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2013 BIENNIAL ADVISORY COUNCIL REPORT CERTIFYING COMPLIANCE WITH THE NIH POLICY ON INCLUSION GUIDELINES

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NATIONAL HUMAN GENOME RESEARCH INSTITUTE

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Background

NIH mandates that women and members of minority groups and their subpopulations be included in all NIH-funded clinical research, 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. Exclusion under other circumstances may be made by the Director, NIH, upon recommendation of an Institute/Center Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except where the study would duplicate data from other sources. Women of childbearing potential should not routinely be excluded from participation in clinical research. The policy applies to research subjects of all ages in all NIH-funded clinical research studies.

Clinical research is defined 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. It includes:
   - mechanisms of human disease
   - therapeutic interventions
   - clinical trials
   - development of new technologies
2. Epidemiological and behavioral studies.
3. Outcomes research and health services research.

Studies falling under 45 CFR part 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.

Not all studies involving human participants must be tracked. Most training, fellowship and career development awards do not require tracking. In addition, certain types of grants can be coded as exempt from tracking when the grant checklist is completed. Tracking data are collected in two forms: proposed or "target" data as described in an investigator's grant application and actual or "enrollment" data based on participants actually recruited and examined in the course of the study.

Every two years, each NIH Institutional advisory council is required to review the aggregate data on the actual enrollment of participants in research supported by the Institute to ensure that the Institute: 1) is in compliance with the mandate for appropriate gender and minority inclusion and 2) has in place adequate procedures to ensure these inclusion levels are monitored and maintained.

The following report discusses the aggregate enrollment data reported in FY2011 and 2012 for the NHGRI Division of Extramural Research (DER) and the Office of Population Genomics (OPG) in the NHGRI Director's Office[1] and for the NHGRI Division of Intramural Research (DIR). (Note that DER and OPG have since been reorganized within the Extramural Research Program, but they were separate entities through FY2012.) This report also includes the procedures followed by NHGRI staff to ensure appropriate gender and minority inclusion in all NHGRI research. The information

[1] For the remainder of this report, these two units will be described as "extramural research."

contained in this report was discussed at the February 11-12, 2013 meeting of the National Advisory Council on Human Genome Research (NACHGR).

Discussion of Data Reported in FY 2011 and FY 2012

The clinical research studies funded by NHGRI tend to fall into a few basic categories: 1) qualitative studies that include a small number of research participants in focus group or structured interview settings; 2) larger phone, paper, or internet-based studies that survey the attitudes, beliefs or practices of either discrete populations (e.g. health professionals, genomic researchers, IRB chairs, individuals who have undergone genetic testing, disease/disability communities, minority communities) or the general population; and 3) studies that utilize existing or prospectively identified cohorts for statistical analysis, prospective linkage/gene identification, or genome-wide associations. A number of the qualitative, survey, and genetic testing studies are limited to specific populations, such as health or research professionals or individuals who have undergone genetic testing for specific diseases or conditions. These discrete target populations may not be always racially or ethnically diverse. As a result, the demographic breakdown of NHGRI research enrollment may be slightly less representative than the US population, depending on the types of studies that are active in a given year. In addition, there are a small number of DIR studies with large enrollment numbers that report a high percentage of participants with "unknown" race, ethnicity, and gender. These studies are using existing coded data to perform statistical analyses and methods development, which do not include demographic data. We excluded those data from this report. It should also be noted that NHGRI does not support any Phase III clinical trials.

