Enrolling and Over Enrolling Study Subjects

Modified: February 2018

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: 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
- Whose medical record you have reviewed (in the cases where consent is not required).

Every record you look at is an enrolled subject.

2. 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.

3. 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.

4. 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.