

**2015 Biennial Advisory Council Report Certifying
Compliance with Inclusion Guidelines
Eunice Kennedy Shriver National Institute of Child Health and Human Development**

I. Background/Overview

Mission Statement

The NICHD was established by President John F. Kennedy, with the support of congress, in 1962 to study the "complex process of human development from conception to old age." The mission of the NICHD is to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation.

Description of NICHD Portfolio.

In pursuit of its broad mission, the NICHD conducts and supports laboratory research, clinical trials, and epidemiological studies that explore health processes; examines the impact of disabilities, diseases, and variations on the lives of individuals; and sponsors training programs for scientists, health care providers, and researchers to ensure that NICHD research can continue. NICHD research programs incorporate the following concepts:

- **Events that happen prior to and throughout pregnancy, as well as during childhood, have a great impact on the health and well-being of children and adults.**
 - The Institute supports and conducts research to:
 - Advance knowledge of pregnancy, fetal development, and birth for developing strategies that prevent maternal, infant, and childhood mortality and morbidity;

- Identify and promote the prerequisites of optimal physical, mental, and behavioral growth and development through infancy, childhood, and adolescence; and
 - Contribute to the prevention of and treatment for intellectual and developmental disabilities.
- **Human growth and development is a life-long process that has many phases and functions.** Much of the research in this area focuses on cellular, molecular, and developmental biology to build understanding of the mechanisms and interactions that guide a single fertilized egg through its development into a multicellular, highly organized adult organism.
- **Learning about the reproductive health of women and men and educating people about reproductive practices is important to both individuals and societies.** Institute-supported basic, clinical, epidemiological, behavioral and social science research in the reproductive sciences seeks to:
 - Develop knowledge that enables women and men to overcome problems of infertility and to regulate their fertility in ways that are safe, effective, and acceptable for various population groups.
 - Understand the causes and consequences of reproductive behavior and population change.
- **Developing medical rehabilitation interventions can improve the health and well-being of people with disabilities.** Research in medical rehabilitation seeks to develop and improve techniques and technologies related to the quality of life and rehabilitation of individuals with physical, intellectual, and developmental disabilities resulting from diseases, disorders, injuries, or variations.

II. Strategies for Ensuring Compliance

Peer Review

NICHD's Scientific Review Branch (SRB) is responsible for a broad range of functions related to the review of grant applications for research and training and contract proposals for

research. The Branch also provides policy direction and coordination for planning and conducting initial scientific and technical merit reviews of applications for numerous types of grant applications, including:

- Program projects (P01s)
- Centers (P30s, U54s)
- Institutional training grants (T32s)
- Career development awards (various Ks)
- Conference grants (R13s)
- Small research grants (R03s)
- Multisite clinical trial (R01s)

Other mechanisms, such as fellowships (Fs), small business grants (SBIRs/STTRs), R21s, R01s and others are reviewed by the NIH Center for Scientific Review.

In addition, the SRB coordinates and conducts the review of grant applications for all mechanisms that are received by the NICHD in response to requests for applications (RFAs) or program announcements with referral (PARs), which are published with the aim of fostering work in a research area of particular relevance to the mission of the Institute. The Branch also manages the technical evaluation of contract proposals that arrive in response to requests for proposals (RFPs) issued by the Institute.

Procedures for Ensuring Compliance

The NICHD has implemented the following procedures to monitor the inclusion of women and minorities as subjects in research projects and to assure that the legislative requirement has been met:

- The procedures used by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) to implement NIH policy on the inclusion of woman and minorities in clinical research were presented to the National Advisory Child Health and Human Development (NACHHD) Council on January 22, 2015. Based on this review, The NACHHD Council certified NICHD compliance with the policy guidelines.

- Primary responsibility for implementation of the NIH inclusion policy resides with the Director, NIH, in collaboration with Directors of the NIH Institutes and Centers and various NIH Offices.
- Within NICHD, responsibility for direct oversight of inclusion requirements, including assuring that policy has been addressed, that institute staff and the research community are aware of and complying with policy updates, and that data entry and reporting are accurate and in compliance, has been consolidated and rests with the Office of Extramural Policy, NICHD.
- NICHD procedures to ensure compliance with the policy for tracking and inclusion of women and minorities include specific activities involving program, review, contracts management, grants management, support staff, and the Office of Extramural Policy. These staff members participate as appropriate throughout the process from pre-application through award, with continuing communication among the involved groups. The NICHD Office of Extramural Policy exercises oversight responsibilities for all of these activities. Specific activities include:
 - Communication by program staff with potential applicants in the pre-application stage to assure outreach and dissemination of policy requirements.
 - Administrative review of all grant applications and contract proposals by Scientific Review Officers (SROs) to assure accurate coding of applications for involvement of human subjects and identification of Phase III Clinical Trials prior to review. The SRO performs an administrative review of applications and proposals to assure that they have been accurately identified with respect to the involvement of human subjects and their clinical trial status (i.e., whether they are NIH-defined Phase III Clinical Trials). If the initial identification is erroneous, review staff assures that corrections are made in IMPAC II.
 - Peer review of the adequacy of the grant application or contract proposal with respect to meeting inclusion requirements. At the review group meeting, the SRO ensures that reviewers address the adequacy of inclusion plans, with both narrative comments and appropriate codes. The SRO directs special attention of reviewers to the requirements for Phase III Clinical Trials, assuring that the reviewers address the plans presented in the

application/proposal in the context of those requirements. The SRO intervenes, as appropriate, to assure that the codes assigned and comments made by the reviewers are reasonable with respect to the policy requirements.

