National Institute of Biomedical Imaging and Bioengineering (NIBIB)
Monitoring Adherence to the NIH Policy on the
Inclusion of Women and Minorities in Clinical Research
as Reported in FY2022- FY2024

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 transform, through technology development, our understanding of disease and its prevention, detection, diagnosis, and treatment. NIBIB supports new tools and technologies to improve human health within its internal laboratories and through grants, collaborations, and training.

B. Description of NIBIB portfolio

Extramural program

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).

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
- Photoacoustic/Optoacoustic Technologies
- Ultrasound: Diagnostic and interventional
- X-ray, Electron and Ion Beam
- Collaborations to Accelerate Technology
  - Medical Imaging and Data Resource Center (MIDRC)
  - Human Connectome Project (HCP)
  - Brain Research through Advancing Innovative Neurotechnologies (BRAIN)
  - Initiative
  - Sound Health
  - Medical Device Research Interest Group (MDRIG)
  - NIH-NASA Biomedical Research Activities

Division of Discovery Science & Technology (DDST)

- Bionics
- Medical Devices
- Medical Simulators
- Robotics
- Biomolecular Technologies
- Cellular and Multicellular Technologies
- Living Materials
- Manufacturing and Biomanufacturing Tools
- Molecular Materials
- Nanomaterials
- Physiomimetic Materials
- Screening and High-Throughput Tools
- Small Businesses for Bioengineering Technologies
- Collaborations to Accelerate Technology
    - Interagency Modeling and Analysis Group (IMAG)
    - Synthetic Biology Consortium (SBC)
    - Biomaterials Network
    - RADx Tech Innovation Funnel and Independent Test Assessment Program (ITAP)

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
- Bioanalytical Sensors
- Collaborations to Accelerate Technology
    - Collaborative Research in Computational Neuroscience (CRCNS)
    - Neuroimaging Informatics Tools and Resource Clearinghouse (NITRC)
    - NIBIB Point-or-Care Technologies Research Network (POCTRN)
    - Smart and Connected Health Program
    - RadLex Ontology
    - National Centers for Biomedical Imaging and Bioengineering (NCBIB)

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)
- Collaborations to Accelerate Technology
  - Design by Biomedical Undergraduate Teams (Debut) Challenge
  - Special Population Research Forum
  - Artificial Intelligence for Biomedical Excellence
  - Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative
  - Blueprint R25 Program

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.

The Laboratory of Cellular Imaging and Macromolecular Biophysics (LCIMB)

This lab specializes in the development and application of cutting-edge technologies based upon engineering, mathematics, and the physical sciences, for the solution of problems in biology and medicine. It collaborates with intramural scientists, as well as proposes and develops theoretical and experimental methods important to the long-term needs of the NIH. Its unique expertise spans technologies ranging in scale from near-atomic resolution to intact organisms. The LCIMB includes the Cellular and Supramolecular Structure and Function Section, and the Nanoinstrumentation and Force Spectroscopy Section.

Section on Cellular and Supramolecular Structure and Function (CSSF)

The CSSF develops new methods based on electron microscopy and related techniques to expand knowledge about complex biological and disease processes.

Section on Nanoinstrumentation and Force Spectroscopy (NFS)

The NFS shares a biological atomic force microscopy (BioAFM) facility and develops AFM platforms to higher speed and resolution and multimodal measurements.

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. The focus of LDMA is 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. LDMA is 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. Most recently, these techniques have been applied to the study of SARS-CoV-2 nucleocapsid protein and its interactions in viral assembly, and on the analysis of the mutational landscape to gain insight in the nucleocapsid structure, function, and evolution.

