1. **\***Date of birth (m m / d d / y y y y):
2. \*Gender:

Female\

Male

Unknown

Unspecified

Unreported

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):

Black or African-American

White

Asian

Native Hawaiian or Other Pacific Islander

American Indian or Alaska Native

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

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

## 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.

Important note: Four 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.

## 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.
* Gender – Choose one. Response is obtained by report of the participant/subject or caretaker.
* 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.
* 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.

*\**Element is classified as Core