- Following review, the assigned codes are entered into IMPAC II by review staff, with unacceptable codes leading to a bar-to-funding until acceptable plans are submitted, plans are approved by program staff, and the bar is removed by grants management. Overall, the Director of the NICHD Scientific Review Branch is responsible for monitoring and assuring compliance by review staff.
- Program staff interaction with investigators whose applications/proposals were deemed unacceptable with respect to inclusion requirements, working toward the development of acceptable inclusion plans. The NICHD Grants Management Branch has introduced a quality assurance checklist that requires program staff to verify a number of actions, including examination and approval of the target enrollment data, prior to making any new award.
- Upon receipt of an acceptable plan, communication between program staff and grants management or contracts management staff, who assure that the code is changed and funding proceeds.
- Review of annual progress reports (PHS Form 2590) by program staff to assure appropriate accrual and achievement of inclusion targets.
- Entry and approval of both target and actual enrollment data into the Population Tracking system. The Office of Extramural Policy coordinates and monitors this process, and maintains ongoing communication with program, contracts, grants management, and support staff to assure completeness and accuracy of data entered.

Training approaches

NICHD program, review, grants management, and contracts management staff are encouraged to participate in all NIH training opportunities relevant to the policies on inclusion; newly hired staff are required to have such training as soon as possible after assuming their position. Training opportunities are available live, via videocast, archived video, or computer-

based programs. The NICHD Office of Extramural Policy monitors participation and provides information about upcoming training opportunities.

The following are examples of formal NIH training related to the inclusion policy in which NICHD staff participates:

- NIH Core Training - Orientation to Extramural Activities
- Sex/Gender and Minority Inclusion in Clinical Research Staff Training (archived videocast available to staff)
- Human Subjects Update: A Symposium (archived videocast available to staff)
- Grants Policy Updates: Humans and Animals (archived videocast available to staff)
- Clinical Trials On Trial: Protecting Human Subjects of Clinical Research (archived videocast available to staff)
- Review and Approval of Newly Proposed Human Subjects Research in Active Awards (Delayed onset)
- Human Subjects Protections in Extramural R&D Grants and Contracts
- Human Subjects Protections – Proposed changes to the “Common Rule”
- Human Subjects Protections: Part I – Fundamentals of Human Subjects Protections for NIH Extramural Staff
- Human Subjects Protections: Part II – Using Existing Biospecimens in Research: Ethical and Regulatory Considerations
- Human Subjects Protections: Part III – Research Involving Vulnerable Subjects: Ethical and Regulatory Considerations

In addition to training opportunities offered by NIH, the institute is involved in continuous training and outreach efforts with staff and the research community. These efforts are developed, overseen, and monitored by the NICHD Office of Extramural Policy, which also serves as a resource for staff and the extramural community. These training and outreach efforts include:

- Three sessions outlining the new Inclusion Management System (IMS) were held for staff outlining: 1) Differences in Pop Tracking and IMS; 2) Roles and responsibilities of staff and grantees and; 3) How-to training for IMS program

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

Table A shows the level of compliance of grant applications submitted to NICHD as assessed during scientific peer review in 2013 and 2014. It can be seen that the vast majority of grant applications satisfactorily addressed the inclusion requirement. Applications that are deemed unsatisfactory with regard to inclusion receive an administrative code that results in a bar-to-funding and awards cannot be made unless the bar is lifted.

Table B shows the very small number of awards there had been a bar-to-funding because the application had an unsatisfactory inclusion plan. In order to lift a bar-to-funding, NICHD staff worked with the applicant to resolve any problems with regard to inclusion. This was done by either obtaining additional information about the inclusion plan from the applicant or revising the planned enrollment if necessary.

Tables 1, 2, 5, 6, 9 and 10 show aggregate enrollment figures for both extramural and intramural NICHD projects for FY2013 and FY2014, as described below.

[Please note that the NIH database generated additional tables (e.g., Tables 3,4, 7, 8) that are not shown in this report. Those additional tables displayed aggregate enrollment data for various subsets of studies. Although instructive, those additional tables did not alter the overall trends in terms of inclusion that are reported here.]

All Extramural research protocols

- For all extramural research protocols supported in FY 2013, NICHD enrolment data indicate that the majority of subjects enrolled were female (71.17%) as illustrated in Table 1. Only 1.09% of participants were unidentified with respect to gender. In FY 2014, the majority of participants again were female (56.57%) as illustrated in the Table 2. In FY 2014, there was a significant increase in the number of subjects that were not identified with respect to gender which changed the aggregate unknowns to 15.82% for that year. This increase was due to one

single large survey study conducted in India, where the approved study design precluded accurate identification by gender.

- With respect to minority inclusion in FY 2013, significant numbers of minority subjects were enrolled in NICHD extramural studies. Enrollment of Black or African American participants was 16.64%. In addition, where self-identification is requested in two separate questions, first for Hispanic or Latino ethnicity and then for race, it was found that 18.16% of subjects identified themselves as Hispanic or Latino. The significant representation of Asian participants (38.12%) is attributable to some large studies conducted in Asia. In FY 2014, significant inclusion of minorities continued. Enrollment of Black or African American participants was 16.44%. Inclusion of Hispanic/Latino participants was 13.39%, in 2014, and Asian enrollment was 56.57%.

