

# **National Institute of General Medical Sciences (NIGMS) Report for Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2019 – FY2021**

## **I. Background/Overview**

The NIH Revitalization Act of 1993 (PL 103-43) included a provision that women and minorities must be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Included in this Act was a statement indicating that “The advisory council of each national research institute shall prepare biennial reports describing the manner in which the Institute has complied with this section.” 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. This triennial report provides information on inclusion of participants in NIGMS clinical research from FY 2019 – 2021 and serves to document how NIGMS has continued to comply with this policy requirement.

NIGMS' research mission is aimed at understanding the principles, mechanisms, and processes that underlie living organisms, often using research organisms. NIGMS also supports the development of fundamental methods and new technologies to achieve its mission. NIGMS-supported research may utilize specific cells or organ systems if they serve as models for understanding general principles. Research with the overall goal to gain knowledge about a specific organ or organ system or the pathophysiology, treatment, or cure of a specific disease or condition will, in most cases, be supported by other Institutes or Centers. NIGMS does support research in specific clinical areas that affect multiple organ systems: anesthesiology and peri-operative pain; sepsis; clinical pharmacology that is common to multiple drugs and treatments; and trauma, burn injury, and wound healing. In addition, many NIGMS IDeA state capacity building programs contain clinical research components.

NIGMS' budget increased each year; \$2,872,780 in FY 2019, \$2,937,218 in FY 2020, and \$2,991,417 in FY2021 which correlates with the increased number of awards. In FY 2019 and FY 2020, approximately 9% of the research project grants awarded by NIGMS reported involvement of human subjects in research activities and approximately 6% of the research project grants awarded by NIGMS contained clinical research that is subject to the NIH Policy on Inclusion of Women and Minorities as Subjects in Clinical Research. In FY 2021 this

increased to approximately 11% and 7%, respectively. These increases are explained below in Section II Part D.

Fiscal Year	Number of Research Awards	Number of Research Awards with Human Subjects	Number of Research Awards Subject to NIH Inclusion Policy
2019	5876	535	344
2020	6094	577	378
2021	6287	672	448

## **II. Strategies for Ensuring Compliance**

### **A. Peer Review**

The implementation of inclusion guidelines involves the participation of review, program, policy, and grants management staff. Inclusion is first addressed by peer review. Reviewers on NIH peer review panels are given specific guidance on reviewing inclusion on the basis of sex/gender, race, ethnicity, and age when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for the involvement of human subjects, including the inclusion (or exclusion) of individuals on the basis of sex/gender, race, ethnicity, and the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. Unacceptable inclusion plans must be reflected in the priority score of the application and documented in the summary of the review session. Initial review groups make recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. If issues are raised in review, program staff notify principal investigators and Authorized Organizations Representatives, who are required to address these issues prior to funding. Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received.

## B. Program Monitoring and Grants Management Oversight

Prior to an award, program officers 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. 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.

## C. Intramural

NIGMS does not have an Intramural Division.

## D. Describe IC training approaches.

Until 2019, NIGMS had a single point of contact responsible for ensuring compliance with NIH Human Subjects and Inclusion policy. In 2020, NIGMS formed the Human Subjects Compliance Committee (HSCC). The HSCC is composed of a liaison from each Programmatic Division and liaisons from Scientific Review and Grants Management branches. The HSCC is chaired by a representative from the Division of Extramural Activities. The HSCC Chair is the IC point of contact for the NIH Office of Extramural research (OER) and attends relevant NIH-wide meetings and educational seminars. Information provided from OER is presented at the HSCC monthly meetings, then the liaisons inform their Division or Branch.

The HSCC is responsible for ensuring compliance with NIH Human Subjects and Inclusion policies. Additionally, the HSCC has implemented the following:

- Create and maintain Standard Operating Procedures and guidance for NIGMS staff.
- Disseminate information from OER to NIGMS staff.
- Identify applications that are non-compliant with the Human Subjects/Inclusion policy and resolve the compliance issue.
- Provide training for using the eRA HSS Module to NIGMS staff.
- Track required Good Clinical Practice (GCP) certifications for NIGMS staff.

