NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

COMPLIANCE WITH INCLUSION GUIDELINES

FY 2013 and FY 2014

I. BACKGROUND/OVERVIEW

As the lead federal organization conducting and supporting scientific research on infectious and immunologic diseases, National Institute of Allergy and Infectious Diseases (NIAID) carries out basic, applied, and clinical investigations within our intramural laboratories and provides extramural grant, cooperative agreement, and contract support to research scientists worldwide.

NIAID research has led to new therapies, prevention approaches, vaccines, diagnostic tests, and other technologies that have improved the health of millions of people in the United States and around the world. The scope of the NIAID research portfolio has expanded considerably in recent years in response to new challenges such as the threat of bioterrorism, emerging and re-emerging infectious diseases, the increase in asthma prevalence among children in the United States, and the impact of antibacterial resistance.

The growth of NIAID programs has also been driven by unprecedented scientific opportunities in the core NIAID scientific disciplines of microbiology, immunology, and infectious diseases. Advances in these key fields have led to a better understanding of the human immune system and the mechanisms of infectious and immune-mediated diseases.

The NIAID continues to be in compliance with the National Institutes of Health's (NIH) policies regarding inclusion of women and minorities, and their subpopulation, in clinical research. NIH inclusion policies, initially published in the 1987 NIH Guide to Grants and Contracts, urged and encouraged inclusion of women and minorities in clinical trials. These policies were codified with enactment of the NIH Revitalization Act of 1993.

New standards were mandated in 1997 by the Office of Management and Budget (OMB) Directive 15. These standards were applied to clinical research reporting beginning in FY 2001. The 1997 standards recognized ethnicity as distinct from race and introduced two new categories for race reporting. According to the new reporting standards, enrollees may report one of two possible ethnicities: either Hispanic/Latino or Not Hispanic. Enrollees may also choose to report one of five categories of race: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White; "More Than One Race" may also be reported. Clinical trials initiated prior to 2001 could use either the revised format or the 1977 OMB standard format. All but two clinical trial protocols included in this report use the newer format, which reports both ethnicity and race.

II. STRATEGIES FOR ENSURING POLICY COMPLIANCE WITH INCLUSION GUIDELINES

A. Procedures for Ensuring Policy Compliance

On January 26, 2015, FY 2013 and FY 2014 enrollment tracking data for NIAID extramural clinical research protocols and Phase III clinical research protocols were presented to the National Advisory Allergy and Infectious Diseases Council. Of FY 2013 and FY 2014 applications, 1.0 percent had issues regarding the inclusion requirements. All bars-to-funding were resolved before the applications reached Council. The following table summarizes the results for FYs 2013-2014:

NIAID Competing Extramural Awards Involving Human Subjects

FY 2013- FY 2014

	Number	**Percent**
All Research Grant Awards Made	**3115**	**--**
Awards Involving Human Subjects	**797**	**100.0**
Awards With No Inclusion Issues	**789**	**99.0**
Awards With Inclusion Issues	**8**	**1.0**
Issues Resolved Pre-Council	*8*	*100.0*
Issue Resolved With Council Action	--	--

NIAID has established procedures and strategies to insure compliance with policies regarding the tracking and inclusion of women and minorities in clinical research. These range from the use of an electronic Council Newsletter to target current and potential applicants to the use of internal memoranda and e-mail messages that target program and grants management staff.

One duty of program officers is to evaluate relevant projects for representation of women and minorities. If a problem is identified, it is discussed with senior staff and then the program officer takes the concern(s) and possible solution(s) to the applicant. When the issue(s) is resolved, the program officer releases the project for consideration by the National Advisory Allergy and Infectious Diseases Council.

Beginning in the mid-1980s with the AIDS Clinical Trials Group (ACTG), NIAID policy has held that populations participating in AIDS trials mirror the affected population in race and gender. In its continuing effort to increase efficiencies and harmonization across the HIV/AIDS clinical trials, the NIAID Division of AIDS restructured the HIV/AIDS Clinical Trials Networks. This has enabled NIAID to reallocate resources more efficiently in response to new scientific needs and opportunities and to continue its commitment to the active recruitment of women and minorities into HIV/AIDS clinical trials. Recognizing the roles of families, households, and communities as key partners also is critical to the successful implementation of clinical trials in both domestic and international settings. More recently, NIAID has advanced research by building transformational trials that will change clinical practice and reduce the impact of antibacterial resistance using strategies that comply with the NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research.