NICHD Extramural Phase III Clinical Trials

- Phase III clinical trials show a similar pattern to the overall data in both FY2013 and FY2014. As illustrated in table 5 and 6 the majority of subjects reported were women (FY2013 - 219,197 out of 291,590, or approximately 75.17% and FY2014 – 196,094 out of 268,670, or approximately 72.99%). The relatively high number of Asian subjects during this period (60.26% and 65.07% in FY2013 and FY2014) was due to studies conducted in India and Pakistan through the Global Network for Women’s & Children’s Health during this time frame.

NICHD Intramural Research Protocols

- As illustrated in Table 9 the majority of subjects enrolled in NICHD intramural studies in FY2013 were women (79.05%). Of the 132,955 subjects enrolled in intramural studies, 43,277 (32.55%) identified themselves as Hispanic or Latino; 26,642 (approximately 20.04%) identified themselves as Black or African American; and 12,009 (approximately 9.03%) identified themselves as Asian.

- Table 10 illustrates that the majority of subjects enrolled in NICHD intramural studies in FY2014 were also women (108,934 out of 132,913, or approximately 85.52%). Of the 132,913 subjects enrolled in intramural studies, 43,906 (approximately 33.26%) identified themselves as

Hispanic or Latino; 26,176 (approximately 21.34%) identified themselves as Black or African American; and 12,327 (approximately 9.34%) identified themselves as Asian.

CONCLUSIONS

NICHD has strived to promote the objectives of the NIH inclusion policy, by implementing procedures to monitor and assure compliance with the legislative mandate and by providing appropriate training to staff. The NICHD research mission is quite broad and scientifically diverse; much of our research portfolio focuses on topics relevant to women's health, and a number of our clinical trials are targeted specifically towards women as subjects. Data from the peer review process (Table A) and the award process (Table B) demonstrate that our internal procedures have been effective in assuring compliance with the inclusion requirements. The aggregate enrollment data provide an overview of our research portfolio and clearly show substantial inclusion of women and minorities as subject in clinical research projects and clinical trials supported by NICHD. Not shown in these tables is the ongoing oversight of each individual project by NICHD staff to monitor the progress made in recruitment of subjects to reach the planned enrollment goals set forth in the original application and to provide guidance to investigators as needed. Even more important than the numerical data are the numerous contributions to scientific knowledge that will be generalizable to different populations, as shown by the representative grants and publications listed at the end of this report.

Table A. Level of Compliance with Inclusion Policy in New Extramural Grant Applications as Assessed During Scientific Peer Review
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Council Dates		Jan-13	May-13	Aug-13	Oct-13	Jan-14	May-14	Aug-14	Oct-14
Total Number of Applications Reviewed	(#)	1,452	1,661	389	1,387	1,566	1,670	340	1,369
Number of Applications with Human Subjects	(#)	947	1,025	54	917	988	969	22	892
Number (percent) of Applications approved by IRG as submitted	(#)	934	1,002	51	911	971	944	22	876
	(%)	98.63%	97.76%	94.44%	99.35%	98.48%	97.42%	100%	98.21%
Number (percent) of Applications with unacceptable <i>minority-only</i> inclusion	(#)	3	8	0	5	10	9	0	11
	(%)	0.32%	0.78%	0%	0.55%	1.01%	0.93%	0%	1.23%
Number (percent) of Applications with unacceptable <i>sex/gender-only</i> inclusion	(#)	4	4	3	1	2	3	0	1
	(%)	0.42%	0.39%	5.56%	0.11%	0.2%	0.31%	0%	0.11%
Number (percent) of Applications with both unacceptable <i>minority AND sex/gender</i> inclusion	(#)	6	11	0	0	3	13	0	4
	(%)	0.63%	1.07%	0%	0%	0.3%	1.34%	0%	0.45%
Total Number (percent) of Applications with unacceptable <i>minority</i> inclusion	(#)	9	19	0	5	13	22	0	15
	(%)	0.95%	1.85%	0%	0.55%	1.32%	2.27%	0%	1.68%
Total Number (percent) of Applications with unacceptable <i>sex/gender</i> inclusion	(#)	10	15	3	1	5	16	0	5
	(%)	1.06%	1.46%	5.56%	0.11%	0.51%	1.65%	0%	0.56%
Total Number (percent) of unacceptable Applications as submitted	(#)	13	23	3	6	15	25	0	16
	(%)	1.37%	2.24%	5.56%	0.65%	1.52%	2.58%	0%	1.79%

