

**National Library of Medicine**  
**2015 Biennial Advisory Council Report Certifying**  
**Compliance with NIH Inclusion Guidelines**

**I. Background/Overview**

- **Mission Statement**

The National Library of Medicine (NLM), on the campus of the National Institutes of Health in Bethesda, Maryland, has been a center of information innovation since its founding in 1836. The world's largest biomedical library, NLM maintains and makes available a vast print collection and produces electronic information resources on a wide range of topics that are searched billions of times each year by millions of people around the globe. It also supports and conducts research, development, and training in biomedical informatics and health information technology. In addition, the Library coordinates a 6,000-member National Network of Libraries of Medicine that promotes and provides access to health information in communities across the United States.

- **Description of IC portfolio.**

The Extramural Programs (EP) Division of the National Library of Medicine (NLM) offers grants for research projects, small business development, career transition and research training in biomedical informatics. Biomedical informatics research applies computer and information sciences to improve the access, storage, retrieval, management, dissemination and use of biomedical information. NLM also offers special resource grant programs in history/philosophy of biomedicine and information resources for health disparity populations. Career transition awards assist recent PhDs and MDs who are establishing their research careers in informatics.

Research, career transition and small business grants are available for a wide range of innovative basic and applied biomedical informatics research projects. Fields of interest include: computational representation of biomedical knowledge; integration, organization and retrieval in very large databases, disparate forms of knowledge, and multiple datasets; enhancement of human intellectual capacities through virtual reality, artificial intelligence, and machine learning; support for health decisions; in silico science; natural language understanding; investigations of topics relevant to health information science, computational modeling, and management of information during disasters. NLM places priority on research that is novel, significant, and of high impact.

To assure an adequate national pool of informaticians and health information scientists, NLM support research training in biomedical informatics at 14 educational institutions in the United States. These programs offer graduate education and postdoctoral research experiences in a

wide range of areas including: health care informatics, bioinformatics and computational biology, clinical research translational informatics, and public health informatics. The home institutions of these programs make certain that research undertaken by NLM-funded trainees meets inclusion requirements.

## II. Strategies for Ensuring Compliance

- Peer Review
  - Review panels administered by NLM follow all applicable NIH regulations for inclusion of women, children, and minorities. Inclusion considerations are a specific evaluation point during the peer review of each application. Discussion is open to the entire review committee in the presence of the Scientific Review Officer and other staff of the Extramural Programs Division. If the review panel raises a concern about the adequacy of compliance with inclusion guidelines, this is noted in the assigned reviewer(s)'s critiques. If an application with inclusion concerns is selected for funding, Program staff contacts the Principal Investigator for additional information to ensure that the concerns have been fully resolved. If, at the end of the fiscal year, an award is made before the final revised inclusion documents are received, a bar is placed on spending until satisfactory documents are received.
  - Table A shows the number of applications reviewed in FY 2013 and 2014 that had inclusion deficits. Table B shows the number of those applications selected for funding, and indicates resolution of inclusion issues.
- Training

NLM extramural program staff attends Inclusion Policy compliance and management training provided by NIH Office of Extramural Research (OER) as appropriate. NLM is represented on the Inclusion Operating Procedures Workgroup (IOPW) and thus keep apprised of updates and changes to all Inclusion-related matters. NLM's scientific review officers participate in all NIH review training related to inclusion.

## III. Analysis and Interpretation of Data

- **All clinical research** (NIH defines human clinical research as research with human subjects that is: (1) 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, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research. Note: Studies falling under Exemption 4 for human subjects research are not considered clinical research by this definition.)

For FY 2013, NLM funded 4 clinical research protocols with total enrollment of 1,630 subjects. For FY 2014, NLM funded 2 clinical research protocols with total enrollment of 876 subjects.

- **NIH-defined Phase III clinical trials** (NIH defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.)

NLM did not fund any NIH-defined Phase III clinical trials for the reporting period.

- **Extramural research** (Tables 1 and 2)

For FY 2013, NLM funded 4 extramural clinical research protocols with total enrollment of 1,630 subjects.

For FY 2014, NLM funded 2 extramural clinical research protocols with total enrollment of 876 subjects.

- **Intramural research**

NLM did not fund any intramural clinical research protocols for the reporting period.

- **Analysis**

Extramural clinical research funded by NLM rarely includes a clinical trial. More typical is a comparative effectiveness-type study in which the efficacy of an informatics intervention is assessed against current practice. NLM's extramural research portfolio is expanding to include more consumer informatics, which is likely to increase the number of applications that need to address inclusion guidelines.

