

# **National Cancer Institute Triennial Report: Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2019 – FY2021**

*Presentation to the National Cancer Advisory Board*

# Background

- NIH is mandated by the Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2 to ensure the inclusion of women and minority groups in all NIH-funded clinical research in a manner that is appropriate to the scientific question under study.
  - The primary goal of this law is to ensure that research findings can be generalizable to the entire population.
- The NIH Revitalization Act of 1993 (PL 103-43), amended by the 21<sup>st</sup> Century Cures Act, requires the advisory board of each NIH institute to prepare a triennial report describing the manner in which the institute has complied with NIH inclusion guidelines and tracking requirements.
  - This presentation expands on the data included in the triennial report.

# Source of NIH Inclusion Data for NIH-Defined Clinical Research Studies

- NIH-supported researchers must collect information on participant sex/gender, race, and ethnicity for studies involving human subjects that meet the [NIH definition of clinical research](#):
- Research with human subjects that is:
  - **1) Patient-oriented research.** Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
  - **2) Epidemiological and behavioral studies.**
  - **3) Outcomes research and health services research.**
- Grantees must report this information annually as part of their annual Research Performance Progress Report (RPPR).
- Contracts and intramural program researchers also report annually.

# NCI's Portfolio for Inclusion Reporting Includes Studies Supported by the Following NCI Divisions and Centers:

## Intramural Research

- Division of Cancer Epidemiology and Genetics
- Center for Cancer Research

## Extramural Research

- Division of Cancer Biology
- Division of Cancer Control and Population Sciences
- Division of Cancer Prevention
- Division of Cancer Treatment and Diagnosis

## Extramural Research (cont.)

- OD, Center for Cancer Genomics
- OD, Center for Cancer Training
- OD, Center for Global Health
- OD, Center for Strategic Scientific Initiatives
- OD, Center to Reduce Cancer Health Disparities
- OD, Office for Cancer Centers
- OD, Office of HIV and AIDS Malignancy
- OD, Small Business Innovation Research Development Center

# Strategies for Ensuring Compliance

- Implementation of inclusion guidelines involves participation of review, program, policy, and grants management staff.
  - **Peer review:** Reviewers evaluate applications for the appropriateness of the inclusion plans and analyses and NCI staff work with investigators to resolve any issues.
  - **Program Monitoring and Grants Management Oversight:** Program staff monitor enrollment progress in annual progress reports and address issues as necessary. Grants management staff ensure appropriate terms and conditions are included and documented for the grant.
  - **Intramural:** Intramural investigators provide inclusion plans that are considered during scientific review. Enrollment progress is reviewed as part of annual scientific and IRB review, and any issues are resolved.
  - **Training:** Regular inclusion training is provided to program and review staff.

# Data and Key Limitations

- This presentation covers the enrollment data reported for fiscal years 2019-2021. There are several limitations to these data, so the data are intended as a broad overview of general inclusion trends, not as a precise count of trials or participants:
  - **Inclusion Data Records (IERs) do not represent a count of total studies or trials.** Multiple IERs may be submitted for a single trial; thus, IERs do not represent an exact number of studies.
  - **The inclusion data do not represent the enrollment for a single year.** The data are cumulative for the entire span of the project (e.g., grant, contract, or intramural study).
  - **Grants that are recompeted in a fiscal year are not included in the data for that year.** Type 2 grant applications provide only planned data, not actual data enrollment data for that year, so their records and enrollment are not included in the recompetition fiscal year. Both the National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP) grants were recompeted in FY2019.
  - **One-time data entry error in FY2021:** The FY2021 data included in the Triennial Report included an erroneous record identified after the data tables were frozen by NIH which led to significantly higher FY2021 enrollment counts. This has been noted in the report. Corrected data are noted in the report and corrected data have been used throughout this presentation.

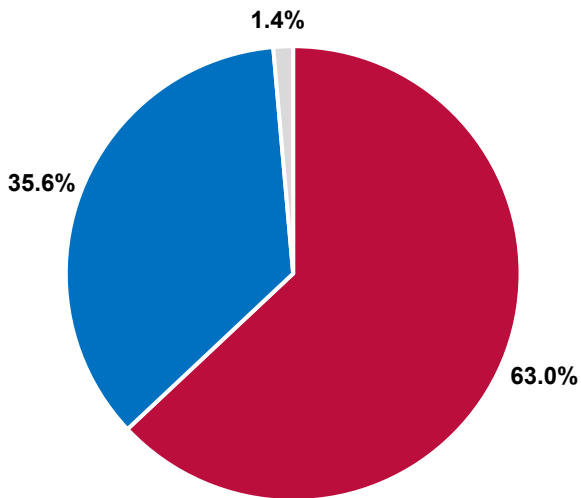
# FY19-21 Summary of Inclusion Records and Enrollment Numbers for All Clinical Research Studies

**Total Inclusion Data Records (IERs) and Enrollment for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2019 and 2021 and Proportion Enrollment by US Sites**

