The Inclusion of Special Populations (ISP) in Clinical Research Dashboard summarizes the demographic representation of participants in Duke clinical research studies.[[1]](#footnote-1) The aim is to monitor inclusion of special populations from underrepresented groups toward reducing disparities. The ISP Dashboard presents information from all studies (any accrual status) as entered into the Duke clinical research management system (OnCore), and makes this information accessible to the public.

The ISP Dashboard is updated periodically (current date is listed on the main ISP Dashboard page) with a key set of variables of interest (age, sex, race, ethnicity, and rurality). The ISP Dashboard pulls information that is entered into the clinical research management system (CRMS). Most Duke Health studies are required to enter each participant encounter. Though the information in the ISP Dashboard comes from the same source as the DOCR Enrollment Dashboard, the ISP Dashboard incorporates a series of Quality Checks to enhance interpretation. These quality checks are outlined below. For further information about this process, please contact SpecialPopulations@dm.duke.edu.

# Quality Checks Overview:

* The variables of interest in the ISP Dashboard are extracted from the source database, Duke’s Clinical Research Management System (CRMS).
* Data are reviewed to ensure there are no duplicate data rows
* Data variables in the extract are then examined to:
	+ Count distinct values
	+ Identify outliers
	+ Characterize degree of data missing and marked as “unknown”

# Participations vs. Participants:

* **Participations.** Each data row in the OnCore extract represents one individual participating in a specific Duke Clinical Research Study. (Currently excluding Studies involving Summary Accrual.)
	+ Individual participants can participate in more than one Study; ‘participations’ counts each of those study enrollments.
	+ Participations reflects representation for each protocol, and allows for an individual to have participated in more than one protocol/study.
	+ ISP Dashboard Variables using Participations: [Age at Accrual](#_Age:).
* **Unique Participants (Individuals).** The number of participants is determined using unique identification numbers for individuals determined within OnCore to be a unique individual and non-duplicitous from other participation records.

This count ***approximates*** the number of individuals, counting them only once, regardless of the number of Duke clinical research studies in which the particular individual enrolls.

* + This count is only approximate because during operational use of OnCore, some individuals are assigned different OnCore identifiers over time. This can lead to an over counting unique participants
	+ Exclusion of protocols using summary accrual reporting to record enrollment information indicates that OnCore records do not reflect the complete set of Duke clinical research participants.
	+ ISP Dashboard Variables using Unique Participants: [Sex](#_Sex:), [Race](#_Race:), [Ethnicity](#_Ethnicity:), [Rurality](#_Rurality:)

# Age:

We used age of participant at the time of enrollment and accrual into a given study protocol, which was reported as a continuous integer value. Outlier values (i.e., negative values and values over 100 years of age) were removed from analysis. We grouped accrual age into categories: ages 65 to 100, ages 27 to 64, ages 18 to 26, ages 5 to 17, under the age of 5, and not reported. The age variable is based on participations (see above).

# Sex:

Participant biological sex has been indicated in OnCore as Females, Males, or Unknown.

# Race:

OnCore has allowed multiple selections of race: 1) American Indian or Alaska Native, 2) Asian, 3) Black or African American, 4) Native Hawaiian or Other Pacific Islander, 5) White, 6) 2 or more races, and 7) Unknown. We created a grouped value “reported two or more” to encompass “2 or more races” and any combination of any two or more of the available seven OnCore selections. The value “unknown” represented a significant fraction (>6% in the initial dashboard in 2021,). Race was recorded independently of ethnicity.

# Ethnicity:

OnCore has recorded participant ethnicity independently of race, as Hispanic, non-Hispanic, or reported Unknown.

# Rurality:

Rurality was determined by Rural-Urban Commuting Area (RUCA) codes designated as nonmetropolitan (RUCA code of 4 or above). We used the ZIP Code approximation of the Census tract-based RUCA codes. For a description, refer to <https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx>.2

Zip codes reported in OnCore were grouped using primary RUCA codes into rural and non-rural participant locations. More specifically, a primary RUCA code of 1, 2, or 3 was considered non-rural/metro and codes 4 through 10 as rural/non-metro.

| **Primary RUCA codes, 2010** |
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| **Code** | **Classification description** |
| 1 | Metropolitan area core: primary flow within an urbanized area (UA) |
| 2 | Metropolitan area high commuting: primary flow 30% or more to a UA |
| 3 | Metropolitan area low commuting: primary flow 10% to 30% to a UA |
| 4 | Micropolitan area core: primary flow within an urban cluster of 10,000 to 49,999 (large UC) |
| 5 | Micropolitan high commuting: primary flow 30% or more to a large UC |
| 6 | Micropolitan low commuting: primary flow 10% to 30% to a large UC |
| 7 | Small town core: primary flow within an urban cluster of 2,500 to 9,999 (small UC) |
| 8 | Small town high commuting: primary flow 30% or more to a small UC |
| 9 | Small town low commuting: primary flow 10% to 30% to a small UC |
| 10 | Rural areas: primary flow to a tract outside a UA or UC |
| 99 | Not coded: Census tract has zero population and no rural-urban identifier information |

1. Only studies which are required to enter individual encounter information for each participant in a study are included in the OnCore CRMS and the ISP Dashboard. Excluded from these individual participation records are those studies using summary, aggregated accrual reports of enrollment: non-interventional, international, observational or survey/focus group/interview studies. [↑](#footnote-ref-1)