The responsibility for ensuring that the inclusion- and tracking-policy guidelines are followed resides in the NIAID Division of Extramural Activities' Office of Research Training and Special Programs. Dr. Paula Strickland is the Director of this Office.

The Director of each extramural division nominates a representative to assist Dr. Strickland in the documentation of tracking data. Division representatives ensure that the data for their Division are updated quarterly and verify the accuracy of the data for the annual report.

The Division representatives, as well as Dr. Strickland or her designee, attend the monthly meetings of the Inclusion Operating Procedures Workgroup (IOPW) that are conducted by the Office of Extramural Research.

The Scientific Review Program (SRP) conducts peer review of NIAID's contract proposals and grant applications that address Institute-specific needs. These typically include program projects (P), cooperative agreements (U), and training (T) and research career (K) grants, as well as Small Business Innovation Research (SBIR) projects and applications responding to requests for applications (RFAs) and requests for proposals (RFPs). Scientific Review Officers assist NIAID staff members with the design, development, and review of initiatives. They also conduct initiative phasing, perform quality control of RFAs and RFPs, and formulate peer review strategies. Scientific review procedures have been instituted to ensure that program and grants staff review, monitor, and document adherence by the grantee with the Inclusion Guidelines. Procedures updated since the last reporting period include the following:

1. Scientific Review Officers (SROs) read all applications and proposals and determine if clinical research or a clinical trial is being proposed, and, if applicable, what type of clinical trial is involved (Phase I, II, or III).

2. SROs provide guidance and instructions to reviewers regarding human subject research in grant applications and contract proposals. Reviewers assess the acceptability of each human subjects issue with respect to the requirements of the PHS 398, FOA and RFP.

3. SROs determine if applications or proposals are in compliance with NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research. SROs ask reviewers whether applications or proposals have included subjects of both genders and appropriate racial and ethnic groups in the application or proposal.

4. SROs explain that the NIH defines a child as a person under the age of 21 years. SROs ask reviewers to evaluate whether the submission(s) include(s) the most appropriate age groups to conduct a clinical trial or research, considering the relevant scientific and ethical issues. SROs ask reviewers to assess the appropriateness of the justification provided for excluding children and, if applicable, for excluding a specific age group.

5. Following the review of grant applications: SROs ensure the reviewer's codes match the discussion and record the human subjects, inclusion of women, minorities, and children inclusion codes in IMPAC II. SROs document in the Summary Statement of each application the final human subject protection codes and their explanations and the reasons for the Scientific Review Group's determination of acceptability or unacceptability.

6. SROs also record comments and concerns of the Scientific Review Group regarding the Data and Safety Monitoring Plan for Phase I and Phase II clinical trials, and Data and Safety Monitoring Boards (DSMB) for Phase III multi-site clinical trials.

7. For grants, SROs enter "Yes" or "No" for a Phase III clinical trial in IMPAC II. The Summary Statement includes a section in the text that captures review information on the Phase III clinical trial.

8. For contract proposals, the Technical Evaluation Report (TER) captures review information on clinical trials. The presence of a Phase III trial is captured via a check box on the reviewer score sheet; details of the trial are documented in the Technical Evaluation Report. The TER captures reviewer information on human subject protections as well as information about women, children, and minority inclusion; which are rated as acceptable or unacceptable. However the numerical score of a proposal can be affected only if the Technical Evaluation Criteria cover inclusion issues.

NIAID's Grants Management Program has codified its procedures and developed a policy note **(Attachment 1)** relating to programmatic oversight required for clinical research applications.

The NIH Guidelines on the Inclusion of Women and Minorities As Subjects of Clinical Research (updated October 1, 2001) and the earlier 1994 Guidelines require that, for NIH supported Phase III clinical trials, studies must include analyses to detect significant differences in gender and minority subpopulations (subsets) except when prior studies do not support significant differences. Inclusion of subset analyses in all publications is strongly encouraged. If the analyses show no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice.