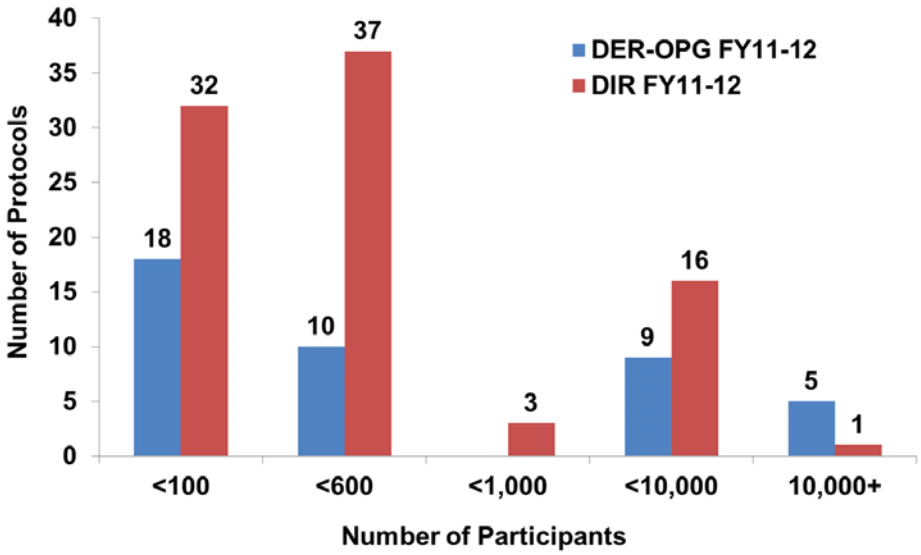
Table 1 shows the number of protocols and actual enrollment during FY2011-FY2012. There were 5 extramural and 82 intramural research protocols in both FY2011 and FY2012. In 2012, cumulative numbers of enrollment were recorded for those protocols. Therefore, the total number of protocols and total number of participants during 2011 and 2012 were not the sum of these numbers in the two individual years. In this biennial report, we preferred not to break down the numbers separately for FY2011 and FY2012.

Table 1. Number of Protocols and Actual Enrollment

		DER-OPG*	DIR	Total
FY2011	Number of Protocols	24	88	112
	Number of Participants	209,127	98,923	308,050
FY2012	Number of Protocols	23	83	106
	Number of Participants	61,339	91,068	152,407
Both Years	Number of Protocols	5	82	87
	Number of Participants	405	84,501	84,906
FY2011-FY2012	Number of Protocols	42	89	131
	Number of Participants	270,061	105,490	375,551

* Former Division of Extramural Research and Office of Population Genomics

Figure 1. Size of Study Enrollment



Extramural Research (DER and OPG)

In FY 2011-FY12, 270,061 individuals were enrolled in 42 ongoing extramural research protocols (Table 1). The sample size for these protocols ranged from 5 to 67,124; 18 protocols had a sample size less than 100, 10 protocols had a sample size of 100-600, 9 protocols had a sample size of 1,000-10,000, and 5 protocols had a sample size greater than 10,000 (Figure 1).

Table 2 presents FY2011-FY2012 actual enrollment by race, ethnicity and gender. Among the 270,061 enrolled individuals, there were 53.6% White, 19.2% Black/African American (Bl/AA), 17.8% Asian, 3.0% American Indian/Alaskan Native (AI/AN), 4.3% Hawaiian and Pacific Islanders (Haw & Pac), 0.3% reported identification of more than one race, and 1.7% had no racial identification reported. Comparing the racial distribution of FY2011-FY2012 with the distribution of FY2010 (no Extramural Research data in FY2009), the proportion of minority participants increased for Asians from 7.2% to 17.8%, for Haw& Pac from 1.8% to 4.3%, and for Bl/AA from 18.6% to 19.2%. The ethnic breakdown of the participants enrolled in studies reported in FY2011-FY2012 was 82.5% Not Hispanic (Not Hisp), 15.1% Hispanic/Latino (Hisp/Lat), and 2.4% unknown (Unk). The proportion of Hisp/Lat slightly increased from FY2010 (12.4%) to FY2011-2012 (15.5%). The gender breakdown of these participants was 61.2% female, 37.9% male, and 0.9% unknown.

