DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director

2019 TRIENNIAL ADVISORY COUNCIL REPORTS CERTIFYING COMPLIANCE WITH THE NIH POLICY ON INCLUSION GUIDELINES

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February 2019

National Institute of Allergy and Infectious Diseases (NIAID) Report on Monitoring Adherence to the National Institutes of Health (NIH) Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2016 – FY2018

I. Background/Overview

As the lead federal organization conducting and supporting scientific research on infectious and immunologic diseases, the 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 including infectious disease outbreaks and the increasing prevalence of resistance to antimicrobial drugs worldwide.

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. 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.

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.

II. Strategies for Ensuring Compliance

A. Peer Review

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 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 . 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.

B. Program Monitoring and Grants Management Oversight

Prior to an award, program officials/program directors are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate. Program staff monitor actual enrollment progress in annual progress reports and provide consultation when necessary. For NIH-defined Phase III clinical trials, program officials/program directors monitor the requirement for sex/gender and race/ethnicity analyses in applications and annual progress reports.

Grants management staff ensure that appropriate terms and conditions of award are included in the Notice of Award, and that this information is appropriately documented in the official grant file. 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.

C. Intramural

All intramural clinical research studies require investigators to provide plans for the appropriate inclusion of women and minorities and/or a justification whenever representation is limited or absent, as part of their NIH protocol reviews. Intramural institutional review boards (IRBs) review intramural research protocols for compliance with inclusion guidelines and conduct annual monitoring. With each annual review and renewal, the investigator documents the number, gender, and race and ethnicity of those who were accrued during the past year; any issues with accrual are addressed at the annual review by the investigator and reviewed by the pertinent IRB. The Clinical Center's Office of Protocol Services (OPS) coordinates annual reporting of demographic participant data to the Office of Extramural Research (OER) and the Office of Research on Women's Health (ORWH).

D. **IC Training Approaches**

NIAID Program Officials and Scientific Review Officers (SROs) attended the May 11, 2018, training, *Ensuring Inclusion in NIH Clinical Research: Policies and Procedures for Grants and Contracts*. Staff may access the archived training on the NIH staff intranet.

Within NIAID, training requirements are disseminated to all 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 Extramural Research Policy and Operations (OERPO) sponsored the Extramural Policy Grand Rounds given by the NIAID Division of Extramural Activities (DEA) Director that includes all updates on clinical trials and inclusion issues. This was given twice per year in FY 2016, 2017 and 2018. All extramural staff are invited to these sessions and have access to the archived training on the NIAID intranet site.

NIAID DEA staff gave clinical trial update training to each programmatic division at NIAID that included the Division of Allergy Immunology and Transplantation (DAIT), Division of Microbiology and Infectious Diseases (DMID), and the Division of Acquired Immunodeficiency Syndrome (DAIDS) in FY 2017. This training included all updates to the clinical trial policy from the NIH, the 21st Century Cures Act, and the Common Rule. All program officers were required to attend these training sessions.

In August of 2018, OER provided a brown bag training for SROs and program officers on the new HSS system. The training was led by the NIH Inclusion Policy Officer Ms. Dawn Corbett, MPH. A total of 63 NIAID staffers were in attendance.

III. Analysis and Interpretation of Data

Aggregate data for FY 2016–2018 were provided by OER through the Human Subjects System (HSS) that utilized the current NIH dataset. The HSS database is the centralized repository for collecting and storing data for all NIH Institutes and Centers (ICs) on human subjects and clinical trials. These data can be captured electronically on the Human Subjects and Clinical Trial Information form and for reporting on their Research Performance Progress Report (RPPR) in non-competing years. The HSS provides the tools that allow NIH staff to better monitor and manage the data.

All study and enrollment data for FY 2016–2018 are shown in Tables 1 through 5 in the appendix section of this report.