B. Staff Training on the Utilization of the Tracking System

Within NIAID, training requirements are disseminated to all Scientific Review Officers (SROs), program officers, Contracting Officer's Representatives (CORs), grants management specialists, contract specialists, and other professional staff via email. SROs and program officers are required to accrue two policy and administrative credits per year and must attend all mandatory training courses regardless of the number of credits amassed. All training sessions are mandatory for the grants management staff but they are not required to accrue any set number of credits within a calendar year.

New program officers are directed to the NIH website for initial training. The website includes training modules on human subjects and population tracking.

A link to the NIH Office of Extramural Research (OER) website, through the NIAID human subjects' resource portal, provides access to several archived training sessions and courses relevant to population tracking. Training modules can be viewed as video casts or as slide shows.

The NIAID Office of Knowledge and Educational Resources (OKER) sponsored four courses related to clinical trials and inclusion issues in FY 2013. NIH sponsored a training module in FY 2014 to update staff on upcoming changes in inclusion policy processes.

- *Investigator-Initiated Clinical Trials Funding – March 13, 2013*. NIAID accepts, reviews, and considers for funding R01 and U01 applications to implement investigator-initiated clinical trials (IICT). While still supported, NIAID Clinical Trial Planning Grants (R34) are not a prerequisite for R01 or U01 implementation awards. IICT Working Group members joined Anna Ramsey-Ewing, Ph.D. to explore policy intricacies and answer questions. Case studies were also presented.

- *International Research Ethics and the Reasonability Requirement – June 19, 2013*. Ethical guidance documents require that investigators make the products of research reasonably available to host communities in resource-limited settings. However, significant controversy has arisen over whether this should be an ethical requirement. In this session, Seema K. Shah, J.D. offered insight into the debate, including what reasonable availability entails. Researchers who want to develop products that make a difference to people in resource-limited areas face many barriers in getting their products to the people who need them. What constitutes reasonable attempts to overcome existing barriers?

- *Common Statistical Errors in the Design and Analysis of Clinical Trials – June 26, 2013*. Michael Proschan, Ph.D. presented case studies of errors made in the design and analysis of clinical trials. Investigators could have identified some of the errors by thinking about basic elements of the scientific method, while other errors were more subtle. Participants learned how to recognize potential errors in clinical trial design in time to avoid them, mitigate the damage if errors were not caught in time, and critically evaluate clinical trial manuscripts in the literature.

- *The Development of Training for Data Monitoring Board Members – September 26, 2013*. As stewards of clinical trials, DSMBs protect participant safety and ensure trial credibility and integrity. To prepare new or inexperienced DSMB members for these responsibilities, NIAID has developed three publicly available training modules. Attendees were given an overview of these resources and their intended audience in this session. The presenters also briefed the audience on DSMBs and applicable regulatory requirements.

  Total enrollment in these courses was **185** staff members.

- *Inclusion Policy-Warning: Curves Ahead – February 4, 2014.* NIAID staff participated in this training module, which was open to all NIH staff. The module addressed policies and procedures for inclusion in clinical research based on sex/gender, race, and ethnicity, and reviewed the research that is subject to the policy. Upcoming changes resulting from re-engineering efforts and the rollout of a new eRA module in 2014 were also discussed.

III. Analysis and Interpretation of Data

Data tables for FYs 2013 and 2014 were produced using the current NIH population tracking system. This database is the centralized module for storing and reporting data for the NIH progress reports. Data for FY 2013 and FY 2014 are shown in Tables 1 through 6. The introduction of the 1997 OMB reporting format, which distinguishes race and

ethnicity, precludes full aggregation of the data reported in one year. Protocols that used the newer OMB 1997 standard are reported separately from those that used the 1977 OMB standard. In FY 2013 and FY 2014, only two protocols used the old reporting system.

A. Enrollment Data for FY 2013 and FY 2014 – All Extramural NIAID Protocols

Tables 1 and 2, which summarize enrollment data for extramural research protocols reported in FY 2013 and FY 2014, respectively, illustrate the commitment of NIAID grantees to the inclusion of women and minorities and their subpopulations in NIAID clinical research projects. The combined aggregate data, using the two reporting standards show that 298,862 women enrolled as research participants in FY 2013, constituting 47/50%* percent of the total enrollment, and 411,117 women enrolled as research participants in FY 2014, constituting 47/51% percent of the total enrollment.

*The two values reflect aggregate data from trials that used respectively the old or the new reporting standard that includes ethnicity as a reporting category distinct from race.

