1. Genotypic sex:

XX

XY

XXX

XYY

XXY

Other

1. \*Phenotypic sex (Gender):

Female

Male

Unknown

Unspecified

Not reported

1. \*Date of birth (m m/d d/y y y y):
2. \*Ethnicity (“X” ONLY one with which you MOST CLOSELY identify):

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

Unknown

Not Reported

## Additional Pediatric-specific Elements

These elements are recommended for pediatric studies.

1. Maternal ethnicity (Chose ONLY one with which the participant/subject’s mother MOST CLOSELY identifies):

Hispanic or Latino

Not Hispanic or Latino

Unknown

Not Reported

1. Maternal race (Choose all those with which the participant/subject’s mother identifies):

American Indian or Alaska Native

Asian

Black or African-American

White

Unknown

Not Reported

Native Hawaiian or Other Pacific Islander

1. Maternal country(s) of origin:
2. Paternal ethnicity (Choose ONLY one with which the participant/subject’s father MOST CLOSELY identifies)

Hispanic or Latino

Not Hispanic or Latino

Unknown

Not Reported

1. Paternal race (Choose all those with which the participant/subject’s father identifies):

American Indian or Alaska Native

Asian

Native Hawaiian or Other Pacific Islander

Black or African-American

White

Unknown

Not Reported

1. Paternal country(s) of origin:

\*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 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.([LINK: 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.

* Phenotypic sex (Gender) – 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))
* Genotypic sex – Choose the genetic make-up that best describes the participant’s/subject’s sex
* Date of birth – Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times (http://www.iso.org/iso/home.html). 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.).
* Ethnicity – Choose only one that the participant/subject most closely indentifies.
* Race – Choose all those that the participant/subject identifies. Race should be reported by 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))

* Maternal ethnicity^ – Choose only one that the participant/subject’s mother most closely indentifies. This is a pediatric-specific element.
* Maternal race^ – Choose all that the participant/subject’s mother most closely identifies. This is a pediatric-specific element.
* Paternal ethnicity^ – Choose only one that the participant/subject’s father most closely indentifies. This is a pediatric-specific element.
* Paternal race^ - Choose all that the participant/subject’s father most closely identifies. This is a pediatric-specific element.
* Maternal country(s) of origin^: Choose one. It may be easier to record the full name of the country and code the data later using the ISO 3166-1 alpha-2 codes. This is a pediatric-specific element.
* Paternal country(s) of origin^: Choose one. It may be easier to record the full name of the country and code the data later using the ISO 3166-1 alpha-2 codes. This is a pediatric-specific element.

^Depending on the study, investigators should clarify whether maternal and paternal ethnicity and race should be collected for only biological parents.