A. Enrollment for All NIH-Defined Clinical Research, by Sex/Gender, Race, and Ethnicity

In Table 1, we find the NIAID summary of aggregate enrollment data for extramural and intramural research protocols reported in FY 2016, 2017, and 2018, for sex/gender by race and ethnicity respectively. The combined aggregate data show that 811,387 women enrolled as research participants in FY 2016, constituting 50.1% percent of the total enrollment, and 419,658 women enrolled as research participants in FY 2017, constituting 51.3% percent of the total enrollment followed by a total of 509,757 women enrolled as research participants in FY 2018, constituting 49.4% of the total enrollment for that year. Total aggregate enrollment of men and women for both extramural and intramural clinical research were 1,618,229, 818,366, and 1,031,743 for the three fiscal years of 2016–2018 (Table 2).

The same years FY 2016–2018, respectively, show that minorities comprised 84.4%, 57.6%, and 54.8% (Table 2) of total enrollment. The decline in minority enrollment from FY 2016 to 2017 represent the completion of two major studies in Asia and Africa representing malaria and HIV research. Overall for all three years, NIAID is on par for inclusion of women and minorities in our research studies comparative to the enrollment for the three years in this report.

B. Enrollment for All NIH-Defined Phase III Clinical Trials, by Sex/Gender, Race, and Ethnicity

Aggregate enrollment data for NIAID extramural and intramural NIH-defined Phase III protocols reported in FY 2016, 2017, and 2018 (Table 3) show that a greater percentage of women enrollees in all years with percentages ranging from 52.3% - 60.2 % respectively. Minority populations enrolled in these studies at high rates, especially Black African Americans in extramural studies, with average enrollment for men and women combined ranging from 97.5 % – 70 %.

In FY 2016–2018, women made up 52.3%, 57%, and 60.2 % of all enrollees in Phase III clinical trials (Table 4). These data for FY 2016–2018 represent a total of 30, 45, and 34 inclusion data records (IDRs) for NIAID's Phase III trials (Table 5B.) Aggregate total IDRs for FY 2016–2018 individually, were 1300, 1438, and 1406 (Table 5A) for all study records.

C. Research, Condition, and Disease Categorization (RCDC) Report

The RCDC Report is used by NIH to inform the public of how tax dollars are being spent on biomedical research within the 27 institutes and centers. RCDC is a computer-driven process that reports more than 289 categories of diseases, conditions, or research areas. This is the first time this information will be captured in the triennial report on inclusion. The RCDC data will only report on FY 2018 for this reporting period. The data will include IC and NIH totals and median proportions for each category via the website here in mid-January 2019 https://report.nih.gov/RISR/. The use of median proportions illustrates what a typical study looks like in a particular category.

IV. Additional information

The 21st Century Cures Act, enacted December 13, 2016, included several new requirements related to inclusion of participants in clinical research. As a result, NIH updated its policy on the Inclusion of Women and Minorities as Subjects in Clinical Research on November 28, 2017, to require studies that are both NIH-defined Phase III clinical trials and applicable clinical trials to report the results of analyses by sex/gender and/or race/ethnicity to ClinicalTrials.gov. This requirement is effective for competing grant awards on or after December 13, 2017, as well as contract solicitations and intramural studies initiated after this date. Additionally, NIH revised its Inclusion of Children Policy on December 19, 2017. The revised policy, now called the *NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects*, applies to individuals of all ages and requires reporting of participant age at enrollment in annual progress reports. The policy is effective for applications submitted on or after January 25, 2019, and contract solicitations and intramural studies initiated after this date. The 21st Century Cures Act amended the frequency of the Report of the NIH Director on the inclusion of women and minorities from biennial to triennial. Thus, this first triennial report provides information on inclusion of participants in NIH clinical research from FY 2016 – 2018. Section IV of the Report of the Advisory Committee on Research on Women's Health includes IC reports on monitoring adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research for FY 2015 and 2016.

Attachment 1
Text 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 grantees to certify for all competing applications that any key personnel who are responsible for the design and conduct of the study have completed human subjects training. For noncompeting applications, only new personnel that have not previously been reported should be certified by the grantee.

The NIH requires grantees to certify for all competing applications that any key personnel who are responsible for the design and conduct of the study have completed human subjects training. For noncompeting applications, only new personnel that have not previously been reported should be certified by the grantee.