B. Enrollment Data for FY 2013 and FY 2014 NIAID Phase III Clinical Trials

Aggregate enrollment data for NIAID extramural Phase III protocols reported in FY 2014 (Table 4) show that a greater percentage of women and most minority populations enrolled in trials compared to FY 2013(Table 3). In FY 2013 and FY 2014, women comprised 35 percent (1,406) and 46 percent (9,682), respectively, of all enrollees in Phase III clinical trials. These data for FY 2013 and FY 2014 represent a total of 4 and 12 protocols respectively, with participants totaling 25,007 compared to aggregate enrollment data for all extramural trials which totaled 1,423,015 participants in 1,507 trials in FY 2013 and FY 2014 combined.

C. Enrollment Data for FY 2013 and FY 2014 NIAID Intramural Research Protocols

Aggregate enrollment data for NIAID Intramural Research Protocols reported in FY 2014 (Table 6) show that a greater percentage of women and some minority populations enrolled in trials compared to FY 2013 (Table 5). In FY 2013 and FY 2014, women comprised 45 percent (27,084) and 47 percent (26,460), respectively, of all enrollees in Intramural Research Protocols. NIAID sponsored 184 Intramural Research Protocols in FY 2013, and 190 protocols in FY 2014.

Attachment 1

Copy of NIAID Grants Management Program policy note relating to programmatic oversight required for clinical research grant applications.

Programmatic Oversight of Clinical Research – What is required

Human Subjects Training Certification –

The NIH requires that a letter be submitted for all competing and noncompeting applications that include the names of the key personnel who are responsible for the design and conduct of the study; the title of the education program completed by each named personnel plus a one sentence description of the program. This letter must be signed by the principal investigator and co-signed by an institution official.

Link - http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

Responsibility – The Program Official should review the letter submitted and compare it to the list of key personnel in the application to determine if it is complete, as well as review the type of course described to ensure its adequacy.

NIAID Review Process Prior to Study Initiation –

Prior to patient accrual/participant enrollment, the grantee must provide (as applicable) for review and approval by the NIAID:

- Data and Safety Monitoring Board organization and responsibilities including a description of the Board, its operating procedures, roster and CV from all members.
- Copy of the clinical research protocol including details of the study design, proposed interventions, patient eligibility and exclusion criteria.
- A plan for the management of side effects.
- Procedures for assessing and reporting adverse events.
- A site monitoring plan.
- Copy of informed consent document.
- Document of IRB approval

Link – www.niaid.nih.gov/ncn/pdf/clinterm.pdf

Responsibility – NIAID program staff comments must be forwarded to the grantee within three weeks of receipt of the above information.

Required Reporting –

The NIAID is required to report the number and demographics of participants enrolled in NIAID-supported studies. For clinical trials, the grantee must complete a table showing cumulative accrual information for each clinical trial protocol semi-annually. For clinical studies, yearly submission of the table with the noncompetitive grant renewal is required.

Link – www.niaid.nih.gov/ncn/pdf/clinterm.pdf

Responsibility – For clinical trials, ensure that this table is received six months after enrollment opens and each six months thereafter. For clinical studies, confirm that this table is included in the non-competing application.

Time-sensitive notification –

Grantees are responsible for informing the Program Official of all major changes in the status of on-going protocols including:

- All amendments to the protocol.
- Termination of the protocol.
- Temporary suspension of the protocol.
- Any change in informed consent or IRB approval status.
- Temporary suspension or permanent termination of patient accrual.
- Any other problems or issues that could affect the human subjects in the studies.

Grantees are responsible for notifying the Program Officer of these changes within three working days by email, followed by a signed letter cosigned by the PI and institutional business official detailing the change of status notification to or from the local IRB.

Link – www.niaid.nih.gov/ncn/pdf/clinterm.pdf

Responsibility – In cases of specific problems or issues, the Program Official must contact the grantee within 10 working days (email or fax if acceptable) followed by an official letter to the Principal Investigator with a copy to the institutional business official within 30 days to discuss appropriate actions to be taken.

Inclusion of Woman and Minorities (Gender coding) –

Reviewers will evaluate each application to determine whether the grantee has proposed an acceptable plan.