Table 2. FY2011-FY2012 Extramural Research Actual Enrollment by Race, Ethnicity and Gender

	Race							
	White	**Bl/AA**	**Asian**	**Haw & Pac**	**AI/AN**	**>1 Race**	**Unk**	**Total**
n	144,796	51,961	48,047	11,666	8,184	834	4,573	270,061
%	53.6	19.2	17.8	4.3	3.0	0.3	1.7	100.0

	Ethnicity			
	Not Hisp	**Hisp /Lat**	**Unk**	**Total**
n	222,847	40,802	6,412	270,061
%	82.5	15.1	2.4	100.0

	Gender			
	Female	**Male**	**Unk**	**Total**
n	165,193	102,385	2,483	270,061
%	61.2	37.9	0.9	100.0

Intramural Research

In FY 2011-FY2012, there were 105,490 research participants in 89 NHGRI intramural research protocols (Table 1). The sample size for these 89 protocols ranged from 1 to 32,450; sample size was less than 100 in 32 protocols, 100-600 in 37 protocols, 600-1,000 in 3 protocols, 1,000-10,000 in 9 protocols, and greater than 10,000 in one protocol.

The distribution of race, ethnicity and gender is shown in Table 3. Among the participants, 78.4% were White, 8.2% Black/African American, 7.9% Asian, 0.1% American Indian/Alaskan Native, 3.5% identified themselves as more than one race, and 0.03% were Hawaiian/Pacific Islanders. No racial identification was reported for approximately 1.9% of the research participants. The ethnic breakdown of these participants was 88.2% non-Hispanic, 4.5% Hispanic, and 7.3% unknown. The gender breakdown was 46.2% female, 45.6% male and 8.2% unknown.

Table 3. FY2011-FY2012 Intramural Research Actual Enrollment by Race, Ethnicity and Gender

Race

	White	Bl/AA	Asian	Haw & Pac	Al/AN	>1 Race	Unk	Total
n	82,712	8,695	8,291	33	158	3,643	1,958	105,490
%	78.4	8.2	7.9	0.03	0.1	3.5	1.9	100.0

Ethnicity

	Not Hisp	Hisp/Lat	Unk	Total
n	93,039	4733	7718	105,490
%	88.2	4.5	7.3	100.0

Gender

	Female	Male	Unk	Total
n	48,707	48,133	8,650	105,490
%	46.2	45.6	8.2	100.0

NHGRI Data Compared to 2012 NIH Aggregate Data and 2010 US Census Data

The Table 4 provides a comparison among: (1) the NHGRI actual enrollments in FY2010 and FY 2011-2012; (2) the aggregate actual enrollment data reported for all of NIH; and (3) and the demographic breakdown from the 2010 US Census.

In FY11-12, NHGRI improved enrollment of minorities and reduced proportions of unknown race, ethnicity and gender. Notably, Black/African American increased from 13.4% in FY10 to 17.7% in FY11-12; Hispanics/Latinos increased from 8.7% to 12.1%. Asia and Hawaii/Pacific Island participants were also increased comparing FY10 vs. FY11-12: for Asians 4.1% vs. 13.7%; for Hawaiian/Pacific Islanders 1.0% vs. 3.2%. The unknown category was decreased from 15.8% in FY10 to 1.7% in FY11-12 for race; from 15.6% to 3.8% for ethnicity; and from 11.9% to 3.0% for gender.

Comparing the NHGRI FY11-12 enrollment data with the NIH FY12 data, NHGRI had considerably fewer individuals reported unknown for race, ethnicity and gender than NIH: for race 1.7% vs. 21.6%; for ethnicity 3.8% vs. 24.5%, and for gender 3.0% vs. 9.6%. The NHGRI figures were higher than the NIH in the inclusion of Black/African Americans (17.7% vs. 11.1%), Asians (13.7% vs. 6.9%), Hawaiians/Pacific Islanders (3.2% vs. 0.4%), and Hispanics (12.1 % vs. 8.4%). It should be pointed out that the race, ethnicity and gender difference between NHGRI and NIH enrollment might be due to the significantly higher amount of unknowns in those categories in the NIH data.

