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 FY2019 – FY2021

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 such as the increasing prevalence of resistance to antimicrobial drugs worldwide and infectious disease outbreaks, including the COVID-19 pandemic.

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 comply 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.

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. 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 also amended the frequency of the Report of the NIH Director on the inclusion of women and minorities from biennial to triennial.

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 18 years and an older adult as a person 65 years of age or older. 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 or older adults 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 individuals across the lifespan 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 inclusion of women, minorities, and individuals across the lifespan, 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 has developed a number of relevant SOPs relating to

programmatic oversight required for clinical research applications (https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award-guidance-compliance, https://www.niaid.nih.gov/research/human-subjects-research-training-sop, https://www.niaid.nih.gov/research/grants-bar-awards-human-subjects, https://www.niaid.nih.gov/research/children-research-policy, https://www.niaid.nih.gov/research/human-subjects-certifications-irb-or-iec-sop).

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 2020 *Inclusion Training for Program Staff* and the 2020 *Inclusion Training for Review Staff* in April 2020. 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 videocasts or as slide shows.

Several trainings were offered to NIH staff covering requirements associated with the implementation of the Inclusion Across the Lifespan Policy (NOT-OD-18-116). NIAID Program and Grants Management staff attended the September 1, 2019 training *How Program and Grants Management Staff Find Inclusion Data in the RPPR.* NIAID

Scientific Review Officers attended a video tutorial on *Handling Inclusion Codes When Sweeping Meetings, A Quick Guide for Review Staff.* Staff may access the archived trainings on the NIH staff intranet.

In 2021, NIAID extramural staff also attended NIH training on the implementation of the OER policy *Harmonizing NIH Institutes and Centers Clinical Trial Operating Procedures.* Implementation of this policy ensures that ICs include the appropriate clinical trial elements in their SOPs, including those associated with inclusion of clinical trial subjects, and harmonization of clinical trial SOPs across NIH.

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, including the implementation of the Inclusion Across the Lifespan policy. This was given twice per year in FY 2019, 2020 and 2021. All extramural staff are invited to these sessions and have access to the archived training on the NIAID intranet site.

III. Analysis and Interpretation of Data

Aggregate data for FY 2019–2021 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 2019–2021 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 of the appendix, we find the NIAID summary of aggregate enrollment data for extramural and intramural research protocols reported in FY 2019, 2020, and 2021, for sex/gender by race and ethnicity respectively. The combined aggregate data show that 468,899 women enrolled as research participants in FY 2019, constituting 45.9% percent of the total enrollment, and 911,551 women enrolled as research participants in FY 2020, constituting 44.3% percent of the total enrollment followed by a total of 546,079 women enrolled as research participants in FY 2021, constituting 43.0% of the total enrollment for that year. Total aggregate enrollment of men and women for both extramural and intramural clinical research were 1,021,211, 2,059,265, and 1,270,789 for the three fiscal years of 2019–2021 (Table 2).

The same years FY 2019–2021, respectively, show that minorities comprised 70.6%, 56.0%, and 59.5% (Table 2) of total enrollment. When the total enrollment increased in 2020, a larger proportion of the increase included non-minority participants. Notably, the precent of white participants increased from 24.6% to 32%, and 24.4% of the participants who had unknown race reported in that same year.

The U.S. site enrollment for all clinical research sex/gender by race and ethnicity reflects the detailed percentages for FY 2019-2021 (Table 3). The largest minority group was Black/African American at 29.0% females and 23.8 % males in FY 2019; 23.7% females and 13.3% males in FY 2020; and 14.0% females and 14.1% males in FY 2021. This change in male percentages can be attributed to the completion of a study with a large male population in FY 2020.The smallest minority group was Native Hawaiian/Pacific Islander at 0.2% females and 0.3% males in FY 2019; 0.4% females and 0.5% males in FY 2020; and 0.2% females and 0.3% males in FY 2021. However, in FY 2020 American Indian/Alaska Native had a lower percentage rate of 0.2% females and 0.3% males.