Table B. Extramural Research Awards: Bars-To-Funding and Resolutions
 EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Council Dates		Jan-13	May-13	Aug-13	Oct-13	Jan-14	May-14	Aug-14	Oct-14
Total number of awards	(#)	214	224	117	178	212	243	125	92
Number of awards Involving Human Subjects	(#)	114	133	4	117	129	130	3	59
Number (percent) of awards Involving Human Subjects that met the Inclusion requirements as submitted	(#)	114	130	4	117	129	128	3	59
	(%)	100%	98%	100%	100%	100%	98%	100%	100%
Number (percent) of awards where <i>minority-only</i> bar-to-funding was removed by program staff (M_U)	(#)	0	1	0	0	0	1	0	0
	(%)	0%	1%	0%	0%	0%	1%	0%	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 <i>minority AND sex/gender</i> bar-to-funding were removed by program staff	(#)	0	1	0	0	0	1	0	0
	(%)	0%	1%	0%	0%	0%	1%	0%	0%
Total Number (percent) of awards where <i>minority</i> bar-to-funding was removed by program staff	(#)	0	2	0	0	0	2	0	0
	(%)	0%	2%	0%	0%	0%	2%	0%	0%
Total Number (percent) of awards where <i>sex/gender</i> bar-to-funding was removed by program staff	(#)	0	1	0	0	0	1	0	0
	(%)	0%	1%	0%	0%	0%	1%	0%	0%
Total Number (percent) of awards where bar-to-funding was removed	(#)	0	2	0	0	0	2	0	0
	(%)	0%	2%	0%	0%	0%	2%	0%	0%

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

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN

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: 723

	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	136,765	573,679	257,373	2,022	491,783	8,174	68,988	1,538,784	944,383	233,703	360,698	1,538,784
	8.89%	37.28%	16.73%	0.13%	31.96%	0.53%	4.48%	71.17%	61.37%	15.19%	23.44%	71.17%
Male	96,451	236,052	101,066	531	124,131	5,413	35,979	599,623	428,507	158,372	12,744	599,623
	16.09%	39.37%	16.85%	0.09%	20.7%	0.9%	6%	27.73%	71.46%	26.41%	2.13%	27.73%
Unknown	44	14,477	1,314	116	876	149	6,598	23,572	16,880	599	6,113	23,572
	0.19%	61.42%	5.57%	0.49%	3.72%	0.63%	27.98%	1.09%	71.53%	2.54%	25.93%	1.09%
Total	233,260	824,208	359,753	2,669	616,790	13,736	111,563	2,161,979	1,389,750	392,674	379,555	2,161,979
	10.79%	38.12%	16.64%	0.12%	28.53%	0.64%	5.16%	100%	64.28%	18.16%	17.56%	100%

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

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN

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: 673

	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	60,548	545,660	215,208	763	173,746	6,458	64,215	1,066,598	884,997	159,455	22,146	1,066,598
	5.68%	51.16%	20.18%	0.07%	16.29%	0.61%	6.02%	56.57%	82.97%	14.95%	2.08%	56.57%
Male	20,992	231,119	93,973	448	129,800	4,513	39,738	520,583	410,100	91,945	18,538	520,583
	4.03%	44.4%	18.05%	0.09%	24.93%	0.87%	7.63%	27.61%	78.78%	17.66%	3.56%	27.61%
Unknown	45	291,717	792	4	3,742	42	1,873	298,215	296,135	1,023	1,057	298,215
	0.02%	97.82%	0.27%	0%	1.25%	0.01%	0.63%	15.82%	99.3%	0.34%	0.35%	15.82%
Total	81,585	1,068,496	309,973	1,215	307,288	11,013	105,826	1,885,396	1,591,232	252,423	41,741	1,885,396
	4.33%	56.67%	16.44%	0.06%	16.3%	0.58%	5.61%	100%	84.4%	13.39%	2.21%	100%

Table 5: FY 2013 Aggregate Enrollment Data for Extramural Phase III Research Protocols
 EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

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: 24

	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	18,770	127,863	48,651	40	10,417	112	13,344	219,197	185,007	34,186	4	219,197
	8.56%	58.33%	22.2%	0.02%	4.75%	0.05%	6.09%	75.17%	84.4%	15.6%	0%	75.17%
Male	6,390	43,939	14,732	0	124	2	3,017	68,204	58,764	9,417	23	68,204
	9.37%	64.42%	21.6%	0%	0.18%	0%	4.42%	23.39%	86.16%	13.81%	0.03%	23.39%
Unknown	9	3,923	241	0	0	0	16	4,189	4,164	25	0	4,189
	0.21%	93.65%	5.75%	0%	0%	0%	0.38%	1.44%	99.4%	0.6%	0%	1.44%
Total	25,169	175,725	63,624	40	10,541	114	16,377	291,590	247,935	43,628	27	291,590
	8.63%	60.26%	21.82%	0.01%	3.62%	0.04%	5.62%	100%	85.03%	14.96%	0.01%	100%

Table 6: FY 2014 Aggregate Enrollment Data for Extramural Phase III Research Protocols
 EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN

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: 14

	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	18,765	126,967	41,411	0	310	3	8,638	196,094	168,640	27,443	11	196,094
	9.57%	64.75%	21.12%	0%	0.16%	0%	4.41%	72.99%	86%	13.99%	0.01%	72.99%
Male	6,493	43,940	14,777	1	147	2	3,027	68,387	58,814	9,522	51	68,387
	9.49%	64.25%	21.61%	0%	0.21%	0%	4.43%	25.45%	86%	13.92%	0.07%	25.45%
Unknown	9	3,923	241	0	0	0	16	4,189	4,164	25	0	4,189
	0.21%	93.65%	5.75%	0%	0%	0%	0.38%	1.56%	99.4%	0.6%	0%	1.56%
Total	25,267	174,830	56,429	1	457	5	11,681	268,670	231,618	36,990	62	268,670
	9.4%	65.07%	21%	0%	0.17%	0%	4.35%	100%	86.21%	13.77%	0.02%	100%

Table 9: FY 2013 Aggregate Enrollment Data for Intramural Research Protocols For On-Site and Off-Site Combined