The distribution of NHGRI enrolled research participants in FY11-12 was more diverse than the 2010 US Census. Comparing the FY11-12 NHGRI data with the 2010 US Census, NHGRI studies enrolled high proportions of Black/African Americans (17.7% vs. 12.6%), Asian (13.7% vs. 4.8%), Hawaiians/Pacific Islanders (3.2% vs. 0.2%) and a low proportion of unknown race (1.7% vs. 6.2%).

The NHGRI studies also enrolled a slightly higher proportion of female participants in FY11-12 (57.0%) as compared with the 2010 US Census data (50.8%).

Table 4. Comparison with 2012 NIH Aggregate Data and 2010 US Census Data

Category	2010 NHGRI	2011-12 NHGRI	2012 NIH	2010 US Census
White (%)	60.8	60.3	57.1	72.4
Black/African American (%)	13.4	17.7	11.1	12.6
Asian (%)	4.1	13.7	6.9	4.8
Hawaiian/Pacific Islander (%)	1.0	3.2	0.4	0.2
American Indian/Alaska Native (%)	3.4	2.2	0.8	0.9
>1 Race (%)	1.6	1.2	2.2	2.9
Unknown (%)	15.8	1.7	21.6	6.2
Not Hispanic (%)	75.7	84.1	67.1	83.7
Hispanic/Latino (%)	8.7	12.1	8.4	16.3
Unknown (%)	15.6	3.8	24.5	
Female (%)	53.4	57.0	52.3	50.8
Male (%)	34.7	40.1	38.1	49.2
Unknown (%)	11.9	3.0	9.6	
Total	**245,563**	**375,551**	**15,077,760**	**308,745,538**

Summary

- NHGRI improved enrollment of minority and female participants in FY11-FY12 compared with FY10
- NHGRI had higher proportions of minority and female participants and lower proportions of unknown race, ethnicity, and gender compared with NIH in FY11-FY12
- NHGRI had a more diverse group of enrolled research participants compared with the 2010 US census

Staff Responsibilities and Procedures to Ensure Compliance with Inclusion Guidelines

Extramural Research

- Extramural conducts an annual review of NHGRI's inclusion efforts and provides data to the NIH Office of Research on Women's Health. During the FY 2011 and 2012 reporting period, Dr. Mark Guyer, Director of the Division of Extramural Research oversaw the process and provided leadership. He was assisted in this task by Ms. Joy Boyer, Dr. Rongling Li and Dr.

Bettie Graham and the Population Tracking Approvers, Mr. Ian Marpuri and Ms. Carolyn Taylor.

- The Extramural Research Program Directors document enrollment targets and progress on enrollment of human participants. If the information is missing or incomplete, the Program Director contacts the Principal Investigator and notifies her/him of the need to provide the necessary documentation. After ensuring that the data in the target/enrollment form are correct, the document is given to the extramural staff members that input the information into the Population Tracking Database. The extramural assistants key in the data. Ms. Carolyn Taylor and Mr. Ian Marpuri review, approve, and sign-off on the data in the database. A document providing detailed guidance on the roles and responsibilities of Program Directors in implementing the inclusion process is provided in the Appendix. All NHGRI extramural staff members are provided with these guidelines and a presentation and discussion of the guidelines is provided at regularly scheduled staff meetings as needed.

- Scientific Review Officers (SROs) read all applications and proposals and note if clinical research is being proposed, and if the application is in compliance with the NIH policy on the Inclusion of Women and Minorities.

- SROs send "NIH Instructions to Reviewers for Evaluating Research Involving Human Subjects in Grant and Cooperative Agreement Applications" (http://grants.nih.gov/grants/peer/hs_review_inst.pdf) to scientists/clinicians/scholars that serve as peer reviewers on Scientific Review Panels to ensure that they are up to date on all human subject policy issues when evaluating applications.