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

Responsibility – The Program Official should review the certification documents 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 – https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award-guidance-compliance

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

Required Reporting –

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 – https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award-guidance-compliance

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 – https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award-guidance-compliance

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 – https://grants.nih.gov/grants/funding/women_min/guidelines.htm

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) –

The 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 – https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-010.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: Total Enrollment: All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity

FY	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported	American Indian Alaska Native	% American Indian Alaska Native
2016	Female	709,818	87.5	811,387	50.1	702,394	86.6	52,653	6.5	56,340	6.9	4,585	0.6
2016	Male	649,418	83.4	778,335	48.1	647,810	83.2	49,746	6.4	80,779	10.4	4,498	0.6
2016	Unknown	6,814	23.9	28,507	1.8	6,274	22.0	1,099	3.9	21,134	74.1	2	0
2017	Female	272,506	64.9	419,658	51.3	276,647	65.9	37,227	8.9	105,784	25.2	4,609	1.1
2017	Male	194,618	53.5	363,863	44.5	206,892	56.9	36,278	10.0	120,693	33.2	4,416	1.2
2017	Unknown	4,316	12.4	34,845	4.3	4,727	13.6	667	1.9	29,451	84.5	6	0.0
2018	Female	302,479	59.3	509,757	49.4	311,663	61.1	41,717	8.2	156,377	30.7	5,758	1.1
2018	Male	257,874	51.8	497,532	48.2	281,704	56.6	47,438	9.5	168,390	33.8	5,689	1.1
2018	Unknown	4,727	19.3	24,454	2.4	4,704	19.2	1,298	5.3	18,452	75.5	2	0

FY	Sex Gender	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2016	Female	190,625	23.5	462,325	57.0	4,740	0.6	105,228	13.0	11,918	1.5	31,966	3.9
2016	Male	223,252	28.7	369,830	47.5	4,761	0.6	127,968	16.4	10,825	1.4	37,201	4.8
2016	Unknown	4,352	15.3	1,361	4.8	0	0	328	1.2	13	0.0	22,451	78.8
2017	Female	21,630	5.2	211,118	50.3	186	0	75,733	18.0	9,367	2.2	97,015	23.1
2017	Male	27,715	7.6	126,822	34.9	232	0.1	95,218	26.2	7,826	2.2	101,634	27.9
2017	Unknown	2,775	8	880	2.5	0	0	766	2.2	11	0.0	30,407	87.3
2018	Female	86,148	16.9	174,948	34.3	427	0.1	84,026	16.5	12,072	2.4	146,378	28.7
2018	Male	94,797	19.1	113,960	22.9	595	0.1	113,915	22.9	12,324	2.5	156,252	31.4
2018	Unknown	2,779	11.4	503	2.1	2	0.0	988	4.0	359	1.5	19,821	81.1

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 2: Total Enrollment of All NIH-Defined Clinical Research By Race

FY	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander
2016	1,618,229	1,300	1,366,050	84.4	9,085	0.6	418,229	25.8	833,516	51.5	9,501	0.6
2017	818,366	1,438	471,440	57.6	9,031	1.1	52,120	6.4	338,820	41.4	418	0.1
2018	1,031,743	1,406	565,080	54.8	11,449	1.1	183,724	17.8	289,411	28.1	1,024	0.1

FY	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2016	233,524	14.4	22,756	1.4	91,618	5.7
2017	171,717	21.0	17,204	2.1	229,056	28.0
2018	198,929	19.3	24,755	2.4	322,451	31.3

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 3: ALL Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

