1. \*Date of birth:
2. \*Country of birth:
3. Zip / Postal Code:
4. \*Country of residence:

USA (US)

Canada (CA)

United Kingdom (GB)

Mexico (MX)

Australia (AU)

Other, specify:

1. \*Gender:

Female

Male

Unknown

Unspecified

Not reported

1. Maternal date of birth:
2. Mother’s country of origin:
3. Paternal date of birth:
4. Father’s country of origin:
5. Language(s) fully fluent (Choose all that apply):

English (eng)

Spanish (spa)

American Sign Language (sgn)

Chinese languages (chi)

French/ Creole (cpf)

German (ger)

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 (Mark 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

1. Number of years of education1: years
2. SNOMED CT Code:
3. Medical History Term:

Years of education is Supplemental – Highly Recommended

\*Element is classified as Core

## General Instructions

Most of the data elements on this form are known as General Core CDEs and will be collected for every study population. The data element “Number of years of education” is classified as a Supplemental – Highly Recommended CDE (highly recommended and commonly collected in clinical research studies but whose relevance depends on the study design or type of research involved). These items will be 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](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.

For pediatric studies, the data elements on this CRF reflect child characteristics, not caregiver characteristics.

## 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. 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 ([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 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.
* Condition/Disease – Record one Medical History term per line. See the data dictionary for additional information on coding the condition using SNOMED CT.