- The Scientific Review Panels evaluate each application dealing with human participants during the initial review to determine if it is in compliance with the Inclusion Policy. The evaluation results are noted on the Summary Statement. The reviewers are instructed to include compliance with the inclusion policy when assigning an impact score.

- SROs document the gender and minority codes in summary statements.

- In cases where the Scientific Review Panel determines that a study is not in compliance or the applicant has not addressed the requirements in the application, a code is placed in the system that bars funding. If an award is to be made, the bar must be lifted, and documentation for the grounds on which the bar was lifted must be included in the official grant file. In general, the Grants Management Specialist will detect the bar and refer the issue to the Program Director. The Program Director must justify the lifting of the bar. This usually entails contacting the applicant institution and receiving additional information for inclusion in the official file. It is the responsibility of the Program Director to work with the applicant and her/his institution to comply with the NIH regulations. A document providing guidance is included in the appendix.

- Once the Program Director is assured that all the concerns have been addressed adequately, the Grants Management Specialist can request that the bar be lifted so that the award can be made.

- The non-competing renewal application (Type 5) is reviewed to determine how well the recruitment is going. If a Program Director determines that the recruitment is behind schedule, s/he will contact the grantee to determine what measures can be taken to ensure that the recruitment goals are met within the specified time.

- NHGRI arranges for staff to participate in NIH-wide and institute training sessions on population tracking.

Intramural Research

- The "Standards for Clinical Research within the NIH Intramural Program" found at http://www.cc.nih.gov/ccc/clinicalresearch/index.html states: "All clinical PIs are required to take an overview training course, or equivalent, on the roles and responsibilities of clinical investigators". The Clinical Center web site http://www.cc.nih.gov/researchers/training.shtml describes the general and degree training programs in clinical research that are available. The "Introduction to the Principles and Practice of Clinical Research" is part of the core curriculum in clinical research training, and is required of all principal investigators before they can submit a protocol for review by an NIH Instutional Review Board. All new clinical fellows are oriented as to the clinical research training programs that are available shortly after they arrive at NIH.

- In addition, as stated on the Office of Human Subjects Research Protections (OHSRP) web site, "All new research staff must complete training before participating on a protocol submitted to an NIH IRB for review." Specific training requirements for the conduct of clinical, epidiomological, behavioral, and basic research involving human subjects can be found at https://federation.nih.gov/ohsr/nih/investigator-training.php. The human research training requirements are in the process of being revised and updated by OHSRP; however, all principal investigators were required to complete OHSRP training for the conduct of the FY 2011-2012 protocols covered in this report.

- The intramural scientists who are conducting clinical studies submit their clinical research protocols to the Intramural Institutional Review Board (IRB) for evaluation. Only protocols that ensure the health and safety of human participants and that meet the NIH standards for appropriate inclusion of women and racial/ethnic minorities are approved. Specifically, investigators submit to the IRB a detailed description of their recruitment strategy for each protocol, including efforts to include under-represented minorities. In addition, investigators project their targeted/planned enrollment, with anticipated numbers of participants in gender, racial, and ethnic categories. Continuing review applications that include ongoing gender and minority enrollment forms are reviewed by the IRB at least annually to ensure compliance. Enrollment data are submitted annually to the Clinical Center for inclusion in their central database. NHGRI receives this data on a biennial basis for reporting purposes.

Appendix

NATIONAL HUMAN GENOME RESEARCH INSTITUTE (NHGRI)
STAFF GUIDANCE FOR INCLUSION OF POPULATIONS IN NHGRI-SUPPORTED RESEARCH GRANTS

The purpose of this document is to provide guidelines for NHGRI staff in tracking and reporting inclusion of human populations in NHGRI-funded studies.

