Study Subject Definitions, Enrolling and Over Enrolling Study Subjects

Modified: October 2019

Background:

The following defines what is considered an enrolled subject, what factors to take into account when determining how many subjects you should enroll, what to do if you need more subjects, and what happens if you over-enroll.

1. **Q: What are the various definitions for study subjects?**

   - **Active subjects** – *consented* subjects who met enrollment criteria and are currently receiving study-related procedures/interventions/activities.
   - **Subjects in follow-up** – *consented* subjects who completed study procedures/interventions/activities, and all that remains is protocol-specific data collection and/or follow-up as described in the protocol.
   - **Subject Withdrawals** – *consented* subjects who met eligibility but participation has ended prior to meeting a study endpoint (ended prematurely). This will include:
     i. A subject who dies before completing the study is considered a withdrawal if survival is not a study endpoint. (Note that if death was related to the study, it must be reported as a reportable event to the IRB within 5 days.)
     ii. A subject who is no longer eligible (no longer meets inclusion or now meets exclusion criteria)
     iii. A subject whose participation is ended by the PI, or
     iv. A subject who no longer wants to participate for any reason.
   - **Subject Screen Failures** – *consented* subjects found to be ineligible (do not meet protocol-specific inclusion criteria or meet protocol-specific exclusion criteria) as a result of study specific eligibility/screening procedures, prior to beginning study-related procedures/interventions/activities.
   - **Completed subject** – *consented* subjects that have completed all procedures required by the protocol (e.g., interventions, tests, monitoring, visits, phone calls, and collection of data from medical or other records, including any protocol-specific follow-up) or have met a study endpoint.

2. **Q: When does the IRB consider a study subject to be enrolled?**

An enrolled subject is someone:

- Who has signed an informed consent form, or
- Whose data you have collected, or
3. **Q: What factors should be taken into consideration when determining how many subjects to enroll?**

In most greater-than-minimal risk studies, you should involve a statistician to determine how many subjects you may need to statistically answer your research question. When submitting to the IRB, please also take into consideration how many subjects may withdraw from the study, and/or how many may be enrolled, but later screen out.

For chart or data base reviews, you may have to provide a good estimate. If at UF, you can utilize the i2b2 database query to enter your inclusion/exclusion criteria to determine how many such patients exist in the UF Health System.

For banking studies, you do not need to submit a number of study subjects, it is typically unlimited.

4. **Q: What should be done if you need more study subjects than you are currently approved for?**

Submit a revision and justify why additional subjects are needed. If your study is a greater-than-minimal risk study, such a revision must be reviewed and approved by the Full Board since you are exposing additional subjects to the risks in your study.

5. **Q: What happens if more subjects are enrolled then approved by the IRB?**

If you inadvertently enrolled more subjects than approved by the IRB, that is considered a protocol deviation and could result in, at a minimum, the removal of those additional subjects (and their data) from your study. Please submit the protocol deviation to the IRB for its determination.