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Triennial Advisory Council Report on Human Subjects Participation in NHGRI-Sponsored Research, FY2019-FY2021

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National Human Genome
Research Institute

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Inclusion Monitoring

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- Public Health Service Act
 - Inclusion of women and minority groups in all NIH-funded clinical research in a manner that is appropriate to the scientific question
 - Research findings can be generalizable to the entire population
 - Clinical trials to be designed to provide information about differences by sex/gender, race and/or ethnicity

Clinical Research

1. Patient-oriented research
 - Mechanisms of human disease
 - Therapeutic interventions
 - Clinical trials
 - Development of new technologies
2. Epidemiological and behavioral studies
3. Outcomes research and health services research

Inclusion Enrollment Report (IER)

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Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0	0	0	0
Total	0	0	0	0	0

NACHGR Review

On a triennial basis, each NIH Institutional Advisory Council is required to review the aggregate data on the cumulative enrollment of participants to ensure that the Institute:

- 1) Is in compliance with the mandate for appropriate sex/gender and minority inclusion
- 2) Has in place adequate procedures to ensure these inclusion levels are monitored and maintained

Total IERs

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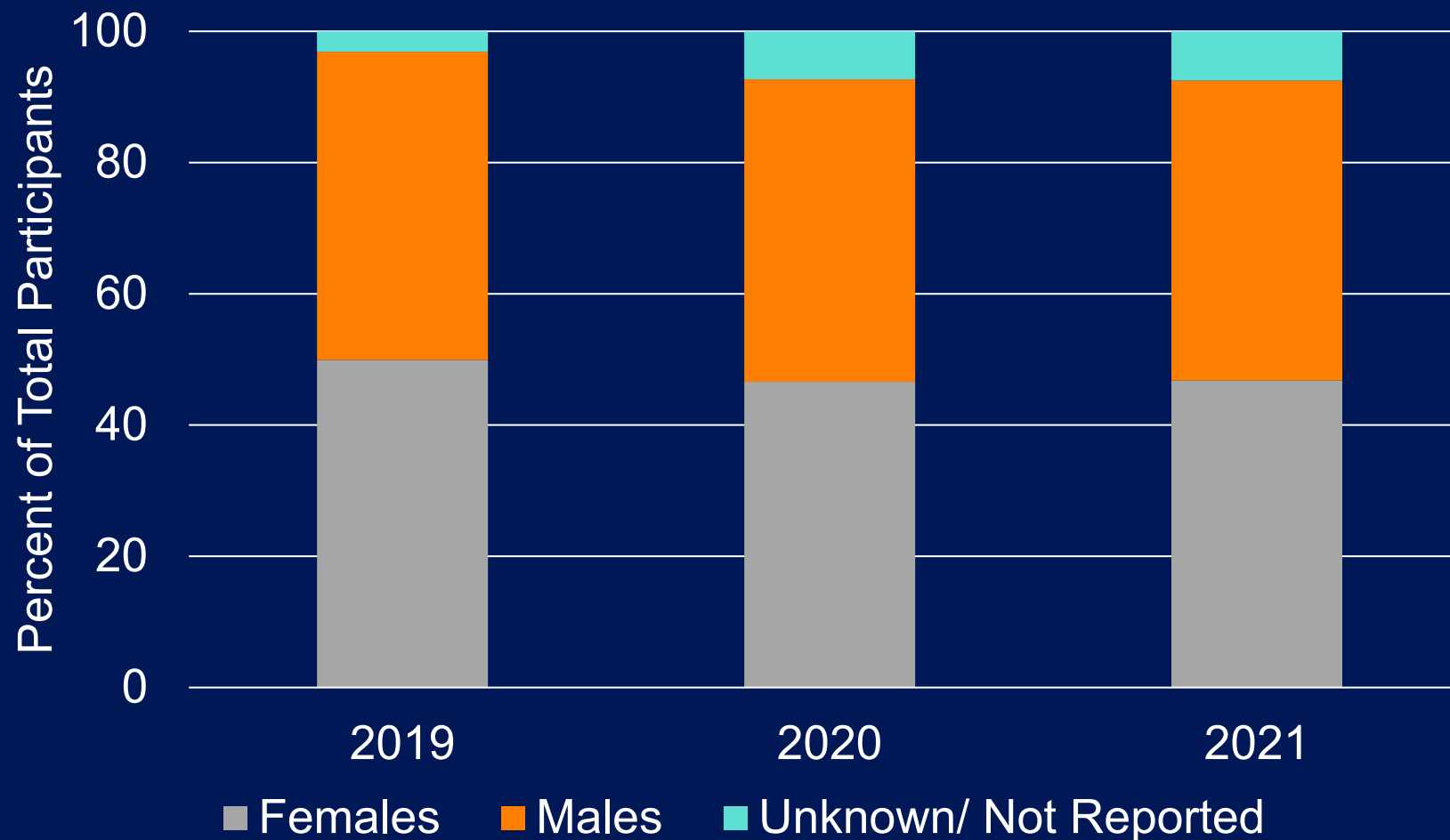
Fiscal Year	IERs				
	Total IERs	Without Enrollment	Non-US Site IERs	Female Only IERs	Male Only IERs
2019	237	68	15	12	0
2020	235	79	16	10	0
2021	260	91	15	8	0