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

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: 107

	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	284	11,221	23,508	220	56,876	2,553	10,447	105,107	62,888	36,929	5,290	105,107
	0.27%	10.68%	22.36%	0.21%	54.11%	2.43%	9.94%	79.05%	59.83%	35.13%	5.03%	79.05%
Male	170	776	3,092	95	11,234	1,207	4,830	21,404	13,431	6,219	1,754	21,404
	0.79%	3.63%	14.45%	0.44%	52.49%	5.64%	22.57%	16.1%	62.75%	29.06%	8.19%	16.1%
Unknown	4	12	44	5	173	19	6,187	6,444	229	129	6,088	6,444
	0.06%	0.19%	0.68%	0.08%	2.68%	0.29%	96.01%	4.85%	3.55%	2%	94.44%	4.85%
Total	458	12,009	26,642	320	68,283	3,779	21,464	132,955	76,548	43,277	13,130	132,955
	0.34%	9.03%	20.04%	0.24%	51.36%	2.84%	16.14%	100%	57.57%	32.55%	9.88%	100%

Table 10: FY2014 Aggregate Enrollment Data for Intramural Research Protocols For On-Site and Off-Site Combined

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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: 103

	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	284	11,502	24,844	236	57,950	2,632	11,486	108,934	65,630	37,378	5,926	108,934
	0.26%	10.56%	22.81%	0.22%	53.2%	2.42%	10.54%	82.52%	60.25%	34.31%	5.44%	82.52%
Male	174	821	3,301	107	12,263	1,262	4,822	22,750	14,285	6,440	2,025	22,750
	0.76%	3.61%	14.51%	0.47%	53.9%	5.55%	21.2%	17.23%	62.79%	28.31%	8.9%	17.23%
Unknown	4	4	31	2	47	12	229	329	81	88	160	329
	1.22%	1.22%	9.42%	0.61%	14.29%	3.65%	69.6%	0.25%	24.62%	26.75%	48.63%	0.25%
Total	462	12,327	28,176	345	70,260	3,906	16,537	132,013	79,996	43,906	8,111	132,013
	0.35%	9.34%	21.34%	0.26%	53.22%	2.96%	12.53%	100%	60.6%	33.26%	6.14%	100%

Additional information

Projects with analysis(es) on sex/gender, race, and/or ethnicity

Title	Grant Number
A Cohort Study of Preterm Delivery in Relation to Partner Abuse, Mood and Anxiety	R01 HD059835-05
A Controlled Trial of Gabapentin in Vulvodynia: Biological Correlates of Response	R01 HD065740
A Lifecourse Approach to Emerging Health Disparities in a US Birth Cohort	R01 HD058515
A longitudinal study: the influence of sex and puberty on neurodevelopment	F32 HD078084-01
A RCT of preconception weight loss vs. OCP in overweight infertile PCOS women	U10 HD038992
A US-UK Comparison of Discrimination & Disparities in Health & Health Service Use	R01 HD061320
Abused and non-abused females' high-risk online behaviors: Impact on development	R01 HD073130-03
Adapting a Decision-Making Task to Explore its ERP Correlates Through Adolescence	5R21HD072363-02
Administrative supplement for research on sex/gender differences – Host epigenetic and mitochondrial function in HIV-infected children	R01 HD073952
Adolescent Trials Network 15-site Behavioral and Demographic Characterization of the (vastly minority) Patient Population at each of the ATN sites	U01 HD40533, U01 HD40474
Adolescent Trials Network 15-site Community Prevention Intervention Aimed at Achieving Structural Changes in Potential HIV Risk Determinants for Minority Youth Across the United States	U01 HD40533, U01 HD40474
Adolescent Trials Network 15-site National Study Evaluating Human Papilloma Virus Vaccine in HIV-Infected Females	U01 HD40533, U01 HD40474
Adolescent Trials Network 15-site Study Looking at How to Best Identify Young Female Youth with Undiagnosed HIV Infection in the United States	U01 HD40533, U01 HD40474
Adolescent Trials Network 15-site Study Looking at How to Best Identify Latino Youth with Undiagnosed HIV Infection in the United States	U01 HD40533, U01 HD40474
Adolescent Trials Network Collaboration with the Centers for Disease Control and Prevention Aimed at Improving the Identification of Minority Youth with Undiagnosed HIV Infection and Linking Them to Care at the 15 US ATN sites	U01 HD40533, U01 HD40474

