1. \* Sex assigned at birth:

[ ]  Male

[ ]  Female

[ ]  Intersex

[ ]  Unknown

[ ]  Other, specify

1. Gender identity:

[ ]  Male

[ ]  Female

[ ]  Unknown

[ ]  Other, specify

1. \*Date of birth (M M/D D/Y Y Y Y):
2. \*Ethnicity(Choose one with which you MOST CLOSELY identify):

[ ]  Hispanic or Latino

[ ]  Not Hispanic or Latino

[ ]  Unknown

[ ]  Not Reported

1. \*Race (Choose 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. 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. Country of residence:

[ ]  USA (US)

[ ]  Canada (CA)

[ ]  United Kingdom (GB)

[ ]  Mexico (MX)

[ ]  Australia (AU)

[ ]  Other, specify:

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

## Additional Pediatric-specific Elements

These elements are recommended for pediatric stroke studies.

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. ([NIH Guideline on The Inclusion of Women and Minorities as Subjects in Clinical Research](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 supplemental if a study requires that level of detail, otherwise the NIH standard should be used as the minimum standard.

Important note: The data elements noted with an asterisk on this CRF Module are classified as Core (i.e., required for all sickle cell disease studies to collect). The remaining data elements are classified as supplemental (i.e., non Core) and should only be collected if the research team considers them appropriate for their study. Please see the Data Dictionary for element classifications.

## 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 – 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.

## 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. ([NIH Guideline on The Inclusion of Women and Minorities](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: Four of the data elements included on this CRF Module are considered Core (i.e., strongly recommended for all stroke clinical studies to collect). The remaining data elements (i.e., non Core) are supplemental and should only be collected 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.

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

* 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. 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](http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm))
	+ 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 – 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](http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm)). Collection of Race and Ethnicity Data in Clinical Trials (FDA, September 2005 - [Click here for FDA Guidance for Race and Ethnicity](http://www.fda.gov/RegulatoryInformation/Guidances/ucm126340.htm))

* Language(s) fully fluent – Choose all that apply. It may be easier to record the full name of the language and code the data later using the ISO 639-2 codes.
* Country of residence – 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.
* First 3 digits of zip code – This is an optional field, if this information is not provided enter 000.
* Social security number – 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.
* Maternal ethnicity – Choose only one with which the mother most closely identifies. This element is recommended for pediatric stroke studies.
* Maternal race – Choose all those with which the mother identifies. This element is recommended for pediatric stroke studies.
* Paternal ethnicity – Choose only one with which the father most closely identifies. This element is recommended for pediatric stroke studies.
* Paternal race – Choose all those with which the father identifies. This element is recommended for pediatric stroke studies.