Informed Consent and Enrollment

[*Study Name/ID pre-filled*]

Site Name: _____

Subject ID: _____

1) Was informed consent obtained?

☐ Yes ☐ No (Skip to 2)

Date of Consent: ____/_____/20_____
m m d d y y y y

Date of Assent: ____/_____/20_____
m m d d y y y y

2) If participant/subject did not consent, reason not interested: _____ (select from below)

a) Family or affected individual does not have the time to participate

b) Family or affected individual cannot travel

c) Family or affected individual is not interested in participating in a clinical study

d) Other, specify _____

3) Is the participant/subject interested in future clinical trials?

☐ Yes ☐ No

Informed Consent and Enrollment CRF Module Instructions

General Instructions

It is important to collect the date of certain study milestones, such as informed consent, study enrollment and randomization, from both an administrative and human subjects' protection standpoint.

For some studies it will be possible to enroll participants/subjects without informed consent, if a waiver of consent is granted. An IRB may waive the requirements to obtain informed consent provided the IRB finds and documents that:

- the research involves no more than minimal risk to the participants/subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the participants/subjects;
- the research could not practically be carried out without the waiver or alteration;
- and whenever appropriate, the participants/subjects will be provided with additional pertinent information after participation.

For studies where participants/subjects are not randomized to different intervention groups, the randomization data elements are not applicable and should not be collected.

Specific Instructions

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

- **Was informed consent obtained?** – If yes, record date informed consent or assent was obtained. Both should NOT be recorded. If no, skip to question #2.
- **If participant/subject did not consent, reason not interested** – If no in previous question, record only one reason from the options
- **Is the participant/subject interested in future clinical trials?** – Check Yes or No