

Inclusion Going Forward – the NIH View/Approach

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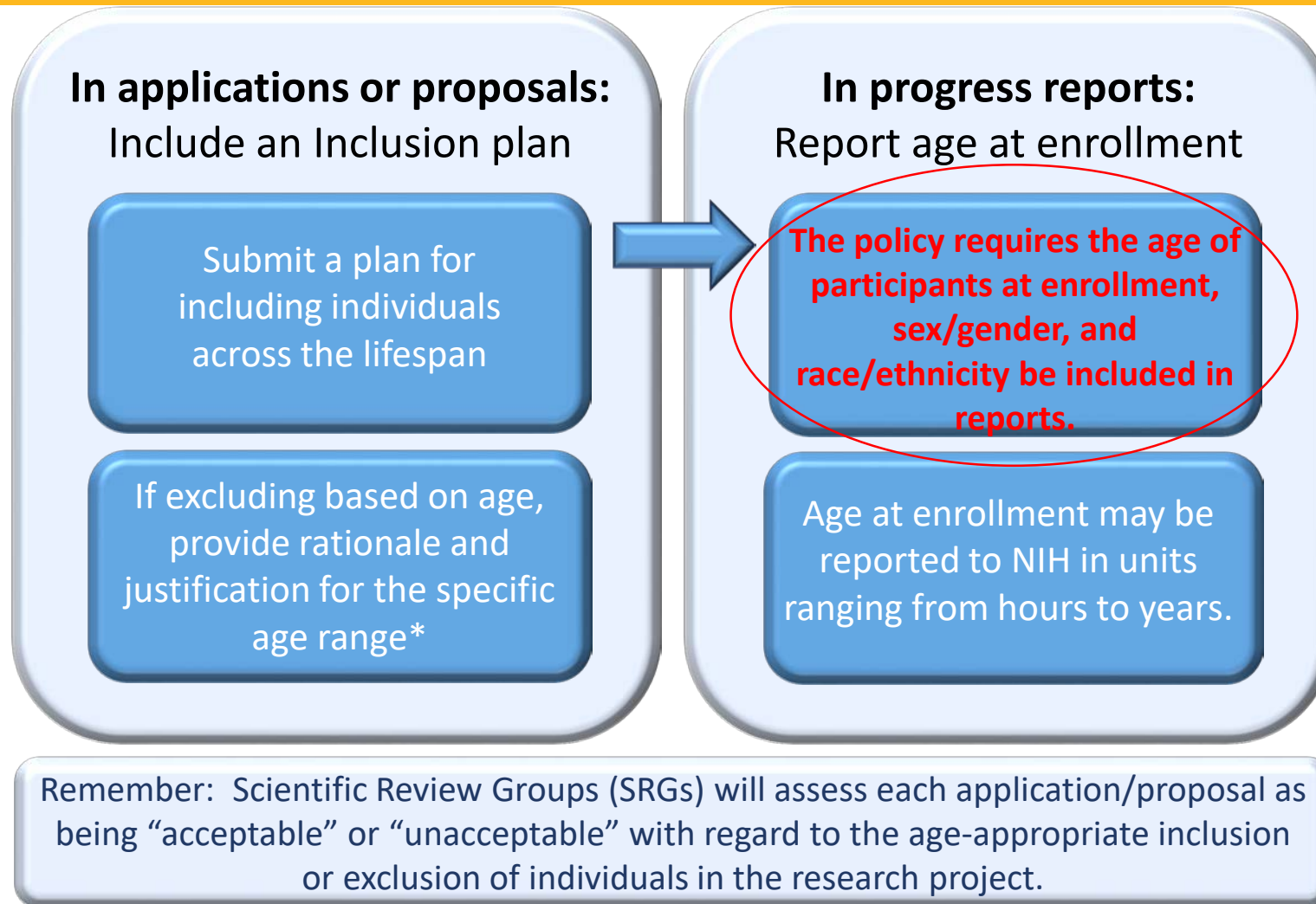
“Sunshine is the best
disinfectant”

- Louis Brandeis

Former Associate Justice, SCOTUS



Annonymized Individual Level Data



Aggregate Demographic Reporting in RCDC

The screenshot shows a web browser window with the NIH RCDC Inclusion Statistics Report. The browser's address bar shows the URL: `report.nih.gov/RISR/#/home?ic=Total,%20NIH&single=Exclude%20Singles`. The page has a dark blue header with the NIH logo and the title "NIH RCDC Inclusion Statistics Report". To the right of the title are two tabs: "Summary" (selected) and "Detail", and two links: "RISR FAQs" and "Contact Us".

The main content area contains the following text:

This report displays the typical representation of participants in human subject studies enrolled in FY2018 projects associated with the listed research, condition, or disease category. Median percent participation is presented for each demographic variable.

