1. \*Gender: Female Male Unknown Unspecified  Not reported
2. \*Date of Birth: // (m m/dd/yyyy)
3. \*Ethnicity: (“X” ONLY one with which you MOST CLOSELY identify)

Hispanic or Latino

Not Hispanic or Latino

Not Reported

Unknown

1. \*Race (Mark all those with which you identify):

American Indian/Alaska Native

African - Black (i.e., south of the Sahara)

African - North (i.e., Sahara or north of the Sahara: e.g., Algeria, Egypt, Morocco, Tunisia, etc.)

American - Black (i.e., people of African descent whose area of origin is within the Americas: e.g., Canada, Caribbean, Brazil, US, etc.)

Asian - East (i.e., China, Japan, Korea, etc.)

Asian - West (i.e., Bangladesh, India, Iran, Iraq, Pakistan, etc.)

Caucasian (e.g., United Kingdom, Germany, Peninsular Spain, Latin America, France, Italy,

Ireland, Sweden, etc.)

Native Hawaiian or other Pacific Islander

Other (i.e., if none of the above categories reflects your area of origin, then specify as precisely as possible)

Unknown

Not Reported

1. Father’s country (s) of origin:
2. Mother’s country (s) of origin:

\* 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 ALS 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.