

The IRB approves a maximum number of subjects to be enrolled in a given study. Study teams at the University of Michigan indicate a study's total enrollment target in the "Subject Participation" section of eResearch Regulatory Management application: section 08, or, for Cancer Center studies, section 03-2. With each continuing review application, study teams report actual enrollment to date as "Subject Enrollment Status": section 02-2. Approved enrollment can be changed when requested by Amendment.

Enrolling more than the approved maximum – "overenrollment" – is a violation of the IRB-approved protocol. Overenrollment is particularly concerning in studies that expose subjects to greater than minimal risk. "Underenrollment" is also problematic: a study that enrolls far fewer subjects than expected might not be able to obtain sufficient data to answer the scientific questions being posed.

As of September 30, 2013, IRBs and other research administration committees at U-M are adopting a single standard definition of "enrolled." This includes eResearch updates in section 08 and 03-2 of the main application, and in section 02-2 of the continuing review application. The standard definition of "enrolled" is *"consented and screened, with eligibility verified."* Study teams should answer questions about subjects "enrolled" with respect to *the number of participants that can be expected to complete the study. This number includes dropouts (withdrawals). It does not include screen failures.*

Please note that the term 'enrollment' applies to studies involving intervention or interaction with individual participants. It generally does not apply to secondary use of samples and/or data.

Most studies have inclusion and exclusion criteria for subjects, which may, for example, be based on age or other demographic information, on health status, or on particular physical or psychological characteristics. Researchers "screen" potential subjects to verify eligibility before enrollment. Screening procedures may or may not involve interaction or intervention. When the IRB approves a waiver of consent for a study's recruitment portion, some screening takes place prior to the informed consent process. Clinical trials also often involve interventions to verify eligibility after potential subjects provide consent.. Some of these may be determined to be ineligible : these should be reported as *screen failures* as part of continuing review in eResearch 2-2.2.

Some studies—for example, multi-site trials with outside sponsorship—may use a protocol-specific definition of "enrolled." Some of these may not be compatible with U-M's standard definition of *"consented and screened, with eligibility verified."* The IRB will take this into account when approving the initial enrollment target and when monitoring actual enrollment.

Contact the IRB with questions about approved enrollment, and the definition of enrolled.

References

- http://www.umich.edu/~eresinfo/erm/rnotes/releasenote_v3.2.html

U-MIC TRANSCRIPT Human Subjects Enrollment

URL for the "additional help" webpage that I'm hoping HRPP will host.

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