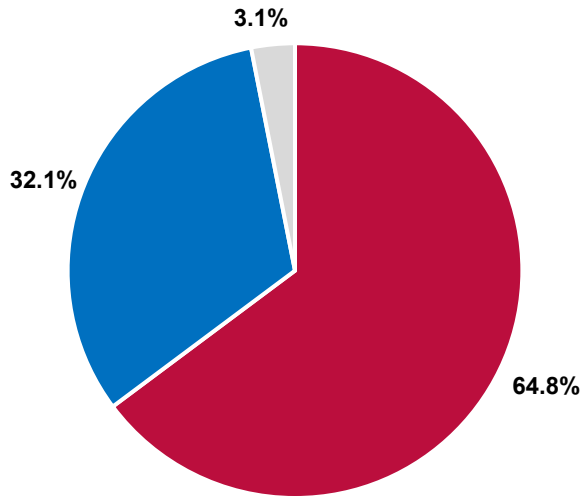
<b>Fiscal Year</b>	<b>IERs With Enrollment</b>	<b>Total Enrollment</b>	<b>US Only Enrollment</b>	<b>% US Only Enrollment</b>
2019	2,401	3,208,121	2,701,330	84.2%
2020	2,294	3,750,202	3,219,014	85.8%
2021	2,532	3,487,702	3,032,666	87.0%

# FY19-21 Inclusion Data for All Clinical Research Studies by Sex/Gender

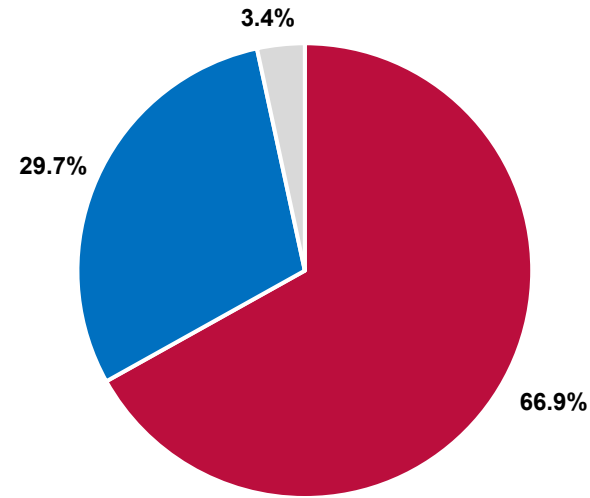
FY2019



FY2020



FY2021

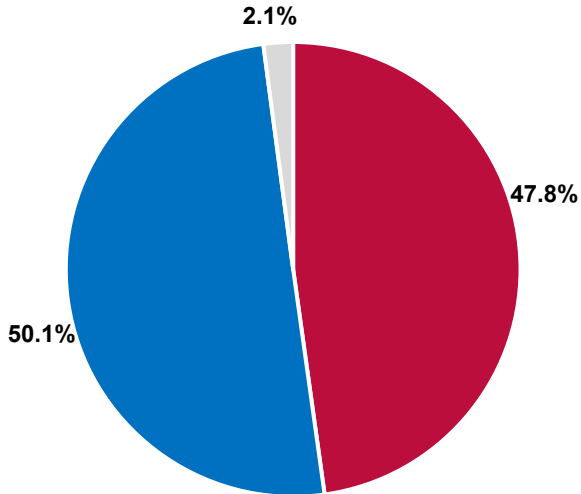


■ % Female   ■ % Male   ■ % Unknown/Not Reported

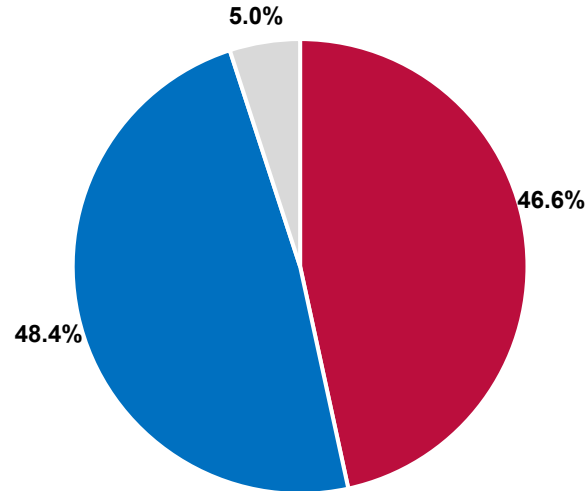


# FY19-21 Inclusion Data for Clinical Research Studies, Excluding All Male/All Female Studies, by Sex/Gender

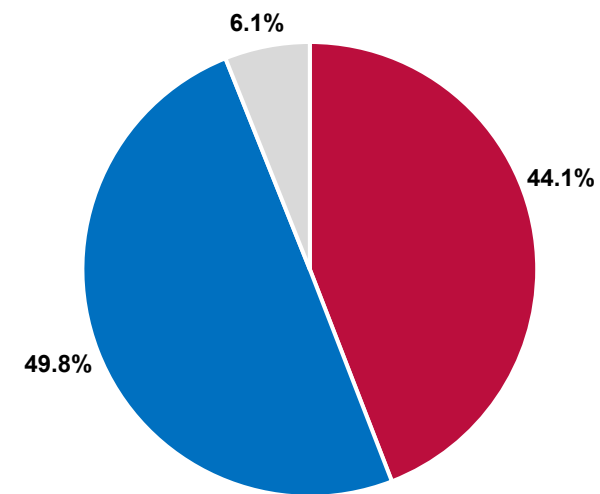
**FY2019**  
(1,738 IERs)