Adolescent Trials Network Collaboration with the Centers for Disease Control and Prevention and with the Health Resources and Services Administration Aimed at Improving the Retention of Minority Youth with Undiagnosed HIV Infection in Care at the 14 US ATN sites and 4 HRSA RWD sites	U01 HD40533, U01 HD40474
Adolescent Trials Network Study "PHASES", an Evaluation of the HHS-Core Indicators and Patterns of Risk among HIV+ Youth in Care.	U01 HD40533, U01 HD40474
Adolescent Trials Network Study "Project ACCEPT", an Intervention Aimed at Engaging Newly Diagnosed HIV+ Youth to Care.	U01 HD40533, U01 HD40474
Adolescent Trials Network Study Assessing the Engagement of Transgender and Other Gender Minority Youth across the HIV Continuum of Care	U01 HD40533, U01 HD40474
Adolescent Trials Network Study Evaluating a Secondary Prevention Intervention for HIV- Positive Black Young Men Who Have Sex with Men	U01 HD40533, U01 HD40474
Adolescent Trials Network Study Evaluating the Safety, Feasibility, Acceptability, Adherence Patterns and Risk Profiles Among at Risk Youth Taking the Antiretroviral Medication Truvada as Pre-Exposure Prophylaxis from HIV Infection across all ATN sites	U01 HD40533, U01 HD40474
Adolescent Trials Network Study of Behavioral, Immunologic, and Virologic Correlates of Oral Human Papillomavirus Infection in Adolescents and Young Adults with Behaviorally Acquired HIV- Infection	U01 HD40533, U01 HD40474
Adolescent Trials Network Study of Epic Allies HIV ART Adherence Intervention	U01 HD40533, U01 HD40474
Adolescent Trials Network Study of the Feasibility of Using a Structured Daily Diary to Assess Mood, Stress, Support, Substance Use, and Sexual Behavior in HIV-Positive Young MSM	U01 HD40533, U01 HD40474
Adolescent Trials Network Study of Transitioning HIV+ Adolescents to Adult Care: Exploring Adolescent and Adult Medicine Clinics Role in the Process	U01 HD40533, U01 HD40474
Adolescent Trials Network Study, a Randomized, Double-Blind, Placebo-Controlled Trial of the Safety and Effectiveness of Vitamin D3 50,000 IU every 4 weeks to Increase Bone Mineral Density and Decrease Tenofovir-Induced Hyperparathyroidism in Youth with HIV infection being treated with Tenofovir-Containing Combination Antiretroviral Therapy	U01 HD40533, U01HD40474
Age-based Reference Ranges for Annual Height Velocity in U.S. Children	R01 HD076321
An Epidemiological and Longitudinal Study of Rural Child Literacy Trajectories	R01 HD080786

Appropriate Gestational Weight Gain in Overweight/Obese Women	R01 HD073572-02
Basis of Reading Deficits in African-American Children	R24 HD075454
Bilingual Proficiency and Memory: An Associative Strength Approach	R15 HD078921
Bimodal Bilingualism	R01HD047736
Bioenergetic and Metabolic Consequences of the Loss of Gonadal Function	P50 HD073063
Biomarkers of Infertility	R01 HD067683
Bone Mineral Density in Children Study	R01 HD058886
Bone Morphogenic Protein Signaling Pathways in Uterine Biology	R01 HD032067
Carolina Population Center	R24 HD050924
CBPR Initiative in Reducing Infant Mortality in American Indian Communities	R01 HD080544-01
Center for Endometrial Biology and Endometriosis	U54 HD052668
Center for Family and Demographic Research	R24 HD050959
Center for Reproductive Biological Research	U54 HD007495
Center for Reproductive Health After Disease	P50 HD076188
Center for Reproductive Science and Medicine	U54 HD012303
Center for the Study of Reproductive Biology and Women's Health	U54 HD058155
Center for Women's Health and Reproduction	U54 HD040093
Children in Transition to Adulthood: Family and Sibling Connections	R01 HD033474
Children's implicit and explicit stereotypes about academic abilities	R03 HD072025
Clinical and Basic Studies in Polycystic Ovarian Syndrome	P50 HD028934
Cognitive and Language Development in Bilingual Children: Mechanisms, Limitation	R01 HD052523
Cognitive Architecture of Bilingual Language Processing	R01 HD059858
Colorado Multicenter Reproductive Medicine Network	U10 HD038998
Communication about sex in the nuclear family and beyond: Implications for health	R03 HD073381-02
Community-Based Prevention of Youth Violence in Latinos	K23 HD068401-05
Cooperative Multicenter Reproductive Medicine Network	U10 HD077841
Cooperative Multicenter Reproductive Medicine Network	U10 HD027049

Cooperative Multicenter Reproductive Medicine Network	U10 HD055936
Cooperative Multicenter Reproductive Medicine Network	U10 HD077844
Corpus Luteal Contribution to Maternal Pregnancy Physiology and Outcomes in ART	P01 HD065647
Cultural Equivalence of Autism Assessment Instruments for Latino Children	R03 HD064828-01
Data Collection for Older NLSY Children	R01 HD037078
Decision Making by Patients Seeking Care for Fertility Problems	R2 HD071332
Demographic Diversity in the Measurement and Meaning of Unintended Pregnancy	F31 HD079182
Demographic Vulnerability, Neighborhood Pollution, and Racial Health Disparities	R01 HD078501
Developing and Enacting Racial/Ethnic Identities	R01 HD048970
Developing Number Sense in Children at Risk for Mathematics Learning Disabilities	R01 HD059170
Differential Diagnosis in Learning Disabilities	P50 HD027802
Disorders of Sex Development: Platform for Basic and Translational Research	R01 HD068138
Disparities in Disability after Traumatic Brain Injury for Hispanic Children	K23 HD078453-02
Disparities in Health and Academics of Sexual Minorities in Urban Middle Schools	F32 HD075531-02
Distal Determinants of Disparities in Unintended Fertility	R01 HD078412
Do Obstetrical Quality Measures Explain Racial Disparities in Perinatal Outcomes	R21 HD068765-02
Early Brain Development in One and Two Year Olds	R01 HD053000
Effect Of Iatrogenic Delivery at 34-38 Weeks Gestation on Pregnancy Outcome	R01 HD077592-01A1
Effect of Insulin on Estrogen Receptor Alpha in Human Endometrial Cells	K08 HD071010
Effects of Placental Transfusion on Early Brain Development	R01 HD076589-01
Effects of the second language on syntactic processing in the first language	R21 HD071758
Effects of Weight and Insulin Sensitivity on Reproductive Function in PCOS	R00 HD060762
Efficacy of Dexamethasone in Polycystic Ovary Syndrome-related	U10 HD055942

Infertility	
Emerging Disparities in Chronic Disease Risk Among Young Adults	R01 HD058535
Emotion processing in develop: An ERP Investigation	R03 HD074724
Enhancing Safe Sleep Practices of Urban Low-Income Mothers	R01 HD072821-02
Evaluating the Head's Response to Impulsive Forces in Young Athletes	K23 HD078502-02
Evaluation of Umbilical Cord Milking on Systemic Blood Flow in Premature Infants	R03 HD072934-01A1
Excess Androgen Production in Overweight Pubertal Girls - Precursor to PCOS	K23 HD070854
Exposure to violence and unsafe sex in late adolescent African American women	R01HD067511-04
Feasibility of an internet-based study of time-to-pregnancy in the United States	R21 HD072326
Fragile Families and Child Wellbeing in Adolescence	R01 HD036916
Function of Toll-Like Receptors Throughout Pregnancy	P01 HD054713
Generations in Families Talking Safe Sleep	R01HD076702-01A1
Genes, Androgens and Intrauterine Environment in PCOS	P50 HD044405
Genetic Analysis of Human First Trimester Trophoblast in Ongoing Pregnancies	R21 HD071408
Genetic Basis of Cryptorchidism	R01 HD060769
Genetic Determinants of Uterine Fibroids in African-American and Caucasian Women	R01 HD064398
Genetic Studies of Uterine Leiomyomata	R01 HD060530
Genetics of Delayed Puberty	R01 HD033004
Genomic Basis of Premature Ovarian Insufficiency	R01 HD070647
Genomic Integrity of the X Chromosome and Ovary-Specific Autosomal Genes	R21 HD074278
Genomics of Spermatogenic Impairment	R0 HD078641
GHSU/WSU Cooperative Multicenter Reproductive Medicine Network	U10 HD039005
Harvard Reproductive Endocrine Sciences Center	P50 HD028138
Health trajectories from age 12-32: Disparities, discrimination, & socialization	R01 HD068298-03S1

Healthy Bodies, Healthy Minds: Helping Adolescents with PCOS	K23 HD061598
How economic and neighborhood factors modify effects of school obesity policies	R00 HD07327
Hyperandrogenemia, Diet and Female Reproductive Health	P50 HD071836
Identifying evidence based strategies to enhance prosocial behaviors of children	F32 HD081838
Improving the Self-Efficacy of African American Parents in Infant Supine Sleep	R01 HD064770-05
Incidence and Outcomes of Ectopic Pregnancy in the Medicaid Population	K08 HD060663-05
Increased Postpartum Testing for Gestational Diabetes	R21 HD075640-01A1
Indiana University Center for Pediatric Pharmacology	U54 HD071598
Innovative Venue-Based Strategies to Identify STI Core Transmitters	R21 HD052438
Intratesticular Sex Steroids and Spermatogenesis in Man	K23 HD073164
Kisspeptin Physiology in the Human	R01 HD043341
Kisspeptin/Kiss1r in the Female Neuroendocrine Axis	R01 HD049651
Lexical structure in monolingual and bilingual Spanish-Speaking Children in US	F31 HD081933
Lighting System for Premature Infant Incubators	R41 HD078126-01A1
Longitudinal Population-Based Study of Vulvodynia	R01 HD054767
Longitudinal study of adverse driving outcomes among adolescents with ADHD	R01 HD079398-01A1
Luteal Progesterone Supplementation in Clomiphene Citrate-IUI Cycles	U1 HD077680
Measuring Stress Among Diverse Adolescents	R21 HD082813-01A1
Mechanisms & Effects of Prenatal Maternal Affect on Pregnancy & Infant Development	R01 HD073491-02 MPI
Mechanisms & Effects of Prenatal Maternal Affect on Pregnancy & Infant Development	R01 HD 073491-01A1
Metformin Use During in Vitro Fertilization in Polycystic Ovarian Syndrome	U10 HD055944
Mexican Children of Immigrants Program	P01 HD062498
Modulation of Hormonal and Systemic Immunity by Hormonal Contraceptive Use	R01 HD072663
Modulation of the Receptive Endometrium by CG	R01 HD042280
Molecular and Metabolic Aspects of Implantation	R01 HD065435