Link – http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html

Responsibility – If the application is coded "U" for unacceptable (**BAR** to funding), the Program Official should request a revised plan from the grantee. If deemed acceptable, the Program Official should notify the Grants Management Specialist and forward a copy of the approved plan for the official file. The Grants Management Specialist will change the code in the system prior to funding of the award.

Inclusion of Children (coding) –

NIH requires that children (individuals under 21) must be included in all human subjects' research, conducted and supported by the NIH, unless there are specific and ethical reasons not to include them. If children will be excluded from the proposed research, the application must present an acceptable justification for the exclusion.

Link – http://grants.nih.gov/grants/guide/notice-files/not98-024.html

Responsibility - If the application is coded "U" for unacceptable (**BAR** to funding), the Program Official should request a revised plan from the grantee. If deemed acceptable, the Program Official should notify the Grants Management Specialist and forward a copy of the approved plan for the official file. The Grants Management Specialist will change the code in the system prior to funding of the award.

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

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards **Number of Protocols with Enrollment Data: 1**

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian / Pacific Islander	Hispanic	White	* More Than One Race	Unknown / Other	Total
Female	0	0	1		0	6		0	7
	0%	0%	14.29%		0%	85.71%		0%	46.67%
Male	0	2	0		1	5		0	8
	0%	25%	0%		12.5%	62.5%		0%	53.33%
Unknown	0	0	0		0	0		0	0
									0%
Total	0	2	1		1	11		0	15
	0%	13.33%	6.67%		6.67%	73.33%		0%	100%

* 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: 681**

	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	2,094	84,928	92,126	1,314	71,351	8,438	38,604	298,855	197,449	86,591	14,815	298,855
	0.7%	28.42%	30.83%	0.44%	23.87%	2.82%	12.92%	50.21%	66.07%	28.97%	4.96%	50.21%
Male	1,841	90,986	97,874	1,165	74,834	5,559	12,902	285,161	220,361	54,950	9,850	285,161
	0.65%	31.91%	34.32%	0.41%	26.24%	1.95%	4.52%	47.91%	77.28%	19.27%	3.45%	47.91%
Unknown	43	231	409	11	2,321	2,171	6,039	11,225	3,788	708	6,729	11,225
	0.38%	2.06%	3.64%	0.1%	20.68%	19.34%	53.8%	1.89%	33.75%	6.31%	59.95%	1.89%
Total	3,978	176,145	190,409	2,490	148,506	16,168	57,545	595,241	421,598	142,249	31,394	595,241
	0.67%	29.59%	31.99%	0.42%	24.95%	2.72%	9.67%	100%	70.83%	23.9%	5.27%	100%

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

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards **Number of Protocols with Enrollment Data: 1**

	American Indian/ Alaska Native	Asian	Black or African American	* Hawaiian / Pacific Islander	Hispanic	White	* More Than One Race	Unknown / Other	Total
Female	0	0	1		0	6		0	7
	0%	0%	14.29%		0%	85.71%		0%	46.67%
Male	0	2	0		1	5		0	7
	0%	28.57%	0%		14.29%	71.43%		0%	46.67%
Unknown	0	0	0		0	0		0	0
									0%
Total	0	2	1		1	11		0	15
	0%	13.33%	6.67%		6.67%	73.33%		0%	100%

* 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: 825**

	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	6,885	109,537	167,717	4,091	72,225	10,132	40,523	411,110	319,639	70,798	20,673	411,110
	1.67%	26.64%	40.8%	1%	17.57%	2.46%	9.86%	51.21%	77.75%	17.22%	5.03%	51.21%
Male	2,724	118,683	157,426	4,240	83,893	8,423	13,376	388,765	333,457	36,482	18,826	388,765
	0.7%	30.53%	40.49%	1.09%	21.58%	2.17%	3.44%	48.43%	85.77%	9.38%	4.84%	48.43%
Unknown	5	165	875	4	46	64	1,703	2,862	798	229	1,835	2,862
	0.17%	5.77%	30.57%	0.14%	1.61%	2.24%	59.5%	0.36%	27.88%	8%	64.12%	0.36%
Total	9,614	228,385	326,018	8,335	156,164	18,619	55,602	802,737	653,894	107,509	41,334	802,737
	1.2%	28.45%	40.61%	1.04%	19.45%	2.32%	6.93%	100%	81.46%	13.39%	5.15%	100%

