

D. The decrease in enrollment in 2020 compared with 2019 was due to the completion of a project on mobile health research platform using mobile and internet technology. The large number of unknowns in 2019 was because that project did not require participants to enter their sex/gender, race or ethnicity data to participate in the study.

E. In 2020 and 2021, the large number of unknowns was because of an incorrect human subject coding made in characterizing the human subjects data in a large project involving de-identified electronic health records (EHR). This project utilizes de-identified existing imaging data and is evaluating the arrangement of images in the EHR to determine the incremental impact of external reports and image availability on rates of repeat imaging and rates of recommended follow-up imaging. There are two data sources for this project: 1) Retrospective existing imaging data and 2) Physicians as human subjects for collecting survey data. The retrospective existing imaging data was erroneously coded as prospective data. In this study, only the physicians should be included as human subjects contributing to prospective data. The data in parenthesis are the corrected data. This aggregated data will be updated in the official record for FY2022 and future years of this project.

F. NIBIB did not support any NIH-defined Phase III clinical trials.

G. Inclusion enrollment data by Research Condition and Disease Categorization (RCDC) category is available at https://report.nih.gov/RISR.

IV. Data Tables

Section 2: Metrics Based on Inclusion Data Records (IERs)

Table 2-1. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2019 and 2021

Fiscal Year	Total IERs	IERs Without Enrollment	IERs With Enrollment	US Site IERs	Non-US Site IERs	Female Only IERs	Male Only IERs	IERs Excluding Male only and Female only*
2019	259	144	115	111	4	9	8	98
2020	314 **(313)**	191	123 **(122)**	119 **(118)**	4	14	6	103 **(102)**
2021	359 **(358)**	227	132 **(131)**	127 **(126)**	5	11	10	111 **(110)**

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

Section 5: Enrollment by Race

Table 4-1-1-C. Total Enrollment of All NIH-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 African American	% Black African 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
2019	303,683	259	35,450	11.7	608	0.2	10,283	3.4	6,171	2.0	195	0.1	120,927	39.8	5,944	2.0	159,555	52.5
2020	31,603 (7,200)	314 (313)	2,344	7.4 (32.6)	17	0.1 (0.2)	925	2.9 (12.8)	957	3.0 (13.3)	11	0.0 (0.2)	3,570	11.3 (49.6)	117	0.4 (0.5)	26,006 (1,603)	82.3 (22.3)
2021	33,432 (9,029)	359 (358)	2,999	9.0 (33.2)	17	0.1 (0.2)	898	2.7 (9.9)	1,574	4.7 (17.4)	11	0.0 (0.1)	4,385	13.1 (48.6)	87	0.3 (1.0)	26,460 (2,057)	79.1 (22.8)

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

Total Enrollment: All NIH-Defined Clinical Research

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

Fiscal Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	15,145	21.7	69,702	23.0	61,497	88.2	5,968	8.6	2,237	3.2
2019	Male	20,128	24.3	82,780	27.3	71,438	86.3	8,598	10.4	2,744	3.3
2019	Unknown	177	0.1	151,201	49.8	67	0.0	74	0.0	151,060	99.9
2020	Female	1,027	31.2	3,294	10.4 (45.8)	2,457	74.6	203	6.2	634	19.2
2020	Male	1,314	36.0	3,645	11.5 (50.6)	2,729	74.9	206	5.7	710	19.5
2020	Unknown	3	0.0	24,664 (261)	78 (3.6)	4	0.0	0	0.0	24,660 (257)	100 (98.4)
2021	Female	1,337	33.8	3,960	11.8 (43.9)	2,980	75.3	218	5.5	762	19.2
2021	Male	1,660	35.7	4,655	13.9 (51.5)	3,567	76.6	254	5.5	834	17.9
2021	Unknown	2	0.0	24,817 (414)	74.2 (4.6)	6	0.0	1	0.0	24,810 (407)	100 (98.3)

Fiscal Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African 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
2019	Female	15,145	21.7	69,702	23.0	334	0.5	2,915	4.2	3,764	5.4	102	0.1	55,561	79.7	3,316	4.8	3,710	5.3
2019	Male	20,128	24.3	82,780	27.3	266	0.3	7,337	8.9	2,344	2.8	89	0.1	64,875	78.4	2,607	3.1	5,262	6.4
2019	Unknown	177	0.1	151,201	49.8	8	0.0	31	0.0	63	0.0	4	0.0	491	0.3	21	0.0	150,583	99.6
2020	Female	1,027	31.2	3,294	10.4 (45.8)	7	0.2	373	11.3	440	13.4	9	0.3	1,795	54.5	56	1.7	614	18.6
2020	Male	1,314	36.0	3,645	11.5 (50.6)	10	0.3	551	15.1	516	14.2	2	0.1	1,768	48.5	60	1.6	738	20.2
2020	Unknown	3	0.0	24,664 (261)	78 (3.6)	0	0.0	1	0.0	1	0.0	0	0.0	7	0.0	1	0.0	24,654 (251)	100 (96.2)
2021	Female	1,337	33.8	3,960	11.8 (43.9)	7	0.2	362	9.1	727	18.4	10	0.3	2,036	51.4	49	1.2	769	19.4
2021	Male	1,660	35.7	4,655	13.9 (51.5)	10	0.2	535	11.5	847	18.2	1	0.0	2,344	50.4	38	0.8	880	18.9
2021	Unknown	2	0.0	24,817 (414)	74.2 (4.6)	0	0.0	1	0.0	0	0.0	0	0.0	5	0.0	0	0.0	24,811 (408)	100 (98.6)

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