Monitoring Brain Health in Neonatal Congenital Heart Disease with Bedside CMR02	R21HD072505-01A1
Motion-Controlled Gaming for Neuroscience Education	5R43 HD075438-02
Multimodal Evaluation of Sensory Processing and Neurodevelopment in NICU Infants	K23HD074736-01A1
Neighborhood and Family Effects on Disparities in Chronic Disease	R01 HD058514
Neonatal Resuscitation with Intact Cord (NRIC)	R21 HD080594-01
Neurobiological bases of paternal nurturance	R21 HD078778-0
Neurosecretory Gene Expression in the Hypothalamus	R01 HD072754
Noninvasive, Optoacoustic Monitoring of Cerebral Circulation in Preterm Neonates	R42 HD076568-01
Novel RF Coils and k-t Space Imaging for Neonatal Chest MRI within NICUs	R21 HD071540-01A1
Nuestros Niños Program: Promoting School Readiness for English Language Learners	U01 HD060299
Online Social Networks and Risky Sexual Behavior in Maltreated Adolescents	K01 HD069457-03
Organizational and activational effects of sex steroids on child self-regulation	K99 HD077058
Origins and Biological Consequences of Human Infertility	P50 HD055764
Parental Trust and Racial Disparities in the Care of Discharged Premature Infants	R01 HD057168
Pathological Adaptation to Exposure to Community Violence in Minority Male Youth	R03 HD072112-02
Patterns of adolescent food intake: Consequences and contextual influences	R03 HD079504
Patterns of Hypoxia and Mortality in the SUPPORT Trial Cohort	R03 HD078528-01A1
Pediatric CFS in a Community-Based Sample	R01 HD072208-02
Pediatric HIV/AIDS Cohort Study (PHACS) Adolescent Master Protocol	U01HD052102, U01HD052104
Pediatric HIV/AIDS Cohort Study (PHACS) Adolescent Master Protocol for Participants 18 Years of Age and Older	U01HD052102, U01HD052104
Pediatric HIV/AIDS Cohort Study (PHACS) Surveillance Monitoring for ART Toxicities Study in HIV-uninfected Children Born to HIV-infected Women	U01 HD052102, U01 HD052104
Penn Center for Study of Epigenetics in Reproduction	P50 HD068157
Phthalates in Drugs and Male Genital Malformation Pluripotent Stem Cells: Modeling Syncytiotrophoblast Development and Pathogenesis	R01HD059861 R01HD077108

Population Research Infrastructure Support	R24 HD041028
Population Research Institute	R24 HD041025
Population Research Training	T32 HD007168
Poverty, Chronic Stress and Neural Regulation of Maternal Mood and Parenting	R21 HD078797
Preconception and Prenatal Stress: Pathways to Child Biology and Behavior	R01 HD072021-01A1
Predictive Informatics Monitoring in the Neonatal Intensive Care Unit	R01 HD072071-01A1
Predictors of Early Menopause	R01HD078517
Predictors of High-Risk Behavior among Youth	R01 HD060072-06A1
Progesterone Action in the Endometrium of Women with Endometriosis	R01HD067721
Promoting Child Inhibitory Control Skills around Food	R21 HD074987-01A1
Pubertal Hyperandrogenemia, Modification of Day-Night GnRH Secretion and PCOS	R01 HD058671
Pubertal Stress Recalibration Hypothesis	R01 HD075349
Race, contraceptive behavior, and unintended pregnancy	R21 HD068736
Race, stress and dysregulated eating: Maternal to child transmission of obesity	R01 HD073568
Race/Ethnicity, Poverty, and Connection Between Child Health and Early Education	R01HD055359
Regulation of Stem Spermatogonia in the Mature Testis	R01HD074542
Retinoid Effects of Inflammation and Cell Growth Associated with Endometriosis	R01HD055379
Role of leptin-mediated PI3 Kinase signaling on reproductive control	R01HD061539
Sexual Behavior Trajectories from Adolescence to Adulthood	R01 HD057046
Sexual Revictimization: Emotional and Psychosocial Mechanisms	R01HD062226-05
Short-term outcomes of interventions for reproductive dysfunction	R01 HD074579
Small RNA Pathways in Mammalian Gametogenesis	P50 HD076210
Social Ecological Model for Community and Home-based Nutrition Education	5R44 HD071679-03
Social Media And Risk-reduction Training for Infant Care Practices (SMART)	R01HD072815-03
Social perception and social communication in adults with traumatic brain injury	R01 HD071089-04
Study of Attitudes and Factors Affecting Infant Care	U10 HD059207-05
Testosterone and Cortisol Levels in Infant Health and Development	R01 HD076871

The FIRSTT Trial: Assessing Outcomes of Minimally Invasive Leiomyoma Therapies	R01 HD060503
The Florida Learning Disabilities Research Center	P50 HD052120
The Genetics of Polycystic Ovary Syndrome	R01 HD65029
The Intergenerational Transmission of Race Disparities in Health	K01 HD064537
The Kiss1 system in the Neuroendocrine Control of Reproduction	K99HD071970
The National Longitudinal Study of Adolescent to Adult Health	P01 HD031921
The Path to Language and Literacy: A Cross-Linguistic Longitudinal Approach	R01 HD068458
Timing of Inguinal Hernia Repair in Premature Infants: A Randomized Trial	U01 HD076733-01A1
Tools of the Mind: Promoting ELLs' Language, Self-Regulation & School-Readiness	U01 HD060296
Translational Research in Polycystic Ovary Syndrome	U54 HD034449
Treatment of Hyperandrogenism vs. Insulin Resistance in Infertile PCOS Women	R01 422HD056510
Unbound fatty acids, Intralipid and Unbound Bilirubin in Preterm Infants	R03 HD077422-01A1
Understanding individual and gender differences in educational and career choices	R03 HD074731
Understanding the genetic risk underlying racial disparities in uterine fibroids	R01 HD074711
Using the Exome to Discover Genetic Determinants of Fibroids in African Americans	R03 HD078567
Web-based Parenting Intervention for Mothers of Infants At-Risk for Maltreatment	R01 HD064870-04

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