1. Gender:\* Female Male Unspecified Unknown  Not reported
2. Date of Birth:\* // m m/dd/yyyy
3. Ethnicity:\* Indicate the ethnicity the participant/ subject most closely identifies.

Hispanic or Latino Not Hispanic or Latino Unknown Not reported

1. Race (Mark 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

Unknown or not reported

1. Father’s country of birth: (please specify)

See ISO 3166-1 alpha-2 codes ([ISO list of country codes](http://www.iso.org/iso/country_codes.htm))

1. Mother’s country of birth: (please specify)

See ISO 3166-1 alpha-2 codes ([ISO list of country codes](http://www.iso.org/iso/country_codes.htm))

## General Instructions

Important note: Some of the data elements on this form are considered Core or Supplemental-Highly Recommended(as specified by an asterisk) and are required by all Huntington’s studies to collect.

\*Element is classified as Core

\*\*Element is classified as Supplemental – Highly Recommended

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 Huntington’s disease clinical studies to collect). The remaining data elements are 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.

* Sex–Choose one
* 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 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 ([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 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.

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)). Collection of Race and Ethnicity Data in Clinical Trials (FDA, September 2005 - [FDA Guidance for Race and Ethnicity](http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm))