# 2015 BIENNIAL ADVISORY COUNCIL REPORT CERTIFYING COMPLIANCE WITH THE NIH POLICY ON INCLUSION GUIDELINES

## National Advisory Council for Biomedical Imaging and Bioengineering (NACBIB)

#### I. Background/Overview

- The mission of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) as noted in the strategic plan (<u>http://www.nibib.nih.gov/about-nibib/strategic-plan</u>) 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.
- The NIBIB portfolio. The Institute funds both NIBIB-defined and investigatorproposed 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. Four of NIBIB's organizational divisions support extramural research and research training that are conducted at colleges, universities, and hospitals across America. The NIBIB has created four operational Divisions from which the projects are administered, the Division of Applied Sciences and Technology (DAST), the Division of Discovery Sciences and Technology (DDST), the Division of Health Information Technology (DHIT), and the Division of Interdisciplinary Training (DIDT). The projects supported by NIBIB fall into one of the Program Areas listed in the following table. The Program Areas are generally administered by a particular Division, although some projects in a particular Program Area might be administered by a different Division depending on the science/technology in the project.

Biomaterials	Magnetic, Biomagnetic and Bioelectric Devices	Sensors		
Biomedical Informatics	Mathematical Modeling, Simulation and Analysis	Structural Biology		
Drug and Gene Delivery Systems and Devices	Micro- and Nano- Systems; Platform Technologies	Surgical Tools, Techniques and Systems		
Image Processing, Visual Perception and Display	Micro-Biomechanics	Telehealth		
Image-Guided Interventions	Molecular Imaging	Tissue Engineering		
Integration of Implantable Medical Devices	Nuclear Medicine	Ultrasound: Diagnostic and Interventional		
Interdisciplinary Training and Career Development	Optical Imaging and Spectroscopy	X-ray, Electron, and Ion Beam		
Magnetic Resonance Imaging and Spectroscopy	Rehabilitation Engineering			

Given that the focus of the NIBIB research is development, NIBIB usually does not support projects through the Phase III clinical trial stage, rather as a project matures its support might be transferred to one of the organ or system specific ICs.

# Intramural Labs at the NIBIB:

The mission of the NIBIB is to improve human health by providing leadership for development and accelerating the application of biomedical technologies. The Institute is committed to integrating engineering and physical sciences with the life sciences to advance basic research and medical care. The Intramural Research Program plays a key role in fulfilling the Institute's mission, particularly to advance knowledge in imaging and bioengineering research using a combination of basic, translational, and clinical science and to develop effective training programs in related fields. All of the NIBIB laboratories are located on the NIH campus.

## **Biomedical Engineering and Physical Science (BEPS) Shared Resource:**

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.

# 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.

## 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.

## Molecular Biomedical Imaging Laboratory (MBIL):

The MBIL's ongoing research includes the imaging evaluation of myocardial fibrosis in heart failure, the use of MRI to evaluate the epidemiology of cardiovascular disease, and reduction of atherosclerosis using image-guided therapy.

## 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 and depth and speed and phototoxicity.

# • A Brief History of NIBIB

From the NIBIB Strategic Plan currently on the NIBIB website (<u>http://www.nibib.nih.gov/</u>):

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 new Institute was created expressly to lead the development and accelerate the application of innovative biomedical technologies for the improved delivery of health care. The NIBIB domain is broad, encompassing research conducted at the nexus of biology, physics, engineering, mathematics, chemistry, and computer science.

Ten years after receiving its first budget appropriation of \$112 million, the NIBIB budget has tripled. NIBIB now also includes a highly creative, internationally recognized intramural research program. NIBIB's overarching goal is scientific and technological innovation to extend healthy living, reduce death and disability, and improve the well-being of our society. NIBIB's intramural division on the NIH campus in Bethesda, Maryland, includes a highly innovative, state-of-the-art scientific program in super-high-resolution optical imaging of living organisms, molecular imaging and theranostics, and emerging clinical imaging technologies.

# **II. Strategies for Ensuring Compliance**

- Peer Review
  - Reviewers are asked to assess the inclusion of women, minorities, and children. The review committee comments are part of the summary statement. The Program staff then resolves any concerns on applications for which an award is anticipated. Table A depicts compliance with the inclusion policy of applications assigned to NIBIB as judged during Scientific Peer Review during 2013 and 2014. In general, the extramural community demonstrates very good compliance with inclusion, with acceptable rates ranging from about 95% to 99% of around 700 applications each of the three principal Council Rounds (January, May, October) in both years.

