**Figure 4: Data collection tool for baseline demographic variables**

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| --- |
| **Study ID:** **Participant Study ID:** **Date of data collection:** (specify MM/DD/YYYY or DD/MM/YYYY) |
| **AGE**Instructions: Provide your date of birth to the best of your ability |
| Date of birth: (specify MM/DD/YYYY or DD/MM/YYYY) |
| Corresponding Age: (specify units: hours, days, months, years) |
| Note:* Collect age as a continuous variable, in order to summarize and/or report as required by the regulatory authority.
* Collect age in hours, days, months, years. Age may be grouped into categories to reflect important age-related distinctions or underlying biological differences.
* If there are limitations to collecting date of birth (often related to national- or region-specific privacy laws), data can be collected as year of birth and corresponding age. Specify the Age Unit (e.g., years, months).
* See Section *Achieving Diversity, Inclusion, and Equity in Clinical Research Guidance Document* 11.2.1 – 11.2.3 regarding data standards for specific age categories including neonates and the elderly.
 |
| **ETHNICITY**Instructions: Select one or more ethnicity that you most closely identify with at the high-level category or within the expanded categories. If you do not consider yourself “Hispanic or Latino,” select “Not Hispanic or Latino.”  |
| Ethnicity | * Hispanic or Latino
 | *Expanded Categories:* * Central American
* Cuban
* Cuban American
* Latin American
 | * Mexican
* Mexican American
* South American
* Spanish
 |
| * Not Hispanic or Latino
 |  |  |  |
| * Not Reported
 |
| Note: * Ethnicity terminology presented here is specific to U.S. During protocol development, a sponsor (or sponsor-investigator) should identify the classification system(s) for ethnicity, and/or national origins where trial will be ongoing. Further, understand what is legally or socially acceptable to ask.
* In the U.S., questions regarding race and ethnicity should be asked in a standard order (e.g., questions about ethnicity precede race) with scripted questions. Individuals assigned to collect personal data should be cognizant of geographic variations and cultural sensitivities, asking questions that are locally respectful and internationally meaningful for the research.
* The Ethnicity, Expanded Categories code list is expanded based on CDISC user community requests. CDISC maintains one overall [ethnicity code-list](https://www.cdisc.org/system/files/members/standard/terminology/Racec-Ethnicc_Codetable.xlsx) that is categorized as either “Hispanic or Latino” or “Not Hispanic or Latino.” The code table is available for download from the CDISC.org terminology page here: <https://www.cdisc.org/standards/terminology>, login required.
* See Section 11.3 of the *Achieving Diversity, Inclusion, and Equity in Clinical Research* Guidance Document for reporting race and ethnicity to U.S. and ex-U.S. regions.
 |
| **RACE**Instructions: Select one or more race that you most closely identify with at the high-level category or within the sub-category. |
| Race | * American Indian or Alaska Native
 | *Expanded categories*: * Alaska Native
* American Indian
* Caribbean Indian
* Central American Indian
 | * Greenland Inuit
* Nupiat Inuit
* Siberian Eskimo
* South American Indian
* Yupik Eskimo
 |
|  | * Asian
 | *Expanded categories*: * Asian American
* Asian Indian
* Bangladesh
* Bhutanese, Burmese
* Cambodian
* Chinese
* Filipino
* Hmong
* Indonesian
* Iwo Jiman
* Japanese
* Korean
* Laotian
 | * Malagasy
* Malaysian
* Maldivian
* Mongolian
* Nepalese
* Okinawn
* Pakistani
* Singaporean
* Sri Lankan
* Taiwanese
* Thai
* Vietnamese
 |
|  | * Black or African American
 | *Expanded categories*: * African
* African American
* African Caribbean
* Bahamian
* Barbadian
* Black Central American
* Black South American
* Botswanan
* Dominica Islander
 | * Dominican
* Ethiopian
* Haitian
* Jamaican
* Liberian
* Malagasy
* Namibian
* Nigerian
* Trinidadian
* West Indian
* Zairean
 |
|  | * Native Hawaiian or Other Pacific Islander
 | *Expanded categories*: * Melanesian
* Micronesian
* Polynesian
 |  |
|  | * White
 | *Expanded categories*: * Arab
* Eastern European
* European
* Mediterranean
* Middle Eastern
* North American
 | * Northern European
* Russian
* Western European
* White Caribbean
* White Central American
* White South American
 |
|  | * Other
 | *Expanded categories*: * Unknown
* Not reported
 |
| Note: * Race terminology presented here is specific to U.S. During protocol development, identify the classification system(s) based on race and/or national origins where trial will be ongoing. Further, understand what is legally or socially acceptable to ask.
* In the U.S., questions regarding race and ethnicity should be asked in a standard order (e.g., questions about ethnicity precede race) with scripted questions. Individuals assigned to collect personal data should be cognizant of geographic variations and cultural sensitivities, asking questions that are locally respectful and internationally meaningful for the research.
* See Section 11.3 of the *Achieving Diversity, Inclusion, and Equity in Clinical Research* Guidance Document for regulatory guidance on reporting race and ethnicity to U.S. and ex-U.S. regions.
 |
| **SEX**Instructions: Select your biological sex at birth. Sex is defined as the different physiological and biological characteristics of males and females, such as reproductive organs, chromosomes, hormones, etc.[[1]](#footnote-2) |
| SEX | * Male
* Female
* Unknown or undifferentiated. Intersex is included in the term undifferentiated.
 |
| **GENDER**Instructions: Select the gender you most closely identify with. Gender is defined as the socially constructed characteristics of women and men – such as norms, roles and relationships of and between groups of women and men. It varies from society to society and can be changed.[[2]](#footnote-3) |
| GENDER[[3]](#footnote-4) | * Male
* Female
* Trans-male
* Trans-female
 | * Gender non-conforming
* Different Identity: Please specify\_\_\_\_\_\_\_\_\_\_
* Chose to not answer the question
 |
| Note: * The collection of gender is sensitive. The individual collecting this information should be sensitive that this may make a participant uncomfortable and use scripted questions to ensure questions are asked in a respectful way.
 |

1. World Health Organization. Glossary of terms and tools. Accessible at <https://www.who.int/gender-equity-rights/knowledge/glossary/en/>. [↑](#footnote-ref-2)
2. World Health Organization. Glossary of terms and tools. Accessible at <https://www.who.int/gender-equity-rights/knowledge/glossary/en/>. [↑](#footnote-ref-3)
3. Adapted from: Bauer GR, Braimoh J, Scheim AI, Dharma C. Transgender-inclusive measures of sex/gender for population surveys: Mixed-methods evaluation and recommendations. PloS one. 2017 May 25;12(5):e0178043. [↑](#footnote-ref-4)