Adjust the filters to view characteristics by race or ethnicity or to exclude single population studies. Drill down to explore more detailed statistics.

****Notes:** Research, condition, and disease categories are not mutually exclusive, so the same projects may appear in more than one category. All participants enrolled in a project's studies are included in all categories associated with that project. Individual research projects can be included in multiple categories so amounts depicted within each column of this table do not add up to the total participants enrolled in NIH-funded research.

Example: R01 IC12345 enrolled 300 participants and is associated with the Basic Behavioral and Social Science and Prevention categories. All 300 participants will appear in both the Basic Behavioral and Social Science and Prevention category totals for that IC.

Below the text is a filter bar with the following elements:

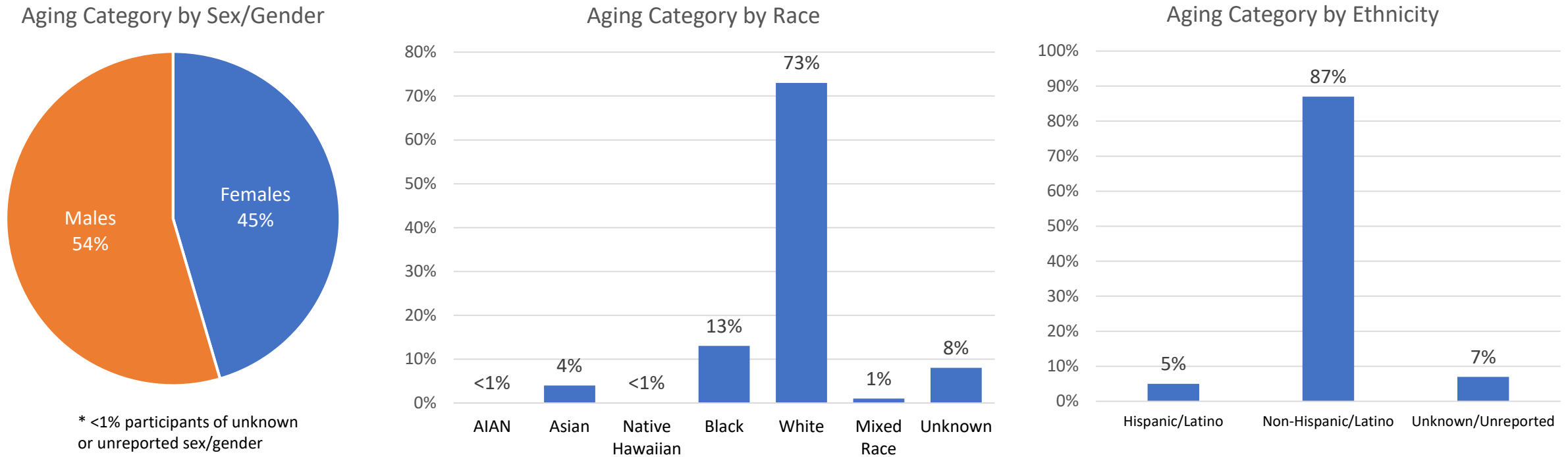
- A dropdown menu labeled "Filter RCDC Categories".
- A dropdown menu labeled "Total, NIH".
- A dropdown menu labeled "Sex/Gender".
- A checkbox labeled "Exclude Single Sex/Gender Studies" which is checked.
- A button labeled "Clear Filters".
- A button labeled "Export" with a download icon.

Below the filter bar is a table header with the following columns:

RCDC Category	Median % Female Participants	Median % Male Participants	Median % Participants of Unknown or Unreported Sex/Gender
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Aggregate Demographic Reporting in RCDC

Based on total NIH human subject studies enrolled in FY2018 projects



N= 3,238,207

Source: NIH RCDC Inclusion Statistics Report

Enhancement of Valid Analysis Policy

Amendment: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research

Purpose

This Notice amends [NOT-OD-02-001](#). The purpose of this Notice is to inform the research community that NIH is amending its [NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research](#) to include a requirement that recipients conducting [applicable NIH-defined Phase III clinical trials](#) ensure results of [valid analyses](#) by sex/gender, race, and/or ethnicity are submitted to Clinicaltrials.gov. All other aspects of the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research remain unchanged.