As a result of the HSCC practices, NIGMS has reduced the number and improved the time of resolution for non-compliant applications. In FY 2019 the total number of awarded Human Subjects Code 48 (unacceptable) applications was several dozen and in late FY 2021 it was under ten. The HSCC actively identifies non-compliant applications. One common issue was the mislabeled Human Subjects coding which reported applications as non-Human Subjects when they did involve Human Subjects research. The HSCC also provides training and guidance to IC Program staff on using the Human Subjects System (HSS) so they can better guide PIs on appropriate data entry.

### I. Analysis and Interpretation of Data

**Table 2-1: Total Inclusion Enrollment Reports (IERs) for NIH-Defined Extramural 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	505	161	344	339	5	42	11	291
2020	714	262	452	445	7	52	9	391
2021	791	356	435	431	4	40	8	387

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

The number of NIGMS inclusion enrollment records as a percentage of NIGMS awarded grants gradually increased in this time period: FY2019 (9%), FY2020 (12%), FY2021 (13%).

**Table 3-1-A: Total Enrollment for All NIH-Defined Extramural and Intramural Clinical Research Between Fiscal Years 2019 and 2021**

Note: This table has been separated into two portions for viewing.

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown
2019	66,811	35,112	52.6	25,267	37.8	6,432	9.6
2020	102,782	55,106	53.6	43,565	42.4	4,111	4.0
2021	115,065	62,798	54.6	48,798	42.4	3,469	3.0

Fiscal Year	Enrollment in Female only	% Female only	Enrollment in Male only	% Male only	% Excluding			
					Females, Female only	Females, Female only	Males, Male only	% Males, Male only
2019	3,705	5.5	100	0.1	31,407	47.0	25,167	37.7
2020	3,794	3.7	68	0.1	51,312	49.9	43,497	42.3
2021	3,487	3.0	31	0.0	59,311	51.5	48,767	42.4

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

Note: This table has been separated into multiple portions for viewing. Below each table is a summary of notable trends or changes.

Tables 5-1-1-C: Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity – Section I

Fiscal Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total
2019	Female	14,120	40.2	35,112	52.6
2019	Male	9,288	36.8	25,267	37.8
2019	Unknown	582	9.0	6,432	9.6
2020	Female	22,297	40.5	55,106	53.6
2020	Male	15,562	35.7	43,565	42.4
2020	Unknown	519	12.6	4,111	4.0
2021	Female	23,496	37.4	62,798	54.6
2021	Male	16,998	34.8	48,798	42.4
2021	Unknown	207	6.0	3,469	3.0

NIGMS has increased total enrollments for minority participants in studies, but their representation has slightly decreased over the last three years.

Tables 5-1-1-C: Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity – Section II

Fiscal Year	Sex Gender	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian
2019	Female	2,335	6.7	1,299	3.7
2019	Male	1,271	5.0	965	3.8
2019	Unknown	57	0.9	47	0.7
2020	Female	2,189	4.0	1,856	3.4
2020	Male	1,758	4.0	1,671	3.8
2020	Unknown	32	0.8	19	0.5
2021	Female	1,037	1.7	2,315	3.7
2021	Male	837	1.7	2,061	4.2
2021	Unknown	34	1.0	17	0.5

From FY 2019-2021, there was a downward trend in the percentage of American Indian/Alaska Native enrollment. This is likely because the NIGMS Native American Research Centers for Health (NARCH) funding opportunity announcement was not available for new applications in 2018-2019 so no new enrollments began in 2020-2021. However, NARCH began accepting new applications in 2020-2021. There were no significant changes to the percentage of ethnic Asian enrollment.

Tables 5-1-1-C: Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity – Section III

Fiscal Year	Sex Gender	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander
2019	Female	4,342	12.4	86	0.2
2019	Male	3,767	14.9	75	0.3
2019	Unknown	373	5.8	6	0.1
2020	Female	9,253	16.8	247	0.4
2020	Male	7,168	16.5	174	0.4
2020	Unknown	43	1.0	2	0.0
2021	Female	9,747	15.5	328	0.5
2021	Male	8,301	17.0	313	0.6
2021	Unknown	70	2.0	0	0.0

From FY 2019-2021, there was an increase in the total enrollment of Black/African Americans and Native Hawaiian Pacific Islanders. The percentage enrollment of participants identifying as male, and female increased over the same time period.