**FY2020**  
(1,746 IERs)

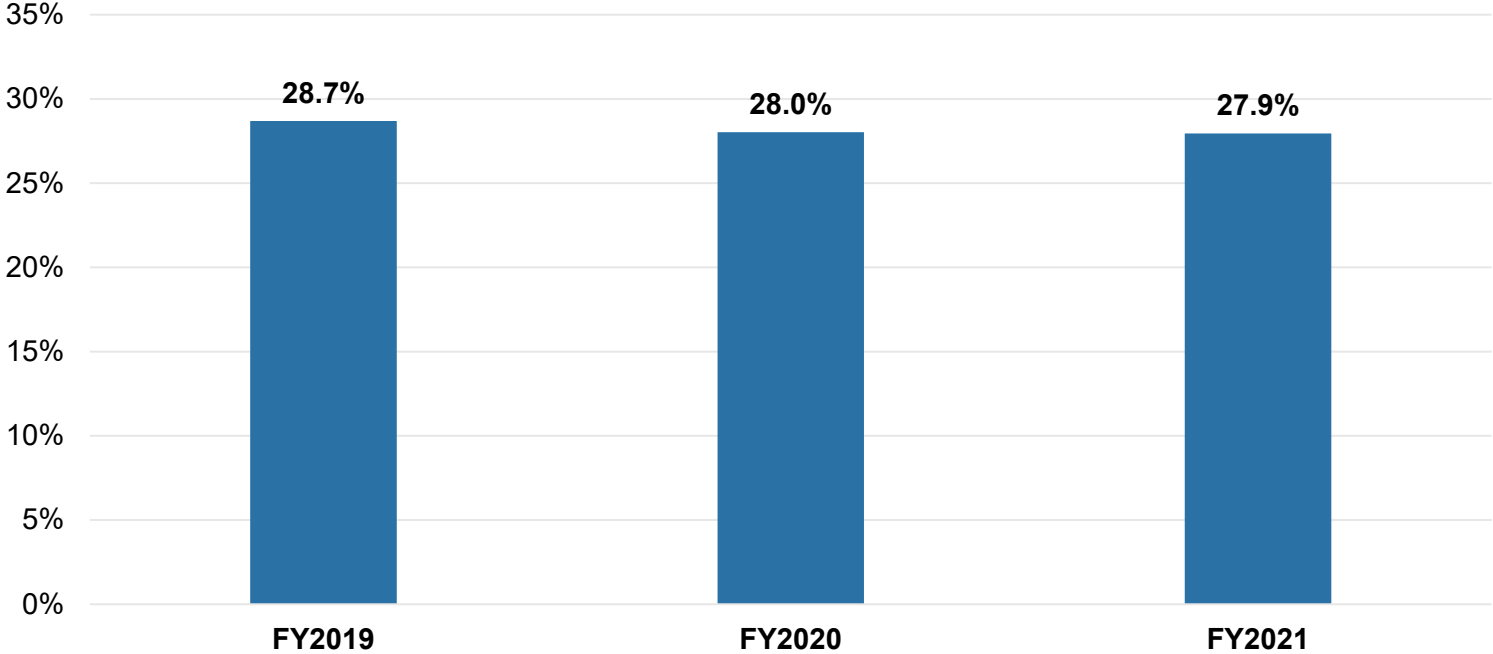


**FY2021**  
(1,902 IERs)



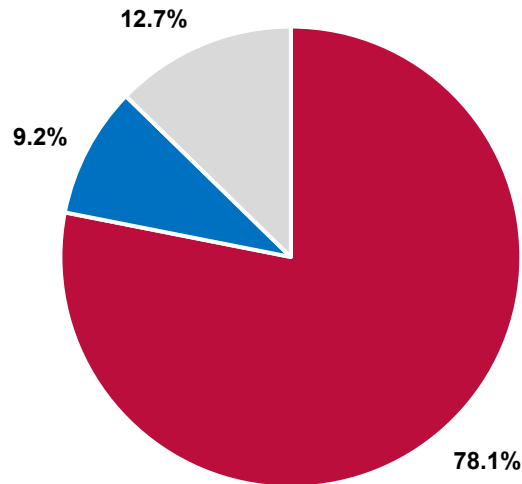
■ % Female   ■ % Male   ■ % Unknown/Not Reported