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 the immune system interacts with materials in the context of traumatic injury, combined with advances in biopolymers and cellular engineering, the Section on Immunoengineering 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 Mechanics and Tissue Remodeling Integrating Computational & Experimental Systems (MATRICES)

The Section on Mechanics and Tissue Remodeling Integrating Computational & Experimental Systems (MATRICES) studies the transition of tissue from healthy to a diseased state and the underlying mechanisms driving disease progression. Of particular interest are enzymes known as proteases, which degrade extracellular matrices and other proteins. The MATRICES Lab seeks to reveal opportunities for new diagnostics and therapeutics for sickle cell disease, cancer metastasis, orthopedic diseases and other conditions. To accomplish these goals, both experimental and computational approaches including label-free MRI, mechanical testing, computational modeling and analysis of gene and protein expression are employed. Through ongoing collaborations, MATRICES aims to develop and deploy technologies in low resource settings, with a focus on diseases related to health disparities in the U.S. and around the globe.

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. Diverse multidisciplinary knowledge is applied 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 (such as Magnetic Resonance Imaging, MRI) that are informative about anatomy and physiology and that provide new, accurate and reliable tools for assessment of various medical conditions.

Resources and Cores

BETA Center

The BETA Center is the NIH-wide resource housed by the NIBIB intramural research program and serves as a new NIH campus model for accelerating technology-driven interdisciplinary research and clinical translation. The BETA Center community brings researchers together with engineering and imaging expertise including biomedical imaging, biosensing, biomechanics, engineered/synthetic biology, nano/biomaterials, artificial intelligence, modeling, computation, and informatics. Central to BETA Center's mission is employing evidence-driven approaches to expand diversity, equity, and inclusion within NIBIB's Intramural Research Program and serving as a model for recruiting diverse biomedical engineering talent to NIH.

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. AIM specializes in large, year-long (or longer) collaborative research efforts with NIH labs – providing sample preparation, microscope operation and development, and data processing/analysis as needed. The AIM Resource focuses on a project's imaging and processing so that you can focus on the biology. Any size imaging project is appropriate to use this resource.

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

The Biomedical Engineering and Physical Science (BEPS) shared resource supports NIH's intramural basic and clinical scientists on applications of engineering, physics, imaging, measurement and analysis. BEPS is centrally located on the main NIH campus and provides expertise that spans technologies ranging in scale from near-atomic resolution to intact organisms. The BEPS Shared Resource consists of the following Units: Electron Microscopy, Micro Analytical lmmunochemistry, Microfabrication and Microfluidics, Quantitative Methods for Macromolecular Interactions, and Scanning Probe Microscopy.

The Instrumentation Development and Engineering Application Solutions (IDEAS)

The IDEAS facility, formerly the Signal Processing and Instrumentation Section (SPIS)) provides the NIH Intramural Research Program (IRP) with electrical, electronic, electro-optical, biomedical, mechanical, computer, and software engineering expertise for projects that require technology development of novel biomedical laboratory and clinical research enabling systems, instrumentation, and methodologies. As the central, on-campus, engineering resource within the IRP, the broad range of IDEAS engineering knowledge and experience establishes a strong infrastructure fostering interdisciplinary, multi-investigator, cross-Institute technology incubators and high-risk high-reward research.

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

C. A brief history of NIBIB

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 peer review panels are given specific guidance on reviewing the inclusion of women, racial and ethnic minorities, and participants across the lifespan when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion. NIBIB does not currently and has not supported NIH-defined Phase III clinical trials. However, in the usual NIH practice for NIH-defined Phase Ill clinical trials, enrollment goals are further assessed for plans to conduct analyses of intervention effects among women, and 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. The NIBIB Advisory Council performs the second level of review and makes recommendations for funding to the NIBIB Director considering the overall impact score, percentile ranking, and summary statement in light of the research priorities for NIBIB. 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 officers/program directors are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate. The NIBIB Inclusion Officer (NIO) in the NIBIB Office of Research Administration (ORA) assists the Program staff in monitoring actual enrollment progress throughout the year and in annual progress reports. The program officers/program directors monitor the requirement for sex and race/ethnicity analyses in applications and annual progress reports. The NIO 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, sex, 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 (ORWH). The NIO, 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 the training sessions on the NIH staff intranet as needed. The NIBIB Health Science Policy Officer (HSPO) and Inclusion Officer (IO) in NIBIB's Office of Research Administration (ORA) are internal resources to train and advise NIBIB staff on inclusion. The NIBIB Inclusion Officer serves on the Sex as a Biological Variable (SABV) working group of the 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. The number of projects actively recruiting human subjects is usually low since NIBIB projects are generally involved in early-stage technology development, not clinical trials.

