1. Date of Birth: // m m dd yyyy
2. Sex assigned at birth:

Male  Unknown

Female  Other, specify

Intersex

1. Gender identity:

Male  Unknown

Female  Other, specify

1. Ethnicity: "The category of ethnicity you most closely identify with?"

Hispanic or Latino Not Hispanic or Latino Unknown Not reported

1. Race (“X” all those with which you identify):

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Other Pacific Islander

White

Not Reported

1. Education Level (select the highest level attained):

7th Grade or less

8th to 12th Grade

High school graduate

2-year college

4-year college

Postgraduate

Unknown

## 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.

The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 defines the minimum standard of basic racial and ethnic categories. ([NIH Guideline on The Inclusion of Women and Minorities](https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm) ) 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 included on the CRF should be used as supplemental if a study requires that level of detail, otherwise the NIH standard should be used as the minimum standard.

Important note: All of the data elements included on this CRF Module are classified as Core (i.e., strongly recommended for all Parkinson’s disease clinical studies to collect) except for two “Other, specify” data elements (Birth sex assigned type other specify; Gender identity type other specify) which are classified as Supplemental (i.e., non-Core) and should only be collected if “Other, specify” is selected in the parent data elements (Birth sex assigned type; Gender identity type). Please see the Data Dictionary for element classifications.

## 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.
* 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.
* Sex at birth – Choose one. Response is obtained by report of the participant/subject or caretaker. The assemblage of physical properties or qualities by which male is distinguished from female. Male is a person who belongs to the sex that normally produces sperm. The term is used to indicate biological sex distinctions, cultural gender role distinctions, or both. Female is a person who belongs to the sex that normally produces ova. The term is used to indicate biological sex distinctions, or cultural gender role distinctions, or both. Intersex is a person (one of unisexual specimens) who is born with genitalia and/or secondary sexual characteristics of indeterminate sex, or which combine features of both sexes. The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 ([Click here for the NIH Guideline on The Inclusion of Women and Minorities](https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm)).
* Gender identity – Choose one. Response is obtained by report of the participant/subject or caretaker. Internally held sense of the participant/subject gender which may or may not correspond to the individual’s genotypic or phenotypic sex.
* Ethnicity – Choose only one with which the participant/ subject most closely identifies.
* Race – Choose all those with which the participant/ subject identifies. 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.

The NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical Research: The Office of Management and Budget Directive No. 15 defines the minimum standard of basic racial and ethnic categories. ([Click here for the NIH Guideline on The Inclusion of Women and Minorities](https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm)). Collection of Race and Ethnicity Data in Clinical Trials (FDA, October 2016 - [Click here for FDA Guidance for Race and Ethnicity](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/collection-race-and-ethnicity-data-clinical-trials))

* Education Level – Choose only one, the highest level of education the participant/subject has attained.