Participants and IERs by Extramural and Intramural

Fiscal Year	Total		Extramural		Intramural	
	Actual Enrollment	No. of IERs	Actual Enrollment	No. of IERs	Actual Enrollment	No. of IERs
2019	250,151	237	165,799	148	84,352	89
2020	130,043	235	42,336	154	87,707	81
2021	118,460	260	27,533	178	90,927	82

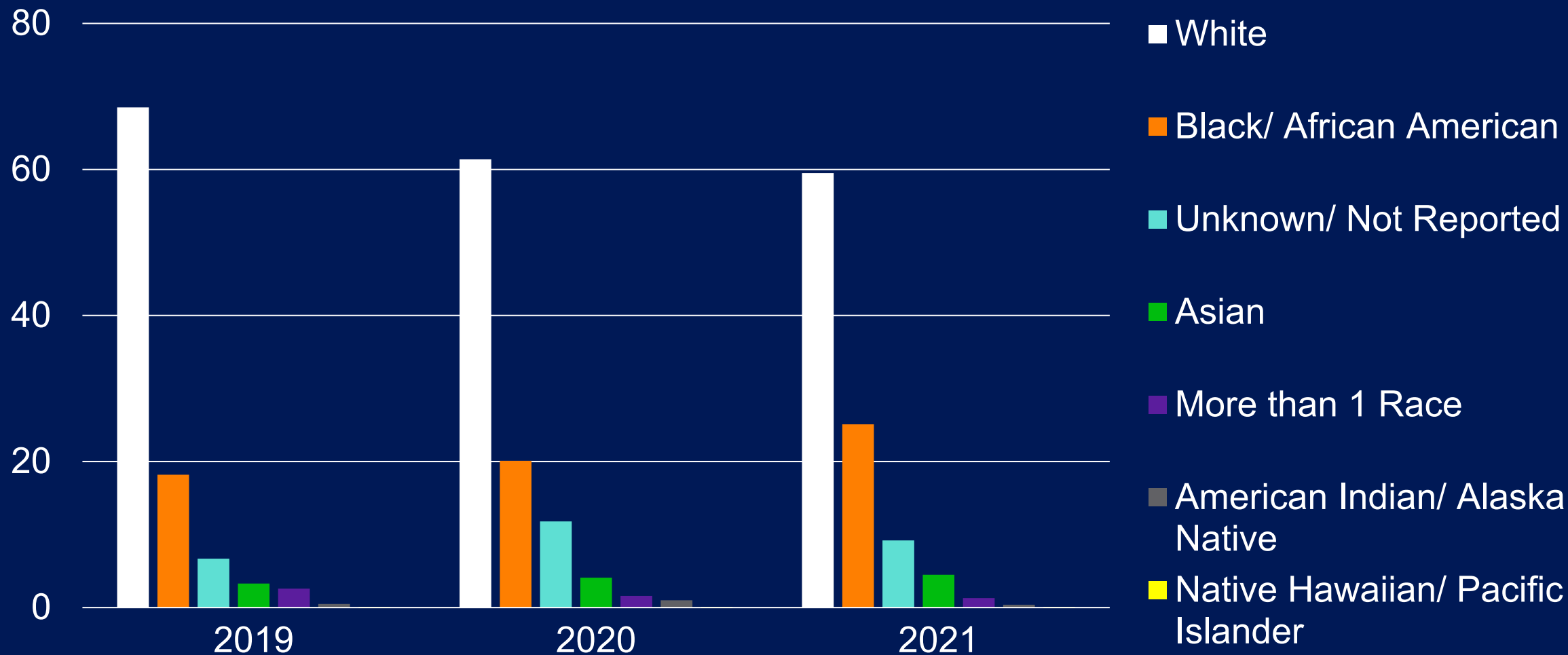
Enrollment by Sex/Gender

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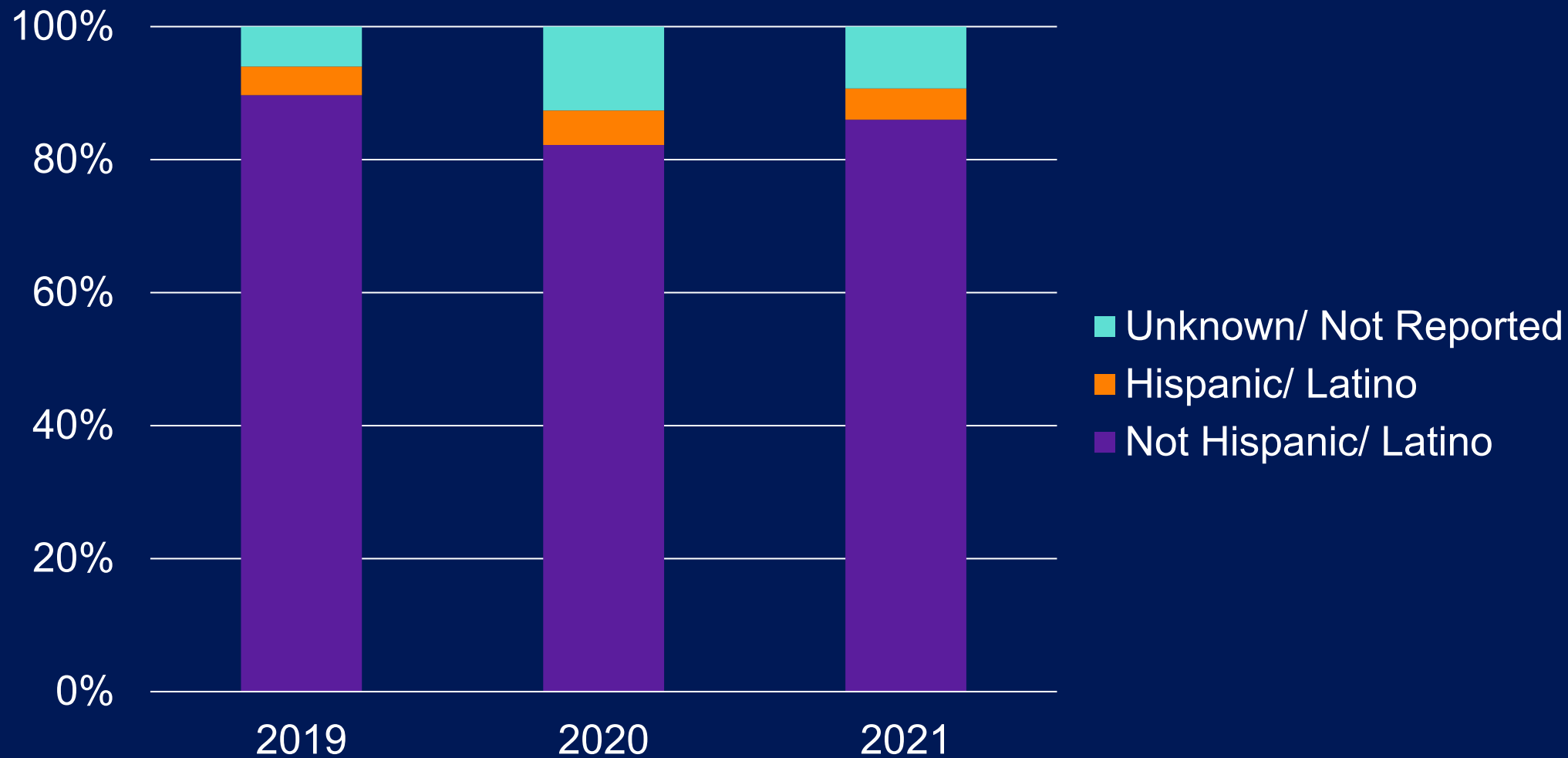
Enrollment by Race

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Enrollment by Ethnicity

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Minority Enrollment

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Fiscal Year	% Minority
2017	25.0
2018	26.6
2019	28.3
2020	31.5
2021	35.6

Inclusion Across the Lifespan

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Fiscal Year	Children (<18 years)	Adults (18-64 years)	Older Adults (65+ years)	Unknown/ Not Reported	Total
2021	115	519	53	20	707
	16.3%	73.4%	7.5%	2.8%	100%

Summary & Next Steps

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- The impact of COVID-19 on biomedical research
- Successful strategies in increasing overall minority participant enrollment, but improvements still needed in certain participant groups



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