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Table B illustrates that compliance as submitted of awarded grants ranges from 96% to 100%.

- NIBIB Training Approach
  - o NIBIB first received funding authority in FY2002, and NIBIB staff members have developed NIBIB procedures for compliance with the NIH Tracking and Inclusion policy. These procedures involve oversight by staff in the Office of Research Administration, Extramural Program staff, Grants Management staff and the NACBIB. Individual NIBIB staff training in policies, procedures and compliance issues had been provided by Marie Gill and Stephanie Sabourin in the Office of Extramural Science Programs until mid-2014. A population tracking policy and procedures manual served as a resource through FY 2014, and was available to staff on the NIBIB SharePoint site. Marie Gill and Stephanie Sabourin were accessible to respond to questions or concerns of staff on issues of inclusion and population tracking until their departure in mid-2014. A new SharePoint Library in the Program SharePoint site is being assembled by Dr. Steve Zullo to maintain information on the new Inclusion Monitoring System that is replacing population tracking. Dr. Zullo is now accessible to Program staff to assist in evaluating and managing inclusion concerns. This FY2015 represents a period of transition as current projects can still be administered in the population tracking system. New awards are beginning to use the IMS mechanism, and as current projects are renewed they will convert to the IMS mechanism.
  - Beginning in mid-2014 Dr. Zullo, of the NIBIB Office of Program Evaluation and Strategic Partnerships (OPESP), monitors Inclusion and guides the Program Staff in proper administration of the new Inclusion Management System (IMS) that replaced the population tracking system beginning in October 2014 with the new fiscal year 2015. With the IMS the use of tracking exceptions has been eliminated, and all human subject projects are now classified as requiring tracking or not. All projects that would have been given a tracking exception will now be tracked. Current projects with tracking exception codes will convert to the IMS

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with the next competing renewal. Definitions of human subject research have not changed; just the tracking system used by NIH has changed.

- The new IMS: NIBIB staff members regularly monitor compliance and accuracy of the Inclusion Data Reports (IDR) provided and uploaded by the investigators into the NIH commons. The IDRs are comprised of the Institutional Review Board (IRB) approved target population numbers of subjects needed to answer the questions being asked in the research, and the cumulative enrollment table which exhibits the progress of inclusion in the research project as measured by the number of human subjects enrolled. Plans to exceed the proposed target numbers require IRB approval. This target population which includes appropriate representation by women, children, and minorities, is proposed by the investigators and approved by the scientific review groups at the first level of peer review of the project. The Program staff works with the investigators to ensure they understand the policies and to serve as an information resource if there are problems recruiting an appropriate sample.
- There are no additional concerns regarding compliance of staff or NIBIB investigators.
- Dr. Zullo serves as the NIBIB representative to the NIH Inclusion Operating Procedures Workgroup (IOPW).
- NIBIB Staff Training on the Utilization of the Tracking System at NIBIB
  A population tracking policy and procedures manual served as a resource through
  FY 2014, and was available to staff on the NIBIB SharePoint site. Marie Gill and
  Stephanie Sabourin were accessible to respond to questions or concerns of staff
  on issues of inclusion and population tracking until their departure in mid-2014. A
  new SharePoint Library in the Program SharePoint site is being assembled by Dr.
  Zullo to maintain information on the new Inclusion Monitoring System that is
  replacing population tracking. Dr. Zullo is now accessible to Program staff to
  assist in evaluating and managing inclusion concerns. FY2015 represents a period
  of transition as current projects can still be administered in the population tracking

system. New awards are beginning to use the IMS mechanism, and as current projects are renewed they will convert to the IMS mechanism.

#### **III.** Analysis and Interpretation of Data

- A. All clinical research Attached are the aggregate data tables for data reported in FY2013 and FY2014 for clinical research protocols funded by the NIBIB (Tables 1 and 2, respectively).
- B. NIH-defined Phase III clinical trials none
- C. Extramural research Attached are the aggregate data tables for data reported in FY2013 and FY2014 for clinical research protocols funded by the NIBIB, essentially the extramural research.
- D. Intramural research There were no clinical research projects documented for the intramural program for FY2013 or FY2014.

The trend of gender participation in NIBIB supported projects in the 2011 and 2013 biennial reports demonstrated increasing proportional participation of men in the NIBIB- supported projects. In FY2009 the approximate percentages of men and women participants were 27% and 73% respectively; in FY2010 the percentages were 43% for men and 57% for women. In FY2011, the percentages diverged somewhat to 66% for men and 34%, while in FY2012, the percentages were 53% women and 45% men. In 2013 and 2014 the percentages again diverged, females represented 64% and males represented 36% of the participants.