Comparatively, for all three years, NIAID is continuing its support of including women and minorities in its clinical research studies as shown in the enrollment data 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 2019, 2020, and 2021 (Table 4) show a greater percentage of women enrollees in all years. In FY 2019-2021, women made up 58.5 %, 55.8 %, and 46.3 % of all enrollees in Phase III clinical trials. Minority populations enrolled in these studies at high rates, especially Black/African Americans, with average enrollment for men and women combined ranging from 68.7 % – 54.7 %. The averages were calculated by combining females and males under the precent (%) Black/African American for each year from FY2019-2021 and presenting them as ranges.

Aggregate total inclusion data enrollment records (IERs) for FY 2019-2021 individually, were 2,026, 2,372, and 2,505 (Table 5A) for all study records. These data for FY 2019-2021 represent a total of 45, 70, and 101 (IERs) for NIAID's Phase III trials (Table 5B).

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

The NIH Report website is used by NIH to inform the public of how tax dollars are being spent on biomedical research within the 27 institutes and centers. Included are reports from Research Condition Disease Categorization (RCDC). RCDC is a NIH-wide,

computer-driven text-mining process that reports spending in more than 300 categories of diseases, conditions, or research areas. The next RCDC Triennial Inclusion Report will cover FY2019-2021 and include IC and NIH totals and median proportions for each of the 300+ categories. This report anticipated update will post to the website in March 2022. The website for the RCDC report can be found here: https://report.nih.gov/RISR/.

IV. Additional information

With the onset of the COVID-19 virus in early 2020, the Division of Microbiology and Infectious Diseases (DMID) faced an urgent public health need for rapid development of novel interventions. Four key priorities to fight the virus included:

- Improve fundamental knowledge of SARS-CoV-2 and COVID-19
- Support the development of diagnostics and assays
- Characterize and test therapeutics
- Develop safe and effective vaccines against SARS-CoV-2

To accomplish these goals, NIAID leveraged current resources, research programs, clinical trials networks, and collaborations with other U.S. government agencies and other key U.S. and global partners.

The result was a shifting of resources that slowed down or delayed some of DMIDs already in place contracts while at the same time rapidly increasing those involved with COVID-19. This shift in resources along with the overall COVID pandemic did have an effect in recruitment of subjects to clinical trials. This change should be temporary, however, as great strides have been made in the development of vaccines and therapeutics to fight COVID-19.

From a participation perspective, the COVID-19 clinical trial that recruited the most subjects was the Phase III trial: A Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19 in Hospitalized Adults.

This trial was an adaptive, randomized, placebo-controlled trial that evaluated the safety and efficacy of novel therapeutic agents in hospitalized adults diagnosed with COVID-19. It was a multi-center trial that was conducted in approximately 100 sites globally that compared different investigational therapeutic agents to a control arm. Most of this trial was completed by the end of FY 21. The Parent ID for this study is: 75N91019D00024-P00004-759102000010-0

Additional COVID trials not yet completed (and some still in development) will include analysis by race, though not as part of the primary endpoint analysis. They include:

ACV01: A study of booster vaccine in immunocompromised people.

CPAT Pilot: A pilot trial of a third dose of mRNA COVID vaccine in kidney transplant recipients (enrollment completed)

CPAT ISR: A randomized trial of immunosuppression reduction to induce a vaccine response in kidney and liver transplant recipients with no antibodies detectable after prior vaccination (not yet started).

CPAT HH: A randomized trial comparing homologous versus heterologous additional doses of vaccine in transplant recipients who have not responded to prior vaccination (in development).

PRISM: An observational cohort study of 250 children with COVID-19, with or without MISC.

Table 1: Total Enrollment: All NIH-Defined Clinical Research

Table 5-1-1-C. Enrollment for NIAID: All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity

Fiscal Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander
2019	Female	365,093	77.9	468,899	45.9	1,595	0.3	99,645	21.3	226,982	48.4	250	0.1
2019	Male	329,790	69.0	478,119	46.8	2,035	0.4	109,822	23.0	148,543	31.1	674	0.1
2019	Unknown	26,361	35.5	74,193	7.3	175	0.2	1,089	1.5	1,806	2.4	2	0.0
2020	Female	620,102	68.0	911,551	44.3	1,579	0.2	93,832	10.3	402,031	44.1	3,456	0.4
2020	Male	493,506	60.1	821,215	39.9	2,332	0.3	98,519	12.0	244,026	29.7	3,788	0.5
2020	Unknown	39,106	12.0	326,499	15.9	11	0.0	779	0.2	5,778	1.8	18	0.0
2021	Female	330,169	60.5	546,079	43.0	2,361	0.4	108,084	19.8	166,422	30.5	2,038	0.4
2021	Male	382,489	56.9	672,041	52.9	2,807	0.4	133,982	19.9	148,376	22.1	2,449	0.4
2021	Unknown	43,384	82.4	52,669	4.1	15	0.0	1,166	2.2	5,178	9.8	84	0.2