B. NIBIB Inclusion data for NIH-Defined Extramural and Intramural Clinical Research reported between Fiscal Years 2022 and 2024 shown in

- Table 2-1: Total inclusion data records for NIH-Defined Extramural and Intramural Clinical Research. They do not represent a count of total studies or trials since multiple Inclusion Enrollment Reports (IERs) may be submitted for a single study.
- Table 5-1-1-C: Enrollment of Sex by Race and Ethnicity.
  - The data presented in this report show inclusion data records only for studies labeled for prospective data collection. It excludes retrospective studies which use existing datasets obtained previously for another research or clinical purpose.
  - The large increase in participants in 2024 is due to 151 new projects being awarded.
  - Total % unknown ethnicity reported decreased from 89.5% in 2023 to 46% in 2024. This is after correcting the erroneous entries for 3 studies using existing datasets (5,200,416 in one study; 24,403 in another; and 8000 in the third) after locking data for Fiscal Year 2023.
  - NIBIB does not currently, and has not supported, NIH-defined Phase III clinical trials.

C. Inclusion enrollment data by Research Condition and Disease Categorization (RCDC) category will be available on the RCDC Inclusion Statistics Report website (https://report.nih.gov/RISR/) at a later date but are available by request. These data will now be published annually at this website.

IV. DATA TABLES

See Appendix

Appendix 1: Table 2-1. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2022 and 2024

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*
2022	391	258	133	130	3	14	14	105
2023	364	228	136	133	3	20	17	99
2024	370	219	151	140	2	16	13	122

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

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

Appendix 2: Table 5-1-1-C. Enrollment for ALL NIH-defined Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex	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	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	1,613	36.5	4,425	47.1	5	0.1	407	9.2	897	20.3	9	0.2	2,195	49.6	89	2.0	823	18.6	3,361	76.0	261	5.9	803	18.1
2022	Male	1,896	38.9	4,873	51.9	5	0.1	581	11.9	995	20.4	3	0.1	2,339	48.0	49	1.0	901	18.5	3,741	76.8	303	6.2	829	17.0
2022	Unknown	11	12.1	91	1.0	0	0.0	3	3.3	1	1.1	0	0.0	6	6.6	0	0.0	81	89.0	12	13.2	7	7.7	72	79.1
2023	Female	1,337	26.3	5,076	44.1	12	0.2	435	8.6	412	8.1	1	0.0	3,674	72.4	69	1.4	473	9.3	4,304	84.8	486	9.6	286	5.6
2023	Male	1,524	30.5	4,997	43.4	9	0.2	561	11.2	361	7.2	5	0.1	3,548	71.0	50	1.0	463	9.3	4,152	83.1	596	11.9	249	5.0
2023	Unknown	40	2.8	1,433	12.5	0	0.0	13	0.9	8	0.6	0	0.0	101	7.0	1	0.1	1,310	91.4	131	9.1	19	1.3	1,283	89.5
2024	Female	10,044	33.3	30,186	56.1	212	0.7	2,026	6.7	4,127	13.7	25	0.1	18,724	62.0	1,142	3.8	3,930	13.0	23,837	79.0	3,106	10.3	3,243	10.7
2024	Male	8,006	37.1	21,558	40.1	187	0.9	2,125	9.9	2,791	12.9	40	0.2	14,836	68.8	783	3.6	796	3.7	18,769	87.1	2,586	12.0	203	0.9
2024	Unknown	376	18.4	2,043	3.8	14	0.7	78	3.8	75	3.7	1	0.0	734	35.9	105	5.1	1,036	50.7	958	46.9	146	7.1	939	46.0

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