# FY19-21 Inclusion Data for All Clinical Research Studies, Proportion Minority Participants by Race/Ethnicity

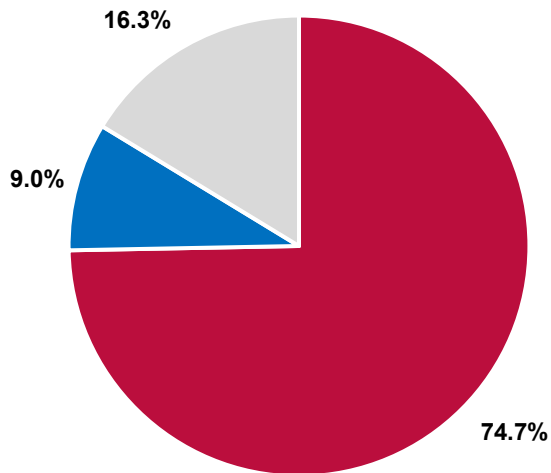


# FY19-21 Inclusion Data for All Clinical Research Studies by Ethnicity

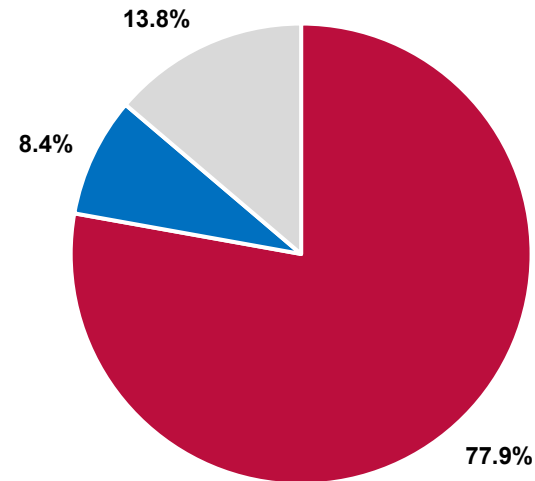
FY2019



FY2020

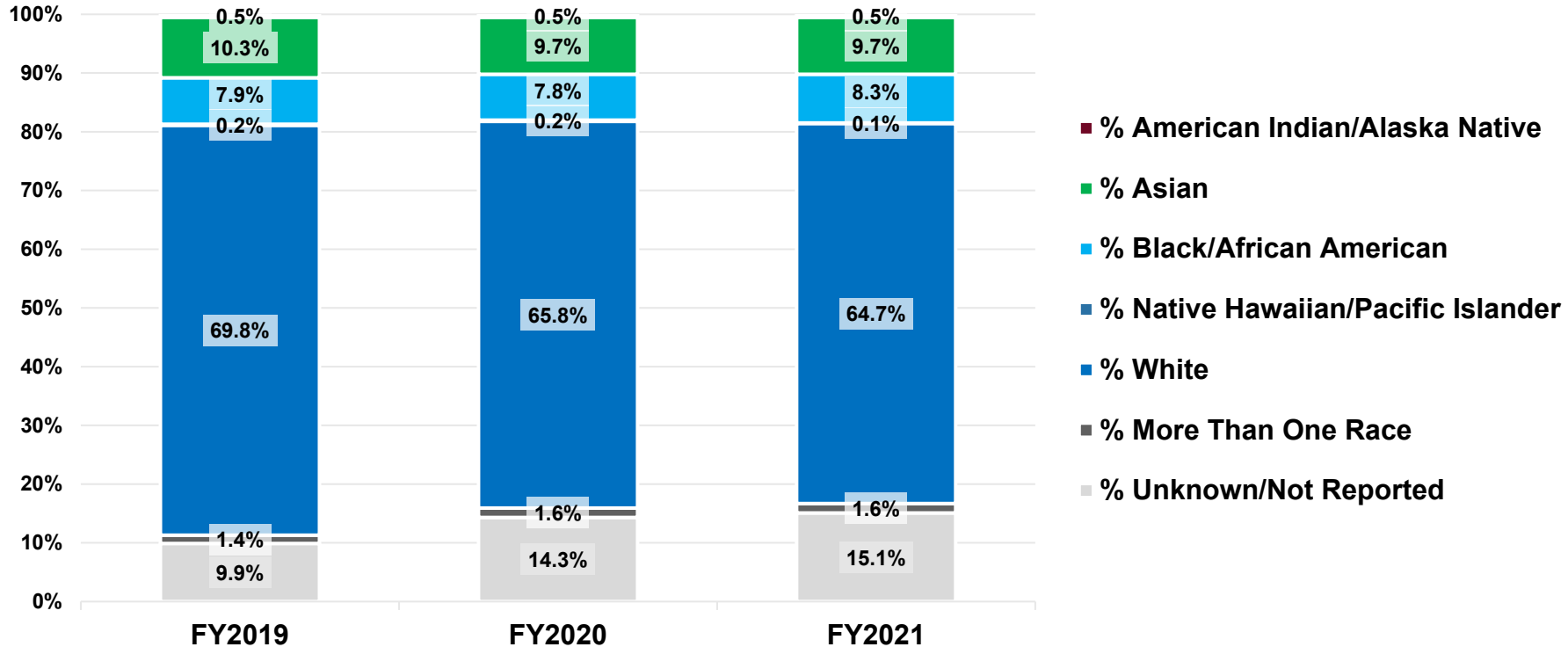


FY2021



■ % Not Hispanic/Latino   ■ % Hispanic/Latino   ■ % Unknown/Not Reported

# FY19-21 Inclusion Data for All Clinical Research Studies by Race



# FY19-21 Inclusion Data for All Clinical Research Studies by Extramural or Intramural Program

	Total Reported Enrollment	Total Inclusion Data Records				<i>Excluding All Male / All Female Studies</i>			
			% Female	% Male	% Unknown / Not Reported	Total Reported Enrollment	% Female	% Male	% Unknown / Not Reported
<b>Extramural</b>									
FY2019	1,608,086	2,653	63.0%	35.6%	1.4%	749,200	51.8%	47.1%	1.1%
FY2020	2,143,104	2,813	64.8%	32.1%	3.1%	1,009,612	48.1%	44.1%	7.7%
FY2021	2,106,009	3,332	66.9%	29.7%	3.4%	833,412	46.5%	43.7%	9.8%
<b>Intramural</b>									
FY2019	1,600,035	633	51.2%	46.6%	2.2%	1,340,162	45.6%	51.8%	2.6%
FY2020	1,607,098	615	51.8%	45.7%	2.5%	1,342,465	45.4%	51.6%	2.9%
FY2021	1,381,693	597	50.5%	46.9%	2.6%	1,113,308	42.3%	54.4%	3.3%

