1. \*Date of birth(m m / d d / y y y y):
2. \*Sex assigned at birth:

[ ]  Male

[ ]  Female

[ ]  Intersex

[ ]  Unknown

[ ]  Other, specify:

1. \*Gender identity:

[ ]  Male

[ ]  Female[ ]  Unknown

[ ]  Other, specify:

1. \*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

## Additional Pediatric-specific Elements

*These elements are recommended for pediatric studies.*

1. \*Date and time of birth:

**Date** (m m / d d / y y y y):

**Time:**

**[ ]** AM

[ ]  PM

[ ]  24-hour clock

1. 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)

**[ ]** Black or African-American

**[ ]** White

**[ ]** Asian

**[ ]** Native Hawaiian or Other Pacific Islander

**[ ]** American Indian or Alaska Native

[ ]  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):

**[ ]** Black or African-American

**[ ]** White

**[ ]** Asian

**[ ]** Native Hawaiian or Other Pacific Islander

**[ ]** American Indian or Alaska Native

[ ]  Unknown

[ ]  Not Reported

Recorder Signature: Date: \_ \_ / \_ \_ / \_ \_ \_ \_

## 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.([NIH Guideline on The Inclusion of Women and Minorities](https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm))

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

Important note: Five of the data elements included on this CRF are considered Core (i.e., strongly recommended for all studies to collect). The remaining elements are Supplemental and should be collected only if the research team considers them appropriate for their study.

*\**Element is classified as Core

## Specific Instructions

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

* Date and Time of Birth – 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.) and in the format acceptable to the study database. 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.
* Sex at birth – Choose one. Response is obtained by report of the participant/subject or caretaker. The assemblage of physical properties or qualities by which male is distinguished from female. Male is a person who belongs to the sex that normally produces sperm. The term is used to indicate biological sex distinctions, cultural gender role distinctions, or both. Female is a person who belongs to the sex that normally produces ova. The term is used to indicate biological sex distinctions, or cultural gender role distinctions, or both. Intersex is a person (one of unisexual specimens) who is born with genitalia and/or secondary sexual characteristics of indeterminate sex, or which combine features of both sexes. 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](https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm)).
* Gender identity – Choose one. Response is obtained by report of the participant/subject or caretaker. Internally held sense of the participant/subject gender which may or may not correspond to the individual’s genotypic or phenotypic sex.
* Ethnicity – Choose one. Response is obtained by report of the participant/subject or caretaker. If more detailed characterizations of ethnicity are collected to enhance data quality and consistency, it is recommended that they be "collapsible" up to the two categories for reportable ethnicity, as needed for reporting to FDA under its guidance. Other regulatory bodies may expect the reporting of ethnicity values which more appropriately reflect the population of their areas (e.g., Japanese ancestry for MHLW reporting to Japan). These may be collected as an extension to the suggested code list.
* 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](https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm)). (FDA, October 2016 <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/collection-race-and-ethnicity-data-clinical-trials>).

* Maternal ethnicity – Choose only one that the participant/subject’s mother most closely identifies.
* Maternal race – Choose all those racial categories that the participant/subject’s mother most closely identifies with.
* Paternal ethnicity – Choose only one that the participant/subject’s father most closely identifies.
* Paternal race – Choose all those racial categories that the participant/subject’s father most closely identifies with.