FY	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unk./Not Reported	% Unk./Not Reported
2016	Female	198,853	99.7	199,396	52.3	197,086	98.8	613	0.3	1,697	0.9
2016	Male	179,292	98.5	182,027	47.7	178,591	98.1	1,834	1.0	1,602	0.9
2016	Unknown	160	100.0	160	0.0	153	95.6	3	1.9	4	2.5
2017	Female	18,860	97.0	19,449	57.0	16,285	83.7	1,363	7.0	1,801	9.3
2017	Male	11,519	79.7	14,457	42.4	10,640	73.6	2,115	14.6	1,702	11.8
2017	Unknown	211	100.0	211	0.6	201	95.3	3	1.4	7	3.3
2018	Female	17,489	97.5	17,931	60.2	14,674	81.8	1,299	7.2	1,958	10.9
2018	Male	10,606	91.3	11,622	39	8,012	68.9	1,660	14.3	1,950	16.8
2018	Unknown	214	97.7	219	0.7	205	93.6	6	2.7	8	3.7

FY	Sex Gender	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unk./Not Reported	% Unk./Not Reported
2016	Female	4	0.0	1,060	0.5	197,321	99.0	0	0.0	543	0.3	14	0.0	454	0.2
2016	Male	13	0.0	2,178	1.2	175,404	96.4	10	0.0	3,079	1.7	19	0.0	1,324	0.7
2016	Unknown	0	0.0	3	1.9	157	98.1	0	0.0	0	0.0	0	0.0	0	0.0
2017	Female	11	0.1	1,745	9.0	16,182	83.2	1	0.0	847	4.4	25	0.1	638	3.3
2017	Male	19	0.1	2,524	17.5	7,035	48.7	11	0.1	3,364	23.3	29	0.2	1,475	10.2
2017	Unknown	0	0.0	7	3.3	204	96.7	0	0.0	0	0	0.0	0.0	0	0
2018	Female	10	0.1	1,729	9.6	14,839	82.8	1	0	703	3.9	84	0.5	565	3.2
2018	Male	17	0.1	2,372	20.4	6,645	57.2	10	0.1	1,565	13.5	133	1.1	880	7.6
2018	Unknown	0	0.0	7	3.2	204	93.2	0	0	0	0	0.0	0.0	8	3.7

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 4: Total Enrollment for All NIH-Defined Phase III Trials Reporting Between FY2016-FY2018

FY	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown
2016	381,583	199,396	52.3	182,027	47.7	160	0.0
2017	34,117	19,449	57.0	14,457	42.4	211	0.6
2018	29,772	17,931	60.2	11,622	39.0	219	0.7

FY	Enrollment in Female-only	% Female-only	Enrollment in Male-only	% Male-only	Females, Excluding Female-only	% Females, Excluding Female-only	Males, Excluding Male-only	% Males, Excluding Male-only
2016	3,075	0.8	5	0.0	196,321	51.4	182,022	47.7
2017	4,176	12.2	5	0.0	15,273	44.8	14,452	42.4
2018	4,176	14.0	5	0.0	13,755	46.2	11,617	39.0

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 5A: Metrics Based on Inclusion Data Records (IDRs)

Total Inclusion Data Records (IDRs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between FY2016 and FY2018

Fiscal Year	Total IDRs	IDRs Without Enrollment	IDRs With Enrollment	US Site IDRs	Non-US Site IDRs	Female Only IDRs	Male Only IDRs	IDRs Excluding Male-only and Female-only*
2016	1,300	150	1,150	814	336	108	58	984
2017	1,438	184	1,254	896	358	113	73	1,068
2018	1,406	165	1,241	855	386	129	87	1,025

*Inclusion Data Records (IDRs) excluding male-only and female-only include unknown sex/gender, and combination of unknown and any sex/gender(s).

Table 5B: Total Inclusion Data Records (IDRs): All NIH-Defined Phase III Trials

Total Inclusion Data Records (IDRs) for NIH-Defined Extramural and Intramural Phase III Trials Reported Between FY2016 and FY2018

Fiscal Year	Total IDRs	IDRs Without Enrollment	IDRs With Enrollment	US Site IDRs	Non-US Site IDRs	Female Only IDRs	Male Only IDRs	IDRs Excluding Male-only and Female-only*
2016	30	4	26	14	12	2	1	23
2017	45	6	39	18	21	4	1	34
2018	34	4	30	12	18	4	1	25

*Inclusion Data Records (IDRs) excluding male-only and female-only include unknown sex/gender, and combination of unknown and any sex/gender(s).

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.