1. \*Date of Birth:(m m/dd/yyyy)
2. \*Gender: Female  Male  Unknown  Unspecified  Not reported
3. \*Ethnicity (Select which population group you MOST CLOSELY identify with):

Hispanic or Latino

Unknown

Not Hispanic or Latino

Not Reported

1. \*Race (Mark all those with which you identify)

American Indian or Alaska Native

White

Asian

Unknown

Black or African-American

Not Reported

Native Hawaiian or Other Pacific Islander

1. Where do you live?

Country: (please specify) State / Province: (please specify) Zip/Postal Code: (please specify)

\*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 participants/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 here. NIH has chosen to continue the use of these definitions because they allow comparisons across many national databases, especially national health databases. 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](http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm))

Responses to categories are obtained from self-report when possible or obtained from parent/legal guardian interview.

## Specific Instructions

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

* Date of Birth – Record the date/time according to the ISO 8601, [International Standard for the representation of dates and times](http://www.iso.org/iso/home/search.htm?qt=ISO+8601&sort=rel&type=simple&published=on). The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.). Recording date of birth will give the most detailed information required for calculation of age and is recommended as first choice. However, in some studies recording date of birth may elicit discussions on a potential violation of privacy legislation and specifically HIPAA regulations. In these cases, the calculated age should be recorded.
* 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 ([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 that the participant/subject most closely identifies. This question may not be applicable to studies outside the U.S.
* 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. ([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))

* Country of residence – Choose only one country which the subject/participant currently lives. If the country code is not included on the form and therefore the country is written-in under 'Other, specify' then code the data later using ISO 3166-1 alpha-2 codes.
* State or province of residence – Enter the abbreviation for the state or province. The 2-letter postal abbreviation should be used for all U.S. states.
* Zip code - This is an optional field, if not provided enter 000.