Fiscal Year	Sex Gender	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported2	% Unknown Not Reported3
2019	Female	93,289	19.9	9,136	1.9	38,002	8.1	372,938	79.5	39,934	8.5	56,027	11.9
2019	Male	151,689	31.7	18,878	3.9	46,478	9.7	343,124	71.8	71,480	15.0	63,515	13.3
2019	Unknown	5,921	8.0	266	0.4	64,934	87.5	33,656	45.4	23,295	31.4	17,242	23.2
2020	Female	311,813	34.2	15,568	1.7	83,272	9.1	749,995	82.3	125,483	13.8	36,073	4.0
2020	Male	347,050	42.3	25,396	3.1	100,104	12.2	624,348	76.0	151,244	18.4	45,623	5.6
2020	Unknown	776	0.2	331	0.1	318,806	97.6	13,487	4.1	32,397	9.9	280,615	85.9
2021	Female	212,565	38.9	14,096	2.6	40,513	7.4	460,529	84.3	53,370	9.8	32,180	5.9
2021	Male	292,534	43.5	31,390	4.7	60,503	9.0	531,420	79.1	98,395	14.6	42,226	6.3
2021	Unknown	608	1.2	4,695	8.9	40,923	77.7	6,838	13.0	36,848	70.0	8,983	17.1

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: Table 4-1-1-C. Total NIAID Enrollment: All NIH-Defined Clinical Research

Fiscal Year	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian
2019	1,021,211	2,026	721,244	70.6	3,805	0.4	210,556	20.6
2020	2,059,265	2,372	1,152,714	56.0	3,922	0.2	193,130	9.4
2021	1,270,789	2,505	756,042	59.5	5,183	0.4	243,232	19.1

Fiscal Year	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
2019	377,331	36.9	926	0.1	250,899	24.6	28,280	2.8	149,414	14.6
2020	651,835	31.7	7,262	0.4	659,639	32.0	41,295	2.0	502,182	24.4
2021	319,976	25.2	4,571	0.4	505,707	39.8	50,181	3.9	141,939	11.2

Table 3: US Site Enrollment: All NIH-Defined Clinical Research

Table 5-1-2-C. US Site Enrollment for NIAID: All NIH-Defined Extramural and Intramural Clinical Research, Sex/Gender by Race and Ethnicity

Fiscal Year	Sex Gender	Minority	% Minority	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander
2019	Female	63,952	43.6	942	0.6	4,190	2.9	42,631	29.0	245	0.2
2019	Male	93,613	43.1	1,421	0.7	7,669	3.5	51,706	23.8	669	0.3
2019	Unknown	1,109	6.7	6	0.0	40	0.2	762	4.6	2	0.0
2020	Female	249,653	48.1	977	0.2	35,186	6.8	122,868	23.7	2,073	0.4
2020	Male	213,608	41.3	1,432	0.3	39,872	7.7	68,891	13.3	2,660	0.5
2020	Unknown	772	0.3	11	0.0	32	0.0	272	0.1	4	0.0
2021	Female	70,388	25.8	1,657	0.6	6,257	2.3	38,210	14.0	635	0.2
2021	Male	113,444	29.5	2,078	0.5	10,090	2.6	54,317	14.1	1,298	0.3
2021	Unknown	620	7.6	15	0.2	31	0.4	227	2.8	5	0.1