- Recipients conducting applicable NIH-defined Phase III trials must conduct and report analyses by sex/gender, race, and or ethnicity in CT.gov

(NOT-OD-18-014, 2017)

Final Research Performance Progress Report Policy

- Final RPPR required for any grant that is terminated and any award that will not be extended, applies as of January 2017 (NOT-OD-17-022)
- Public posting of project outcomes policy applies to all final RPPRs submitted as of October 1, 2017 (NOT-OD-18-103)



The screenshot shows the NIH Grants Policy Statement page. At the top, the NIH logo and "National Institutes of Health Office of Extramural Research" are visible. The main title is "NIH GRANTS POLICY STATEMENT". Below this, a dashed box contains the text: "REVISED DECEMBER 2019. This document applies to all NIH grants and cooperative agreements for budget periods beginning on or after *October 1, 2019*." A breadcrumb trail reads: "You are here: 8 Administrative Requirements > 8.6 Closeout > 8.6.2 Final Progress Report". A search bar is labeled "Search NIH Grants Policy". The section title "8.6.2 Final Research Performance Progress Report" is highlighted. The text below states: "A Final RPPR required for any grant that is terminated and any award that will not be extended through award of a new competitive segment. If a competitive renewal (Type 2) application has been submitted, the recipient must submit an Interim-RPPR while their renewal application is under consideration. In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment. If the Type 2 is not funded, the Interim RPPR will be treated by NIH staff as the institution's Final RPPR." Another paragraph states: "A Final RPPR should be prepared in accordance with the requirements in the RPPR Instructions found on the [NIH RPPR](#) website and any specific requirements set forth in the terms and conditions of the award. In addition to the standard requirements detailed in those Instructions, recipients should also report additional information required by the awarding IC in program-specific final progress report instructions." A final note says: "Final RPPR Instructions for SBIR/STTR Phase II Reports are in Section 7.3. of the [RPPR Instructions](#)."

NIH National Institutes of Health
Office of Extramural Research

NIH GRANTS POLICY STATEMENT

REVISED DECEMBER 2019. This document applies to all NIH grants and cooperative agreements for budget periods beginning on or after *October 1, 2019*.

You are here: 8 Administrative Requirements > 8.6 Closeout > 8.6.2 Final Progress Report

Search NIH Grants Policy

8.6.2 Final Research Performance Progress Report

A Final RPPR required for any grant that is terminated and any award that will not be extended through award of a new competitive segment. If a competitive renewal (Type 2) application has been submitted, the recipient must submit an Interim-RPPR while their renewal application is under consideration. In the event that the Type 2 is funded, NIH will treat the Interim-RPPR as the annual performance report for the final year of the previous competitive segment. If the Type 2 is not funded, the Interim RPPR will be treated by NIH staff as the institution's Final RPPR.

A Final RPPR should be prepared in accordance with the requirements in the RPPR Instructions found on the [NIH RPPR](#) website and any specific requirements set forth in the terms and conditions of the award. In addition to the standard requirements detailed in those Instructions, recipients should also report additional information required by the awarding IC in program-specific final progress report instructions.

Final RPPR Instructions for SBIR/STTR Phase II Reports are in Section 7.3. of the [RPPR Instructions](#).

(NIH Grants Policy Statement 8.6.2, 2019)

Diversity Collaboration with CTTI

- Develop resources to demonstrate the value of
 - increasing diversity in clinical trials and
 - adopting practices that include diverse patient populations in the development process for drugs and devices.

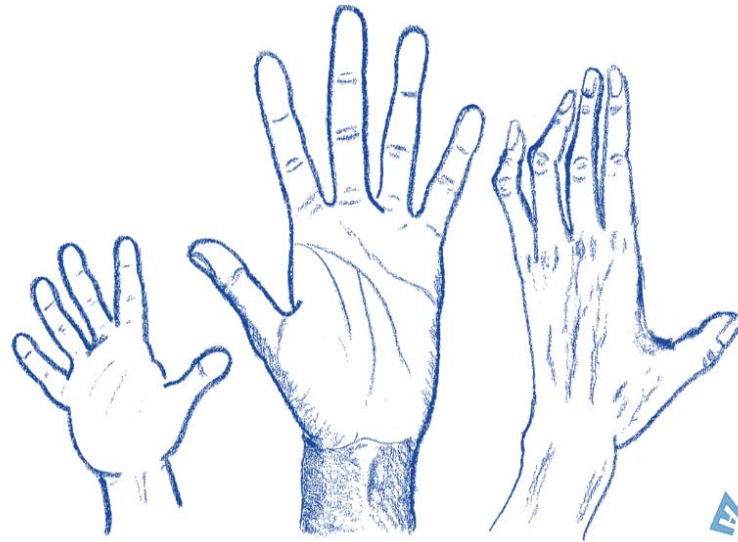


Inclusion Across the Lifespan

NIH's 2nd Inclusion Across the Lifespan (IAL-II) Workshop

<https://www.nia.nih.gov/Inclusion-Across-Lifespan-2020>

*The workshop will
be held virtually
and is free of
charge.*



*Registration
open through
September 1st,
2020.*

September 2nd, 2020



*Turning
Discovery Into
Health*