The Beacon
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FAU DIVISION OF RESEARCH
Florida Atlantic University

Sample Size and Over-enrollment

IRB protocol applications can be a daunting process for some. In this segment, we will review question #6 on the form regarding the number of participants that will be enrolled in the study.

To answer this question, you need to run a statistical analysis to determine how many respondents will yield a significant response. If you are a student, your academic advisor can help you run this analysis. Factors such as population size and the type of study will also influence your "N." For a quick overview of how to determine sample size, see this guidance document from Qualtrics.

For the purposes of the IRB review, we recommend to reasonably overestimate the amount of participants you will need in order to account for withdrawals, attrition or other influences in data collection. Any participant who has signed a consent form is considered enrolled in the study and should be deducted from your total approved participants.

A participant who has signed a consent form is counted toward your number regardless of whether they withdraw from the study, meet the exclusion criteria, ask for their data to be removed, yield data that is unusable and so forth. It is the responsibility of the principal investigator to keep track of the number of participants who have enrolled and to apply to the IRB for an increase in participant numbers using the Protocol Amendment Form when necessary. An increase must be requested and approved *prior to* the enrollment of additional participants.

Failure to maintain enrollment within the approved number is a protocol deviation and may constitute as non-compliance. Corrective actions to remediate such occurrences include but are not limited to:

- Establishing a corrective action/preventive action plan.
- Requiring investigator(s) to complete remedial training.
- Requiring research participants to be re-consented.
- Permitting or disallowing the use of data collected during the protocol deviation.
- Requiring more frequent IRB review of the project.
- Limiting the investigator's human subjects research privileges.