	% Minority	% Not Hispanic / Latino	% Hispanic / Latino	% Unknown / Not Reported	% American Indian / Alaska Native	% Asian	% Black / African American	% Native Hawaiian / Pacific Islander	% White	% More Than One Race	% Unknown / Not Reported
FY2019	34.4%	73.3%	13.2%	13.6%	0.6%	7.5%	11.7%	0.2%	66.6%	2.6%	10.7%
FY2020	31.7%	68.8%	11.6%	19.6%	0.7%	7.2%	10.5%	0.2%	60.9%	2.7%	17.8%
FY2021	30.3%	74.0%	9.7%	16.3%	0.6%	7.2%	11.0%	0.2%	59.4%	2.5%	19.0%
<b>Intramural</b>											
FY2019	22.9%	83.0%	5.2%	11.8%	0.3%	13.1%	4.1%	0.1%	73.0%	0.2%	9.1%
FY2020	23.1%	82.6%	5.5%	11.9%	0.3%	13.1%	4.1%	0.1%	72.5%	0.2%	9.7%
FY2021	24.4%	83.8%	6.4%	9.8%	0.3%	13.4%	4.1%	0.1%	72.8%	0.3%	9.0%

# Special Considerations for NIH-Defined Phase III Clinical Trials

- NIH-defined phase III clinical trials must also be designed to permit “valid analysis” of group differences on the basis of sex/gender, race, and ethnicity, unless there is clear evidence that such differences are unlikely to be seen.
- The following definition is used for [NIH-defined phase III clinical trials](#):

An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.
- Because of the additional requirements for NIH-defined phase III trials, NCI and NIH conduct additional analyses of the inclusion data for these trials.

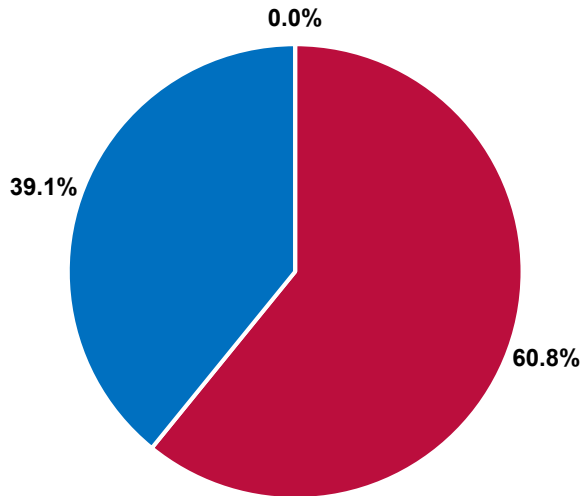
# FY19-21 Summary of Inclusion Records and Enrollment Numbers for All NIH-Defined Phase III Clinical Trials

**Total Inclusion Data Records (IERs) and Enrollment for NIH-Defined Extramural and Intramural NIH-Defined Phase III Trials Reported Between Fiscal Years 2019 and 2021 and Proportion Enrollment by US Sites**

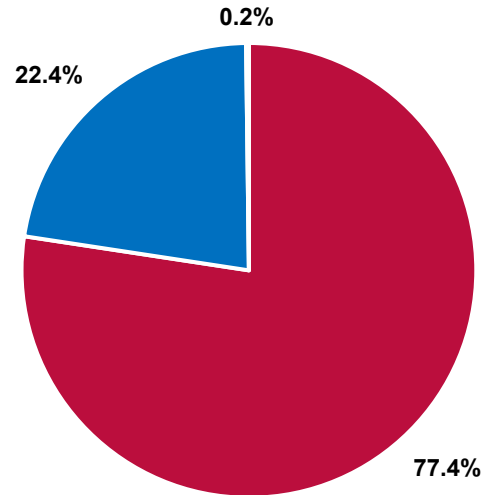
<b>Fiscal Year</b>	<b>IERs With Enrollment</b>	<b>Total Enrollment</b>	<b>US Only Enrollment</b>	<b>% US Only Enrollment</b>
2019	30	50,562	39,685	78.5%
2020	191	90,982	68,075	74.8%
2021	201	123,025	91,460	74.3%

