

CUNY HRPP Guidance: Accounting for Total Subject Enrollment

1. Purpose

The purpose of this guidance document is to assist CUNY researchers in accurately defining the number of subjects expected to be enrolled in a non-exempt human subjects research study at the time of initial submission, and to assist in accurately accounting for subject populations at the time of continuing review.

2. Why does the IRB ask for expected number of subjects to be enrolled?

IRB approval of each research study is granted for enrollment of a specific number of subjects, or a range of subjects to be enrolled. The IRB considers the number of subjects to be enrolled in a given study in its risk/benefit analysis of the study as follows:

- To ensure that the minimum number of subjects necessary for the described research are being exposed to the risks of research, however minimal; and
- To ensure that the research is designed such that it will yield valid results.

3. Why does the IRB ask for an accounting of the number of subjects at the time of continuing review?

At the time of continuing review, the IRB must ensure that the risk/benefit ratio of the study remains favorable. A marked difference between the actual and expected rates of enrollment may indicate a problem with the research project that requires further evaluation, including whether the research project is likely to provide sufficient data to answer the scientific question(s) being posed.

4. How does CUNY HRPP/IRB define subject enrollment?

Number of subjects enrolled refers to the number of subjects who have completed the informed consent process and undergone research related procedures.

5. On the continuing review form, what does “number of subjects excluded from research due to ineligibility” mean?

This refers to the number of subjects that underwent the screening procedures but were found to be ineligible to proceed with further research participation.