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

**NATIONAL LIBRARY OF MEDICINE**

Council Dates		Jan-13	May-13	Aug-13	Oct-13	Jan-14	May-14	Aug-14	Oct-14
Total Number of Applications Reviewed	(#)	106	57	149	96	50	66	2	97
Number of Applications with Human Subjects	(#)	80	36	141	45	25	41	2	51
Number (percent) of Applications approved by IRG as submitted	(#)	61	28	141	34	21	26	2	33
	(%)	76.25%	77.78%	100%	75.56%	84%	63.41%	100%	64.71%
Number (percent) of Applications with unacceptable <i>minority-only</i> inclusion	(#)	0	0	0	1	1	0	0	0
	(%)	0%	0%	0%	2.22%	4%	0%	0%	0%
Number (percent) of Applications with unacceptable <i>sex/gender-only</i> inclusion	(#)	0	0	0	0	0	0	0	1
	(%)	0%	0%	0%	0%	0%	0%	0%	1.96%
Number (percent) of Applications with both unacceptable minority AND sex/gender inclusion	(#)	19	8	0	10	3	15	0	17
	(%)	23.75%	22.22%	0%	22.22%	12%	36.59%	0%	33.33%
Total Number (percent) of Applications with unacceptable minority inclusion	(#)	19	8	0	11	4	15	0	17
	(%)	23.75%	22.22%	0%	24.44%	16%	36.59%	0%	33.33%
Total Number (percent) of Applications with unacceptable sex/gender inclusion	(#)	19	8	0	10	3	15	0	18
	(%)	23.75%	22.22%	0%	22.22%	12%	36.59%	0%	35.29%
Total Number (percent) of unacceptable Applications as submitted	(#)	19	8	0	11	4	15	0	18
	(%)	23.75%	22.22%	0%	24.44%	16%	36.59%	0%	35.29%

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

## NATIONAL LIBRARY OF MEDICINE

Council Dates		Jan-13	May-13	Aug-13	Oct-13	Jan-14	May-14	Aug-14	Oct-14
Total number of awards	(#)	13	7	1	8	9	15	2	10
Number of awards involving Human Subjects	(#)	9	4	1	3	3	8	2	7
Number (percent) of awards involving Human Subjects that met the inclusion requirements as submitted	(#)	9	4	1	2	3	7	1	7
	(%)	100%	100%	100%	67%	100%	88%	50%	100%
Number (percent) of awards where <i>minority-only</i> bar-to-funding was removed by program staff (M_U)	(#)	0	0	0	0	0	0	1	0
	(%)	0%	0%	0%	0%	0%	0%	50%	0%
Number (percent) of awards where <i>sex/gender-only</i> 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	(#)	0	0	0	1	0	1	0	0
	(%)	0%	0%	0%	33%	0%	13%	0%	0%
<i>Total Number (percent) of awards where minority bar-to-funding was removed by program staff</i>	(#)	0	0	0	1	0	1	1	0
	(%)	0%	0%	0%	33%	0%	13%	50%	0%
<i>Total Number (percent) of awards where sex/gender bar-to-funding was removed by program staff</i>	(#)	0	0	0	1	0	1	0	0
	(%)	0%	0%	0%	33%	0%	13%	0%	0%
Total Number (percent) of awards where bar-to-funding was removed	(#)	0	0	0	1	0	1	1	0
	(%)	0%	0%	0%	33%	0%	13%	50%	0%

Table 1: FY 2013 Aggregate Enrollment Data for All Extramural Research Protocols

NATIONAL LIBRARY OF MEDICINE

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									
Male									
Unknown									
Total									

\* Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standard.

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

Number of Protocols with Enrollment Data: 4

	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	1	76	237	1	237	18	170	740	551	188	1	740
	0.14%	10.27%	32.03%	0.14%	32.03%	2.43%	22.97%	45.4%	74.46%	25.41%	0.14%	45.4%
Male	2	70	273	2	265	37	238	887	650	236	1	887
	0.23%	7.89%	30.78%	0.23%	29.88%	4.17%	26.83%	54.42%	73.28%	26.61%	0.11%	54.42%
Unknown	0	0	0	0	0	0	3	3	0	0	3	3
	0%	0%	0%	0%	0%	0%	100%	0.18%	0%	0%	100%	0.18%
Total	3	146	510	3	502	55	411	1,630	1,201	424	5	1,630
	0.18%	8.96%	31.29%	0.18%	30.8%	3.37%	25.21%	100%	73.68%	26.01%	0.31%	100%

Table 2: FY 2014 Aggregate Enrollment Data for All Extramural Research Protocols

NATIONAL LIBRARY OF MEDICINE

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									
Male									
Unknown									
Total									

\* Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standard.

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

Number of Protocols with Enrollment Data: 2

	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	0	87	21	2	243	22	18	393	344	46	3	393
	0%	22.14%	5.34%	0.51%	61.83%	5.6%	4.58%	44.86%	87.53%	11.7%	0.76%	44.86%
Male	2	85	21	3	271	47	28	457	408	48	1	457
	0.44%	18.6%	4.6%	0.66%	59.3%	10.28%	6.13%	52.17%	89.28%	10.5%	0.22%	52.17%
Unknown	0	0	0	0	0	0	26	26	0	0	26	26
	0%	0%	0%	0%	0%	0%	100%	2.97%	0%	0%	100%	2.97%
Total	2	172	42	5	514	69	72	876	752	94	30	876
	0.23%	19.63%	4.79%	0.57%	58.68%	7.88%	8.22%	100%	85.84%	10.73%	3.42%	100%