# IV. Appendix: Further information on the Laws and Inclusion Policies at NIH and NIBIB In 1994, the NIH revised its policy on the inclusion to coincide with changes instituted by the

NIH Revitalization Act of 1993 (PL103-43), that women and minorities be involved in all NIH- funded clinical research studies and clinical trials. The 1997 Report of the NIH Director's Panel on Clinical Research

(<u>http://grants.nih.gov/grants/NIH\_Directors\_Panel\_Clinical\_Research\_Report\_199712.pdf</u>) adopted the following definition of clinical research:

A. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an

investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies.

B. Epidemiologic and behavioral studies.

C. Outcomes research and health services research.

This Act mandated four specific requirements for NIH with regard to inclusion:

- 1. Ensure that women and members of minority groups and their subpopulations are included in all human subjects research;
- For Phase III clinical trials, ensure that women and minorities and their subpopulations be included such that valid analysis of differences in intervention effect can be accomplished;
- 3. Not allow cost as an acceptable reason for excluding these groups; and
- 4. Initiate programs and support for outreach efforts to recruit these groups into clinical studies.

It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. According to the provisions of the Act, the requirements shall not apply when the inclusion of women and members of minority groups:

- > Is inappropriate with respect to the health of the subjects;
- > Is inappropriate with respect to the purpose of the research; or
- Is inappropriate under such other circumstances as the Director of NIH may designate.

The NIH system for tracking inclusion before the beginning of FY 2015 on October 1, 2014 allowed for certain exceptions as reviewed and approved by the NIH Tracking and Inclusion Committee. Justifiable exceptions include early stages of technology development, a sample size of fewer than 10 subjects, administrative justifications (i.e., duplicate reporting etc.), and particular grant mechanisms, such as fellowships and grants for resources/infrastructure. This system is being replaced by the Inclusion Management System (IMS) at the start of FY 2015 beginning with new and renewing grants. Current grants will be transitioned to the IMS with their next competing renewal.

In addition, the NIH Revitalization Act states, "the advisory council of each national research institute shall prepare biennial reports describing the manner in which the institute has complied with [the policy]. Each such report shall be submitted to the Director of the institute involved for inclusion in the biennial report under section 403."

The law also requires that the Institutes and Centers of NIH develop internal policies for tracking the inclusion of women and minorities in clinical research and make these policies available to the Office of Research on Women's Health that has primary oversight responsibility for this law.

# Table A. Level of Compliance with Inclusion Policy in New Extramural Grant Applications as Assessed During Scientific Peer Review

Council Dates	Jan-13	May-13	Aug-13	Oct-13	Jan-14	May-14	Aug-14	Oct-14
Total Number of Applications Reviewed	689	670	6	703	690	706	16	640
Number of Applications with Human Subjects	164	174	2	189	166	208	1	174
Number (percent) of Applications approved by IRG as submitted	161	165	2	187	158	201	1	170
	98.17%	94.83%	100%	98.94%	95.18%	96.63%	100%	97.7%
Number (percent) of Applications with unacceptable minority- only inclusion	1	0	0	1	0	0	0	1
	0.61%	0%	0%	0.53%	0%	0%	0%	0.57%
Number (percent) of Applications with unacceptable sex/gender-only inclusion	0	0	0	0	0	0	0	2
	0%	0%	0%	0%	0%	0%	0%	1.15%
Number (percent) of Applications with both unacceptable minority AND sex/gender inclusion	2	9	0	1	8	7	0	1
	1.22%	5.17%	0%	0.53%	4.82%	3.37%	0%	0.57%
Total Number (percent) of Applications with unacceptable minority inclusion	3	9	0	2	8	7	0	2
	1.83%	5.17%	0%	1.06%	4.82%	3.37%	0%	1.15%
Total Number (percent) of Applications with unacceptable sex/gender inclusion	2	9	0	1	8	7	0	3
	1.22%	5.17%	0%	0.53%	4.82%	3.37%	0%	1.72%
Total Number (percent) of unacceptable Applications as submitted	3	9	0	2	8	7	0	4
	1.83%	5.17%	0%	1.06%	4.82%	3.37%	0%	2.3%

## NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

Run Date: 12/19/2014

# Table B. Extramural Research Awards: Bars-To-Funding and Resolutions

# NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

Council Dates	Jan-13	May-13	Aug-13	Oct-13	Jan-14	May-14	Aug-14	Oct-14
Total number of awards	84	101	3	70	101	102	6	56
Number of awards involving Human Subjects	24	24	1	29	20	32	0	14
Number (percent) of awards involving Human Subjects that met the inclusion requirements as submitted	23	23	1	29	20	32	0	14
	96%	96%	100%	100%	100%	100%	0%	100%
Number (percent) of awards where minority-only bar-to-funding was removed by program staff (M_U)	0	0	0	0	0	0	0	0
	0%	0%	0%	0%	0%	0%	0%	0%
Number (percent) of awards where sex/gender-only bar-to-funding was removed by program staff (G_U)	0	0	0	0	0	0	0	0
	0%	0%	0%	0%	0%	0%	0%	0%
Number (percent) of awards where both minority AND sex/gender bar-to-funding were removed by program staff	1	1	0	0	0	0	0	0
	4%	4%	0%	0%	0%	0%	0%	0%
Total Number (percent) of awards where minority bar-to-	1	1	0	0	0	0	0	0
funding was removed by program staff	4%	4%	0%	0%	0%	0%	0%	0%
Total Number (percent) of awards where sex/gender bar-	1	1	0	0	0	0	0	0
to-funding was removed by program staff	4%	4%	0%	0%	0%	0%	0%	0%
Total Number (percent) of awards where bar-to-funding was removed	1	1	0	0	0	0	0	0
	4%	4%	0%	0%	0%	0%	0%	0%

Run Date: 12/19/2014

#### Table 1: FY2013 Aggregate Enrollment Data for All Extramural Research Protocols

## NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Number of Protocols with Enrollment Data: 0

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian/ Pacific Islander	Hispanic	White	*More Than One Race	Unknown/ Other	Total
Female									
rentate									
Malo									
Male									
Linknown									
UTIKHOWH									
Tatal									
i Uldi									

\* Categories not in use in Old Forms, but are provided here for consistency with the1997 OMB Standard.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 41

				Total of All Subjects by Ethnicities								
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	56	265	2,997	4	3,047	235	330	6,934	6,244	323	367	6,934
	0.81%	3.82%	43.22%	0.06%	43.94%	3.39%	4.76%	64.03%	90.05%	4.66%	5.29%	64.03%
Male	25	388	991	8	2,073	88	201	3,774	3,306	244	224	3,774
	0.66%	10.28%	26.26%	0.21%	54.93%	2.33%	5.33%	34.85%	87.6%	6.47%	5.94%	34.85%
Unknown	0	0	0	0	0	0	122	122	0	0	122	122
	0%	0%	0%	0%	0%	0%	100%	1.13%	0%	0%	100%	1.13%
Total	81	653	3,988	12	5,120	323	653	10,830	9,550	567	713	10,830
	0.75%	6.03%	36.82%	0.11%	47.28%	2.98%	6.03%	100%	88.18%	5.24%	6.58%	100%

Run Date: 10-Dec-2014

#### Table 2: FY2014 Aggregate Enrollment Data for All Extramural Research Protocols

## NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Number of Protocols with Enrollment Data: 0

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian/ Pacific Islander	Hispanic	White	*More Than One Race	Unknown/ Other	Total
Female									
remaie									
Male									
IVIAIC									
Unknown									
Unknown									
Tatal									
TOLAI									

\* Categories not in use in Old Forms, but are provided here for consistency with the1997 OMB Standard.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 49

	Total of All Subjects by Race									Total of All Subjects by Ethnicities				
	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total		
Female	112	188	3,741	6	3,579	334	419	8,379	7,525	387	467	112		
	1.34%	2.24%	44.65%	0.07%	42.71%	3.99%	5%	64.1%	89.81%	4.62%	5.57%	1.34%		
Male	44	145	1,455	13	2,591	122	285	4,655	4,091	263	301	44		
	0.95%	3.11%	31.26%	0.28%	55.66%	2.62%	6.12%	35.61%	87.88%	5.65%	6.47%	0.95%		
Unknown	0	0	6	0	0	0	32	38	3	0	35	0		
	0%	0%	15.79%	0%	0%	0%	84.21%	0.29%	7.89%	0%	92.11%	0%		
Total	156	333	5,202	19	6,170	456	736	13,072	11,619	650	803	156		
	1.19%	2.55%	39.79%	0.15%	47.2%	3.49%	5.63%	100%	88.88%	4.97%	6.14%	1.19%		

Run Date: 10-Dec-2014