Tables 5-1-1-C: Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity – Section IV

Fiscal Year	Sex Gender	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2019	Female	19,225	54.8	2,447	7.0	5,378	15.3
2019	Male	14,447	57.2	643	2.5	4,099	16.2
2019	Unknown	2,433	37.8	23	0.4	3,493	54.3
2020	Female	30,169	54.7	5,815	10.6	5,577	10.1
2020	Male	25,178	57.8	2,805	6.4	4,811	11.0
2020	Unknown	330	8.0	364	8.9	3,321	80.8
2021	Female	37,077	59.0	6,490	10.3	5,804	9.2
2021	Male	29,309	60.1	3,060	6.3	4,917	10.1
2021	Unknown	290	8.4	46	1.3	3,012	86.8

FY 2019-2021 there was a gradual increase in male and female White enrollment without significant change in percentage. FY 2020 saw a significant drop in enrollment and the percentage of unknown gender (29.2%) enrollment. In FY 2020 there was a large increase in the total enrollment and percentage of all gender types for persons with more than one race. In FY 2021 the total enrollment gradually increased and percentages stabilized for male and female. However, the unknown gender total enrollment and percentage dropped significantly (7.6%).

Tables 5-1-1-C: Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity – Section V

Fiscal Year	Sex Gender	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	26,430	75.3	5,621	16.0	3,061	8.7
2019	Male	19,858	78.6	2,930	11.6	2,479	9.8
2019	Unknown	3,470	53.9	89	1.4	2,873	44.7
2020	Female	42,332	76.8	7,769	14.1	5,005	9.1
2020	Male	34,705	79.7	4,232	9.7	4,628	10.6

2020	Unknown	474	11.5	63	1.5	3,574	86.9
2021	Female	47,986	76.4	10,008	15.9	4,804	7.6
2021	Male	38,205	78.3	5,867	12.0	4,726	9.7
2021	Unknown	411	11.8	63	1.8	2,995	86.3

In FY 2020 there was a significant increase in the total number of male and female non-Hispanic enrollment which continue to trend update in FY 2021. However, the percentage did not correlate and remained consistent. For unknown gender the total enrollment and percentage dropped significantly (42.4%) which stabilized in FY 2021. Male and female Hispanic and Latino total enrollment increased with no statistical changes to percentage.

FY 2019-2021 enrollment for male and female unknown race increased gradually without significant change in percentage. In FY 2020 the unknown gender increased in enrollment but the percentage nearly doubled from FY 2019. In FY 2021 the enrollment total decreased significantly but the percentage stabilized. For unknown ethnicity the enrollment totals for male and female gradually increased dropped significantly in percentage. The opposite was recorded for unknown gender. Prior to January 1, 2019, awardees were not required to submit participant-level data for their human subject studies. The new policy affected applications awarded after this date. Those applications generally had human subjects studies which began in FY 2020. The increase in reporting of unknown as the gender is the result of this policy change as awardees use unknown to represent de-identified samples when human subjects monitoring is required.

NIGMS does support Phase III clinical trials. However, during FY 2019-2021 there were no new or ongoing awarded Phase III clinical trials that required human subjects and inclusion monitoring.

Inclusion enrollment data by Research Condition and Disease Categorization (RCDC) category are available through this link: <https://report.nih.gov/RISR/>.

## I. Additional information

NIGMS is committed to promoting inclusion in human subjects through targeted funding opportunity announcements. One example is the program announcement “Native American Research Centers for Health (NARCH) (S06 – Clinical Trial Optional)”. The purpose of NARCH is to work toward reducing health disparities and promoting wellness in AI/AN populations by allowing the AI/AN communities to select, control and prioritize health-related research and research career enhancement opportunities.