Reporting of the Extramural Research Program (ERP) projects depends upon staff reviewing applications prior to funding to determine whether the grant is a candidate for population tracking and ensuring that the targeted/planned and inclusion enrollment data are accurate. The Type 5 applications are reviewed to ensure that inclusion efforts are consistent with the goals of the grant and that the data submitted by the PIs are accurate.

When projects that involve human participants are proposed or awarded, there are several points along the continuum from pre-application guidance to final progress report in which staff should be actively involved:

- Pre-Application Consultation.

  When staff members are providing guidance to prospective applicants who plan to conduct studies on human participants, Principal Investigators should be apprised of the NHGRI requirement. In some proposed studies, it may not be appropriate to include certain populations or both genders; in such cases, there must be a strong justification for exclusion.

- Prior to Award.

  There may be instances where an application has received a fundable score, but there is clear evidence that additional populations can be added to expand the diversity of the data set. In such cases, staff may discuss this with the Principal Investigator who may then request supplemental funding, if appropriate, to support the expansion,

  If a study receives a fundable priority score and the study section has not flagged the application for study design concerns, but staff believes that the research can be improved or enhanced by adding additional populations, staff may take the application to Council with the recommendation that it be approve for high program priority (and funding) only on the condition that the additional populations be included.

- Award of Competing Applications.

  Prior to making an award, staff must determine whether the recruitment/enrollment of human participants or the addition of new data on already-recruited participants will be tracked and indicate this decision on the grant checklist through the program module (PGM) of IMPAC II. Staff should use the guidelines provided by the Office of the Director, NIH, (see definition under “Background” of this document and list of exemption codes in http://impacii.nih.gov/popdoc/Tracking_Exception_codes_04-21-04.pdf.) In addition, as noted above, studies that use already recruited populations but for which new data (such as genotyping data) are generated are also tracked.

- Changes in Human Subject Research Post Award

  Any change in research procedures in an active award that would result in an increased risk to human subjects will require prior NIH approval before implementation (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-129.html).

The institution must submit a separate request to the GMO of the funding IC no later than 30 days before the proposed change. The Program Director must review the request and it must be approved by the PD's supervisor before the change is implemented.

If program staff members are unsure of whether a project should be tracked, a small subcommittee, consisting of a representative from the ELSI Program and the Office of Population Genomics will review the project with the Program Director and make a determination. The current representatives are: Ian Marpuri OPG and Carolyn Taylor for DER.

ROLES AND RESPONSIBILITIES:

- NHGRI staff will:

(a) Apprise potential applicants proposing research involving human subjects (including the collection of new data from previously recruited subjects) of NHGRI's requirement. If the proposed project is a candidate for population tracking, then staff should discuss inclusion options;

(b) Determine prior to Council whether additional populations would add value to the study and if so, discuss with the PI and propose a supplement to Council, if necessary;

(c) If appropriate, propose to Council that an application be designated High Programmatic Priority only on the condition that the study population is enhanced to meet NHGRI's requirement for support;

(d) Determine which grants need to be tracked in the population tracking database. If an exception code is warranted, indicate the code on the grant checklist so that it can be entered into IMPAC II (For more information see http://impacii.nih.gov/popdoc/Tracking_Exception_codes_04-21-04.pdf);

(e) Determine the enrollment status of the grant: 1) pending enrollment (P) means that target data has been provided, but enrollment of participants has not started; 2) open enrollment (O) means that enrollment has started but is not complete; and 3) closed enrollment (C) means enrollment is completed and no more participants will be recruited. Enrollment forms submitted before enrollment begins should indicate the status as "P" or pending. After enrollment starts the form should indicate the status as "O" or open. When enrollment is completed, the enrollment status on the form would be "C" or closed.

