1. \*Gender:

Female

Male

Unknown

Unspecified

Not reported

1. \*Date of Birth (M M / D D / Y Y Y Y):
2. \*Ethnicity[[1]](#footnote-1) (“X” ONLY one with which you MOST CLOSELY identify):

Hispanic or Latino

Not Hispanic or Latino

Unknown

Not Reported

1. \*Race[[2]](#footnote-2) (Mark all those with which you identify):

American Indian or Alaska Native

Asian

Black or African-American

Native Hawaiian or Other Pacific Islander

White

Unknown

Not Reported

1. Primary Language (ISO 639-2 code):

English (eng)

Spanish (spa)

Sign Languages (sgn)

Chinese languages (chi)

French (fre)

German (ger)

Other, specify:

(ISO 639-2 code):

\*Element is classified as Core.

## General Instructions

This form contains data elements that are collected to describe the demographics of the study population. The items are used to compare baseline characteristics among study groups and to identify confounding variables.

As stated in the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget (OMB) Directive No. 15 defines the minimum standard of basic racial and ethnic categories, which are used below. NIH has chosen to continue the use of these definitions because they allow comparisons across many national data bases, especially national health data bases. Therefore, the racial and ethnic categories described below should be used as basic guidance, cognizant of the distinction based on cultural heritage. ([NIH Guideline on the Inclusion of Women and Minorities as Subjects in Clinical Research](http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm))

Responses to categories are obtained from self-report when possible.

## Specific Instructions

*Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.*

Responses to the demographic elements should be obtained from self-report when possible.

* Gender type – Self-reported gender of the participant/subject. Gender is the socially constructed identity of sex. Gender is equated with phenotypic sex. Gender may differ from the sex of an individual determined genetically. The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15
  + Unspecified is defined as Undifferentiated/Indeterminant/Intersex
* Date of birth – Record the date of birth to the level of precision known (e.g., month/day/year, year, month/year, etc). The preferred format for recording date is MM/DD/YYYY. 99/99/9999 can be used to indicate an unknown date.
* Ethnicity – Choose only one with which the participant/ subject most closely identifies.
* Race – Choose all that apply. Response is obtained by report of the participant/subject or caretaker. Collecting information on race may not be allowed in some countries for concerns related to discrimination. In other countries, however, these concerns are considered a reason for recording race in order to guarantee equal access to care. Investigators receiving funding from the US National Institutes of Health (NIH) are required to report the number of subjects enrolled on an annual basis using the racial categories listed.

1. Categories must comply with NIH guidelines [↑](#footnote-ref-1)
2. Categories must comply with NIH guidelines [↑](#footnote-ref-2)