# FY19-21 Inclusion Data for All NIH-Defined Phase III Clinical Trials by Sex/Gender

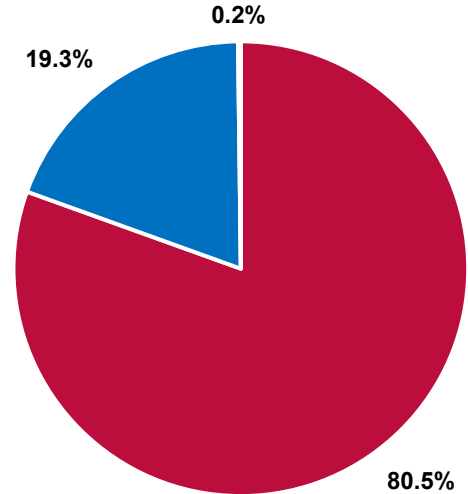
FY2019



FY2020



FY2021



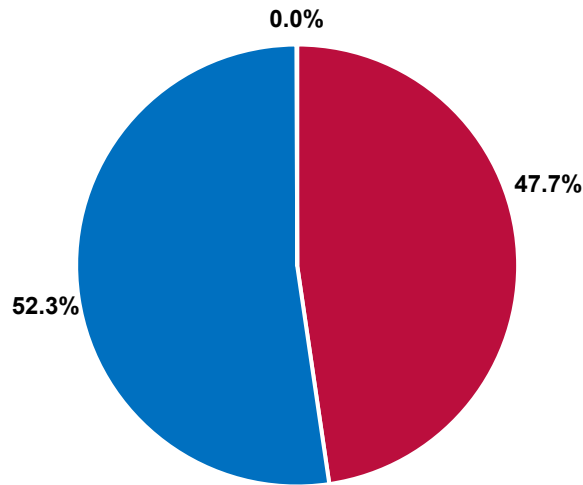
■ % Female   ■ % Male   ■ % Unknown/Not Reported

Note: A higher proportion of female participants were reported in FY2020 and FY2021; this was largely driven by significant enrollment to the NCORP Tomosynthesis Mammographic Imaging Screening Trial (TMIST) trial.

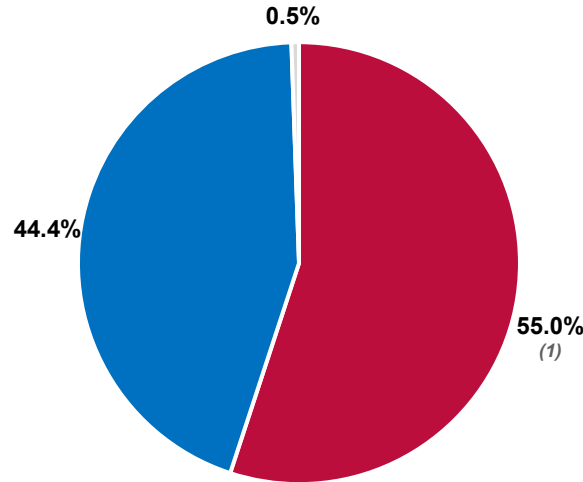


# FY19-21 Inclusion Data for NIH-Defined Phase III Clinical Trials Excluding All Male/All Female Studies, by Sex/Gender

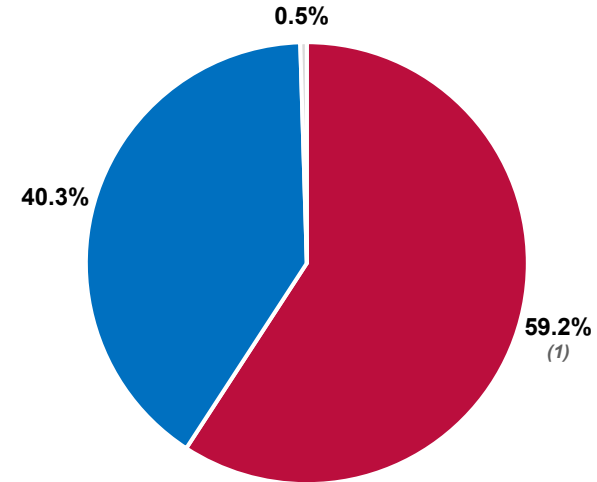
**FY2019**  
(23 IERs)