Table 3: FY 2013 Aggregate Enrollment Data for Extramural Phase III Research Protocols

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

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 the1997 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	0	71	1,109	0	143	1	82	1,406	876	530	0	1,406
	0%	5.05%	78.88%	0%	10.17%	0.07%	5.83%	35.38%	62.3%	37.7%	0%	35.38%
Male	0	156	462	0	1,502	0	448	2,568	2,189	378	1	2,568
	0	6.07%	17.99%	0%	58.49%	0%	17.45%	64.62%	85.24%	14.72%	0.04%	64.62%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
								0%				0%
Total	0	227	1,571	0	1,645	1	530	3,974	3,065	908	1	3,974
	0%	5.71%	39.53%	0%	41.39%	0.03%	13.34%	100%	77.13%	22.85%	0.03%	100%

Table 4: FY 2014 Aggregate Enrollment Data for Extramural Phase III Research Protocols

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

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 the1997 OMB Standard.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards **Number of Protocols with Enrollment Data: 825**

	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	4	747	7,441	0	675	152	663	9,682	6,059	739	2,884	9,682
	0.04%	7.72%	76.85%	0%	6.97%	1.57%	6.85%	46.03%	62.58%	7.63%	29.79%	46.03%
Male	20	1,215	4,171	13	3,578	179	2,175	11,351	6,922	2,923	1,506	11,351
	0.18%	10.7%	36.75%	0.11%	31.52%	1.58%	19.16%	53.97%	60.98%	25.75%	13.27%	53.97%
Unknown	0	0	0	0	0	0	0	0	0	0	0	0
								0%				0%
Total	24	1,962	11,612	13	4,253	331	2,838	21,033	12,981	3,662	4,390	21,033
	0.11%	9.33%	55.21%	0.06%	20.22%	1.57%	13.49%	100%	61.72%	17.41%	20.87%	100%

Table 5: FY 2013 Aggregate Enrollment Data for Intramural Research Protocols For On-Site and Off-Site Combined

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

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 the1997 OMB Standard.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards **Number of Protocols with Enrollment Data: 184**

	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	20	2.191	13,162	14	6,434	131	5,132	27,084	24,147	608	2,329	27,084
	0.07%	8.09%	48.6%	0.05%	23.76%	0.48%	18.95%	45.41%	89.16%	2.24%	8.6%	45.41%
Male	29	3,599	11,147	18	9,415	198	8,090	32,496	28,424	1,257	2,815	32,496
	0.09%	11.08%	34.3%	0.06%	28.97%	0.61%	24.9%	54.49%	87.47%	3.87%	8.66%	54.49%
Unknown	0	2	4	0	1	1	52	60	6	0	54	60
	0%	3.33%	6.67%	0%	1.67%	1.67%	86.67%	0.1%	10%	0%	90%	0.1%
Total	49	5,792	24,313	32	15,850	330	13,274	59,640	52,577	1,865	5,198	59,640
	0.08%	9.71%	40.77%	0.05%	26.58%	0.55%	22.26%	100%	88.16%	3.13%	8.72%	100%

Table 6: FY 2014 Aggregate Enrollment Data for Intramural Research Protocols For On-Site and Off-Site Combined

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

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 the1997 OMB Standard.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards **Number of Protocols with Enrollment Data: 190**

	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	29	2,195	13,287	14	6,189	152	4,594	26,460	24,935	640	885	26,460
	0.11%	8.3%	50.22%	0.05%	23.39%	0.57%	17.36%	46.47%	94.24%	2.42%	3.34%	46.47%
Male	29	3,714	10,637	20	8,893	222	6,905	30,420	28,048	1,298	1,074	30,420
	0.1%	12.21%	34.97%	0.07%	29.23%	0.73%	22.7%	53.43%	92.2%	4.27%	3.53%	53.43%
Unknown	0	0	3	0	1	1	52	57	5	0	52	57
	0%	0%	5.26%	0%	1.75%	1.75%	91.23%	0.1%	8.77%	0%	91.23%	0.1%
Total	58	5,909	23,927	34	15,083	375	11,551	56,9367	52,988	1,938	2,011	56,937
	0.1%	10.38%	42.02%	0.06%	26.49%	0.66%	20.29%	100%	93.06%	3.4%	3.53%	100%