(f) If a project should be tracked but the protocol has not yet been developed and the target data is not available, indicate "ND" for protocol not developed on the target data form (this is sometimes the case with Center grants, or GWA studies that use existing samples);

(g) Review targeted/planned and inclusion tables for accuracy (all the numbers add up) and completeness (all the appropriate cells filled);

(h) Make sure that the "ethnic category: total of all subjects" equals the "racial category: total of all subjects";

(i) If the targeted/planned inclusion for the grant is not representative of the US population, provide a brief explanation on the target/planned form (e.g. condition being studied is most prevalent in individuals of a particular gender, race or ethnic group; or research participants are limited to members of a particular professional or community group which does not include representative gender or racial/ethnic diversity)

(j) If the target/planned gender and minority status of grant participants is unknown, provide a brief justification for this (e.g. study design limits ability to collect demographic data.)

(k) Contact the Principal Investigator if there are questions about the form(s) BEFORE giving it (them) to the extramural assistant;

(l) Ensure that each table is labeled properly and consistently (it is particularly important that the protocol titles on inclusion enrollment forms are consistent from year to year to ensure that duplicate protocols are not inadvertently created in the database.)

(m) Provide separate tables for foreign and domestic participants, defined by their place of residence. All foreign subjects in a given protocol can be lumped together and provided on a single tracking sheet, with the areas of residence that are included listed at the top of the sheet (an individual breakdown of participants by country of residence is not necessary).

(n) Determine how many different protocols are eligible for tracking, and give only the tables for these protocols to the extramural assistant;

(o) Ensure that the grant number, year, and PI name are on each protocol that is given to the extramural assistant; and

(p) Initial and date the form certifying that all of the above steps have been completed.

Summary of Program Staff duties:

1. Ensure that the proposed gender and minority inclusion plan is appropriate prior to funding.
2. Enter the correct tracking code and answer all appropriate questions on the grant checklist.
3. Ensure that the appropriate tracking form has been accurately completed by the PI *(Target forms are shorter and are provided at the beginning of the protocol, usually before enrollment has started. Inclusion forms are longer and are provided with each progress report after enrollment has started).*
4. Note the enrollment status of the protocol (P, O, C, or ND) on the tracking form and provide a justification if the inclusion data is not representative of the US population or if a significant number of research participants' gender/race/ethnicity is reported as unknown.
5. Ensure that the enrollment form includes the correct grant number, PI name and protocol title *(For grants with multiple protocols, it is critical that protocol titles are consistent between the target data form and all the subsequent enrollment forms!)*
6. Submit completed forms to the extramural assistant staff.

- Extramural Assistants will:

(a) Make a printed copy of the target/planning and inclusion forms by budget period.

(b) Discuss with NHGRI staff the list of protocols for inclusion/enrollment data to be sure that the protocols for targeted/planned enrollment match the protocols for inclusion enrollment; this must be done BEFORE the extramural assistant enters the data.

(c) Ensure that each protocol has been initialed BEFORE entering the data.

(d) Ask the NHGRI staff to resolve any discrepancies in target or planned/enrollment numbers, protocol labeling, number of protocols, etc.

(e) Provide the NHGRI approval officer (Carolyn Taylor and Ian Marpuri) with a copy of the forms for her approval in the population tracking database.

- NHGRI Approval Officer

Approval Officers must review and approve the data entered. If there are discrepancies, the extramural assistant must be contacted to resolve the discrepancies.

All Principal Investigators whose projects require population tracking will be sent a letter at the time of award to encourage them to submit data that are accurate and correct and to ensure that the protocol titles are consistent throughout the study.

TRAINING:

The number of protocols handled by NHGRI staff is small. Therefore, there is a need to have refresher sessions periodically as described below:

- An orientation will be provided for NHGRI staff about what types of projects should/should not be included in the population tracking database.

- As new DER and OPG staff are hired, the DER and OPG contacts should set up a training session to orient new staff to the requirements for population tracking.

- In November 2012, Meredith D. Temple-O'Connor,Ph.D., the NIH Inclusion Policy Officer, Office of the Director, NIH, had a training session with NHGRI staff to update them on the latest policies.