**FY2020**  
(126 IERs)



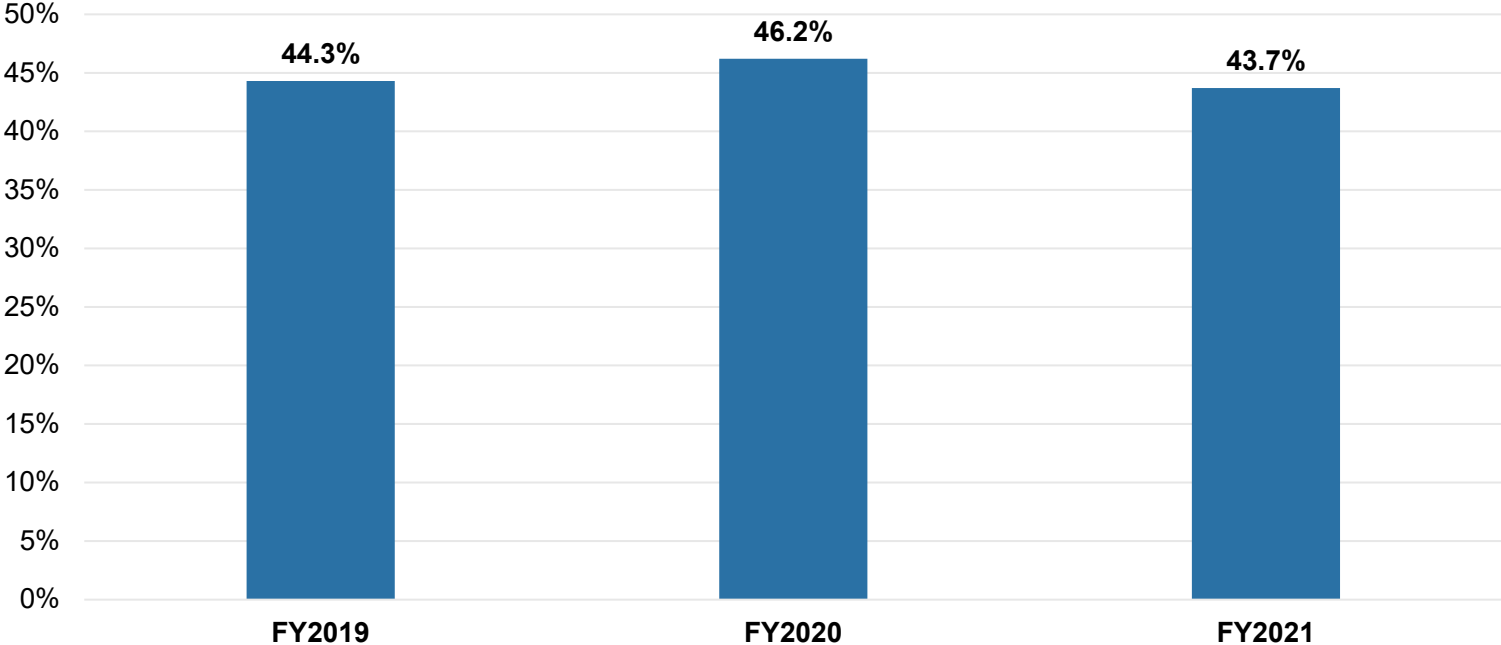
**FY2021**  
(140 IERs)



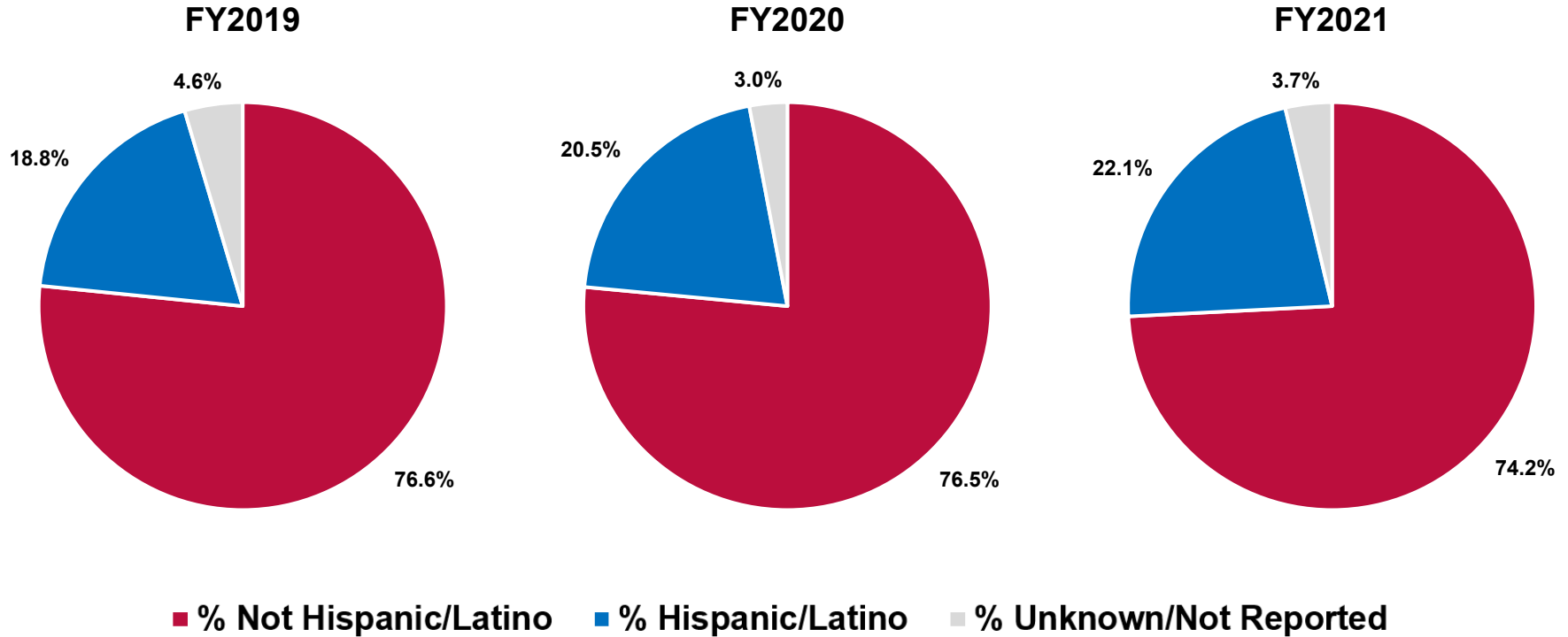
■ % Female   ■ % Male   ■ % Unknown/Not Reported

1) The NCTN supports a number of trials in breast cancer patients that are open to male patients with breast cancer. Because these studies are not single-sex, they are included in these graphs even though the great majority of participants are female.

