1. Date of Birth: // m m dd yyyy
2. Gender:  Female  Male  Unspecified  Unknown Not reported
3. 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/Alaska Native

African - Black (i.e., south of the Sahara)

African - North (i.e., Sahara or north of the Sahara: e.g., Algeria, Egypt, Morocco, Tunisia, etc.)

American - Black (i.e., people of African descent whose area of origin is within the Americas:   
e.g., Canada, Caribbean, Brazil, US, etc.)

Asian - East (i.e., China, Japan, Korea, etc.)

Asian - West (i.e., Bangladesh, India, Iran, Iraq, Pakistan, etc.)

Caucasian (e.g., British Isles, Germany, Peninsular Spain, Latin America, France, Italy, Ireland, Sweden, etc.)

Native Hawaiian or other Pacific Islander

Other (i.e., if none of the above categories reflects your area of origin, then specify as precisely as possible)

Unknown

Not reported

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

Never attended/ Kindergarten only

1st Grade

2nd Grade

3rd Grade

4th Grade

5th Grade

6th Grade

7th Grade

8th Grade

9th Grade

10th Grade

11th Grade

12th Grade, no diploma

High school graduate

GED or equivalent

Some college, no degree

Associate degree: occupational, technical, or vocational program

Associate degree: academic program

Bachelor's degree (e.g., BA, AB, BS, BBA)

Master's degree (e.g., MA, MS, MEng, MEd, MBA)

Professional school degree (e.g., MD, DDS, DVM, JD)

Doctoral degree (e.g., PhD, EdD)

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](http://grants.nih.gov/grants/funding/women_min/guidelines_update.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: Four 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). The remaining data element is classified as supplemental (i.e., non-Core) and should only be collected if the research team considers them appropriate for their study. 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.
* Gender – Choose one. Response is obtained by report of the participant/subject or caretaker. 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 ([Click here for the NIH Guideline on The Inclusion of Women and Minorities](http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm))
  + Unspecified is defined as Undifferentiated/Indeterminant/Intersex
* 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](http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm)). Collection of Race and Ethnicity Data in Clinical Trials (FDA, September 2005 - [Click here for FDA Guidance for Race and Ethnicity](http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm))

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