1. Birth date[\*](#Core):
2. Birth time:
3. Age (years):

If less than 3 years of age (in months):

1. Gender[\*](#Core) (Choose one):

[ ]  Male

[ ]  Female

[ ]  Unknown

[ ]  Unspecified

[ ]  Not reported

1. Genotypic sex (Choose one):

[ ]  XX

[ ]  XY

[ ]  XXX

[ ]  XXY

[ ]  XYY

[ ]  Unspecified

[ ]  Unknown

[ ]  Other, specify

1. Ethnicity[\*](#Core) (Choose one):

[ ]  Hispanic or Latino

[ ]  Not Hispanic or Latino

[ ]  Unknown

[ ]  Not Reported

1. Race Category[\*](#Core) (Choose all that apply):

[ ]  American Indian or Alaska Native

[ ]  Asian

[ ]  Black or African-American

[ ]  Native Hawaiian or Other Pacific Islander

[ ]  White

[ ]  Unknown

[ ]  Not reported

1. Race (Choose all that apply):

[ ]  Black African American

[ ]  Black African

[ ]  Black Afro Caribbean

[ ]  South/Central American Indian

[ ]  North American Indian

[ ]  Alaskan Native

[ ]  Inuit

[ ]  South Asian

[ ]  Far Eastern Asian

[ ]  Western Asian

[ ]  White North American

[ ]  White South American

[ ]  White European

[ ]  White Middle Eastern

[ ]  White African

[ ]  White Australian

[ ]  Hawaiian

[ ]  Pacific Islander

[ ]  Not reported

[ ]  Other

[ ]  Unknown

1. Primary language (ISO 639-2 code)

[ ]  English (eng)

[ ]  Spanish (spa)

[ ]  Sign Languages (sgn)

[ ]  Chinese languages (chi)

[ ]  French (fre)

[ ]  German (ger)

 [ ]  Other, specify ISO 639-2 code:

1. Language spoken fluently (ISO 639-2 code)

[ ]  English (eng)

[ ]  Spanish (spa)

[ ]  Sign Languages (sgn)

[ ]  Chinese languages (chi)

[ ]  French (fre)

[ ]  German (ger)

[ ]  Other, specify ISO 639-2 code:

1. Language written fluently (ISO 639-2 code)

[ ]  English (eng)

[ ]  Spanish (spa)

[ ]  Chinese languages (chi)

[ ]  French (fre)

[ ]  German (ger)

[ ]  Other, specify ISO 639-2 code:

1. Birth country name (ISO 3166 1 alpha 2 code):
2. Hand preference type [ ]  Left hand [ ]  Right hand [ ]  Both hands [ ]  Unknown

## SPECIFIC INSTRUCTIONS

* Gender type – 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.
	+ Unspecified is defined as Undifferentiated/Indeterminant/Intersex
* Date of birth – Record the date of birth to the level of precision known (e.g., month/day/year, year, month/year, etc). The preferred format for recording date is MM/DD/YYYY. 99/99/9999 can be used to indicate an unknown date.
* Ethnicity – Choose only one with which the participant/ subject most closely identifies.
* Race category – Choose all that apply.
* 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.
* Birth country – 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.

\*Element is classified as Core