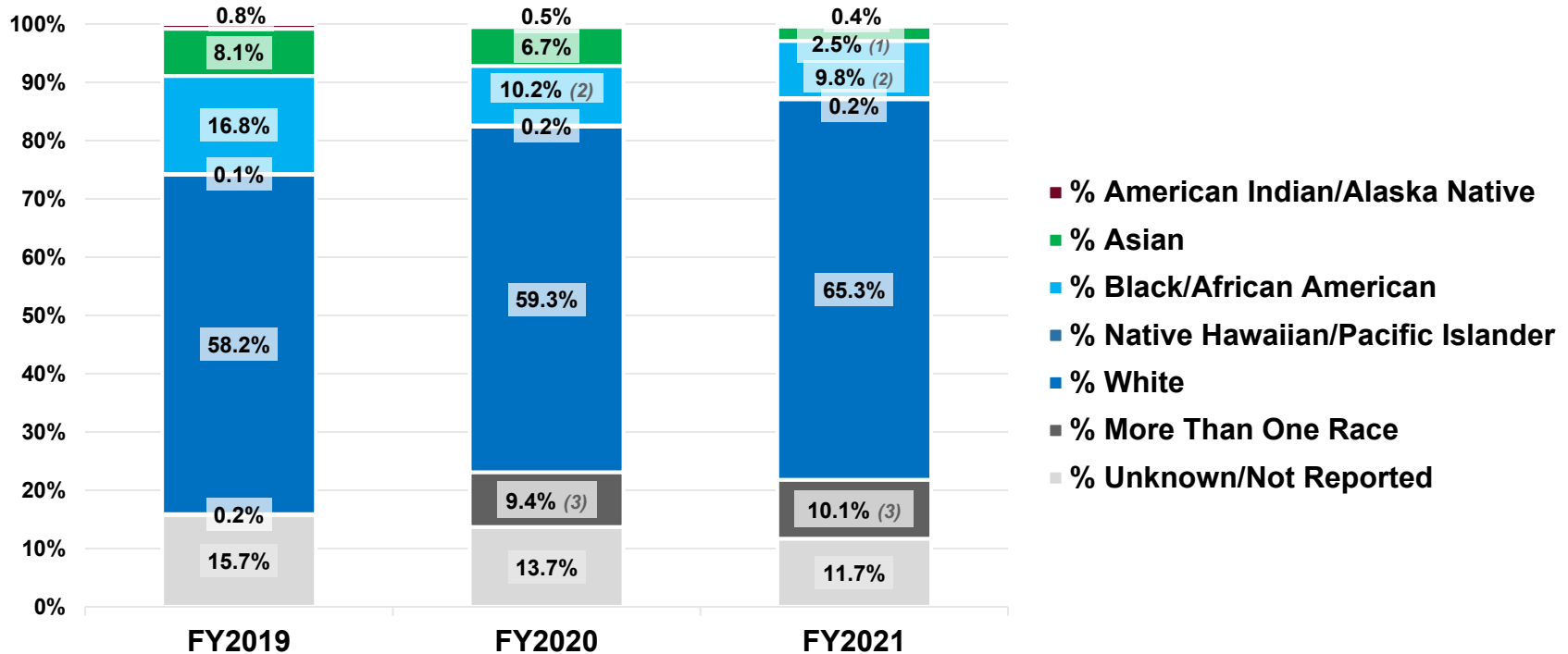
# FY19-21 Inclusion Data for All NIH-Defined Phase III Clinical Trials, Proportion Minority Participants by Race/Ethnicity



# FY19-21 Inclusion Data for All NIH-Defined Phase III Clinical Trials by Ethnicity



# FY19-21 Inclusion Data for All NIH-Defined Phase III Clinical Trials by Race



- 1) A grant with significant non-US enrollment, particularly of Asian participants, completed in FY2020. This resulted in a smaller proportion of Asian participants reported in FY2021.
- 2) The trials reporting enrollment in FY2019 included large trials with particular focus on enrollment of Black and African American participants, resulting in a higher proportion of Black and African American participants in FY2019 and relatively lower proportions in FY2020 and FY2021.
- 3) A data error led to some clinical trial participants being erroneously coded as More Than One Race in FY2020 and FY2021.

***Many thanks to the NCI staff and supported investigators who have worked to ensure the accuracy of NCI's inclusion data.***

# Reference: NIH Inclusion Policies and Resources

- The NIH grants website includes a section on Inclusion Policies with helpful links and resources for the research community for the “Inclusion of Women and Minorities” and “Inclusion Across the Lifespan” policies: <https://grants.nih.gov/policy/inclusion.htm>
  - Full Inclusion of Women and Minorities Policy (2001): NOT-OD-02-001 (<https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm>)
  - Amendment to the Inclusion of Women and Minorities Policy (2017) revising the NIH-defined phase III trial valid analysis reporting requirements: NOT-OD-18-014 (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-014.html>)
  - Inclusion Across the Lifespan Policy (2017): NOT-OD-18-116 (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html>)
- 2020 NCAB presentation of Accrual of Minorities into NCTN and NCORP Clinical Trials: <https://deainfo.nci.nih.gov/advisory/joint/0620/McCaskillStevens.pdf>



**NATIONAL  
CANCER  
INSTITUTE**

[www.cancer.gov](http://www.cancer.gov)

[www.cancer.gov/espanol](http://www.cancer.gov/espanol)