* + 1. Sex:  XX  XY  XXX  XYY  XXY  Other, specify  Unknown  Unspecified
    2. Gender:

Female

Male

Unknown

Unspecified

Not reported

* + 1. Date of Birth yyyy-mm-dd
    2. Ethnicity (“X” ONLY one with which you MOST CLOSELY identify):

Hispanic or Latino

Not Hispanic or Latino

Unknown

Not Reported

* + 1. Race (“X” 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. Country of origin:
    2. Mother’s country of origin:
    3. Father’s country of origin:
    4. Maternal ethnicity(“X” ONLY one with which the mother MOST CLOSELY identifies):

Hispanic or Latino

Not Hispanic or Latino

Unknown

Not Reported

* + 1. Maternal race: (“X” those with which the mother identifies)

American Indian or Alaska Native

Asian

Black or African-American

Native Hawaiian or Other Pacific Islander

White

Unknown

Not Reported

* + 1. Paternal ethnicity (“X” ONLY one with which the father MOST CLOSELY identifies):

Hispanic or Latino

Not Hispanic or Latino

Unknown

Not Reported

* + 1. Paternal race (“X” those with which the father identifies):

American Indian or Alaska Native

Asian

Black or African-American

Native Hawaiian/Other Pacific Islander

White

Unknown

Not Reported

## 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/subject sin 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](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.

* Sex – Choose Female, Male, Unknown, or Unspecified.
* Date of Birth – This data element can be used to calculate the participant’s/subject’s age when the data are analyzed.
* Ethnicity – Choose only one that the participant/subject most closely identifies.
* Race – Choose all those that the participant/subject identifies.
* Race (additional information for genetics studies) – Choose only one that the participant/subject most closely identifies
* \*\*Questions referring to mother and father refer to biological parents