1. \*Date of Interview
2. \*Birth date:
3. Age [derived field]
4. \*Gender (Choose one):

Male

Female

Unknown

Unspecified

Not reported

1. Sexual orientation

Heterosexual

Gay/Lesbian

Bisexual

Unknown

Not Reported

Other

1. Sex at birth

XX; XX

XY; XY

XXX; XXX

XYY; XYY

XXY; XXY

Unspecified; Undifferentiated/ Indeterminant/ Intersex

Unknown

Other, Specify;

1. \*Ethnicity(Mark all those with which you 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. Primary language (ISO 639-2 code):

English (eng)

Spanish (spa)

American Sign Language (sgn)

Chinese languages (Chi)

French/Creole (cpf)

German (ger)

Other, specify (ISO 639-2 code):

1. Country of birth:

See ISO 3166-1 alpha-2 codes (Country Codes ISO 3166)

1. First 3 digits of zip code:
2. Social security number:

## Additional Pediatric-specific Elements

These elements are recommended for pediatric studies.

1. Age: [derived field see instructions]  months  years
2. Birth order?

1st

2nd

3rd

4th

5th

Other, specify

1. Part of a multiple birth?

Yes  No  Unknown

1. Maternal ethnicity (Choose one with which the mother MOST CLOSELY identifies):

Hispanic or Latino

Not Hispanic or Latino

Unknown

Not Reported

1. Maternal race (Choose all 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 (Choose one with which the father MOST CLOSELY identifies):

Hispanic or Latino

Not Hispanic or Latino

Unknown

Not Reported

1. Paternal race (Choose all those with which the father identifies):

American Indian or Alaska Native

Asian

Black or African-American

Native Hawaiian or Other Pacific Islander

White

Unknown

Not reported

\*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.

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 ([Country Code ISO 3166](http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm)). 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 included on the CRF should be used as basic guidance, cognizant of the distinction based on cultural heritage.

Important note: Most data elements on this CRF are classified as Supplemental (should only be collected if the research team considers them appropriate for their study). The remaining elements are classified as indicated by asterisks below:

\* Element classified as core

## Specific Instructions

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

Responses to the demographic elements should be obtained from self-report when possible.

* Date of Interview - Record the date/time of interview
* Birth Date – Record the date/time according to the ISO 8601, the International Standard for the representation of dates and times ([ISO website](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.).
* Gender type – Self-reported gender of the participant/subject. Gender is the socially constructed identity of 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 only one with which the participant/subject most closely identifies.
* 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. ([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 – [(FDA Guidance for Race and Ethnicity](http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm))

* Primary Language – Choose one. It may be easier to record the full name of the language and code the data later using the ISO 639-2 codes.
* Social security number –- The preferred format for recording SSN is: XXX-XX-XXX
  + Providing this information is entirely voluntary and the participant/subject may refuse. This information must be kept confidential according to the Privacy Act of 1974, and must only be used for research purposes.
* Age – It is recommended that age be calculated from date of birth and the study enrollment date. However, if age needs to be collected (e.g., full date of birth is not allowed to be collected) then it should be recorded in months and years. This element is strongly recommended for pediatric headache studies.
* Birth order– If the participant/subject is a multiple birth, select the birth order. This element is recommended for pediatric headache studies.
* Maternal ethnicity – Choose only one with which the mother most closely identifies. This element is recommended for pediatric headache studies.
* Maternal race – Choose all those with which the mother identifies. This element is recommended for pediatric headache studies.