Fiscal Year	Sex Gender	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	75,933	51.7	3,222	2.2	19,598	13.4	106,387	72.5	15,569	10.6	24,805	16.9
2019	Male	126,498	58.3	7,288	3.4	21,790	10.0	157,219	72.4	31,013	14.3	28,809	13.3
2019	Unknown	953	5.8	191	1.2	14,543	88.2	1,097	6.6	287	1.7	15,113	91.6
2020	Female	292,515	56.4	5,176	1.0	59,841	11.5	401,046	77.3	88,249	17.0	29,341	5.7
2020	Male	323,363	62.6	9,122	1.8	71,386	13.8	378,556	73.3	100,450	19.4	37,720	7.3
2020	Unknown	720	0.3	263	0.1	278,388	99.5	1,072	0.4	314	0.1	278,304	99.5
2021	Female	187,710	68.7	5,641	2.1	33,027	12.1	224,403	82.2	22,706	8.3	26,028	9.5
2021	Male	258,343	67.2	10,068	2.6	48,161	12.5	305,378	79.5	44,502	11.6	34,475	9.0
2021	Unknown	443	5.4	90	1.1	7,397	90.1	631	7.7	306	3.7	7,271	88.6

Table 4: All Enrollment: All NIH-Defined Clinical Research

Table 5-2-2-C. All Enrollment for NIAID: All NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

Fiscal Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander
2019	Female	18,200	97.6	18,657	58.5	11	0.1	1,961	10.5	15,205	81.5	2	0.0
2019	Male	11,962	91.9	13,014	40.8	20	0.2	2,815	21.6	7,281	55.9	11	0.1
2019	Unknown	214	97.7	219	0.7	3	1.4	7	3.2	204	93.2	0	0.0
2020	Female	21,164	97.4	21,738	55.8	12	0.1	1,977	9.1	18,149	83.5	1	0.0
2020	Male	12,355	91.5	13,506	34.6	20	0.1	2,893	21.4	7,545	55.9	11	0.1
2020	Unknown	3,743	99.9	3,746	9.6	0	0.0	7	0.2	3,736	99.7	0	0.0
2021	Female	19,599	93.4	20,988	46.3	45	0.2	1,590	7.6	14,064	67.0	12	0.1
2021	Male	17,976	90.0	19,971	44.0	176	0.9	1,574	7.9	8,439	42.3	38	0.2
2021	Unknown	4,395	99.9	4,400	9.7	2	0.0	7	0.2	4,293	97.6	0	0.0

Fiscal Year	Sex Gender	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	812	4.4	147	0.8	519	2.8	15,221	81.6	1,375	7.4	2,061	11.0
2019	Male	1,713	13.2	276	2.1	898	6.9	8,912	68.5	1,855	14.3	2,247	17.3
2019	Unknown	1	0.5	0	0.0	4	1.8	202	92.2	6	2.7	11	5.0
2020	Female	931	4.3	147	0.7	521	2.4	18,277	84.1	1,376	6.3	2,085	9.6
2020	Male	1,819	13.5	298	2.2	920	6.8	9,303	68.9	1,888	14.0	2,315	17.1
2020	Unknown	1	0.0	0	0.0	2	0.1	3,733	99.7	3	0.1	10	0.3
2021	Female	3,656	17.4	208	1.0	1,413	6.7	15,896	75.7	4,130	19.7	962	4.6
2021	Male	5,943	29.8	1,909	9.6	1,892	9.5	11,072	55.4	7,996	40.0	903	4.5
2021	Unknown	67	1.5	0	0.0	31	0.7	4,292	97.5	96	2.2	12	0.3

Table 5A: Section 2: Metrics Based on Inclusion Data Records (IERs)

Table 2-1. Total NIAID Inclusion Data Records (IERs): All NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2019 and 2021

Fiscal Year	Total IERs	IERs Without Enrollment	IERs With Enrollment	US Site IERs	Non-US Site IERs	Female Only IERs	Male Only IERs	IERs Excluding Male only and Female only*
2019	2,026	558	1,468	999	469	130	93	1,245
2020	2,372	863	1,509	1,014	495	135	87	1,287
2021	2,505	982	1,523	1,034	489	120	85	1,318

*Inclusion Data Records (IERs) 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 (IERs): All NIH-Defined Phase III Trials

Table 2-2. Total NIAID Inclusion Data Records (IERs): All NIH-Defined Extramural and Intramural Phase III Trials Reported Between Fiscal Years 2019 and 2021

Fiscal Year	Total IERs	IERs Without Enrollment	IERs With Enrollment	US Site IERs	Non-US Site IERs	Female Only IERs	Male Only IERs	IERs Excluding Male only and Female only*
2019	45	13	32	13	19	4	1	27
2020	70	33	37	14	23	6	2	29
2021	101	32	69	32	37	5	10	54

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