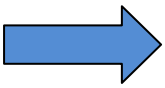
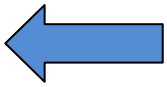
"Enrolled" for human subjects studies in eResearch

For purposes of data collection to track and monitor human subjects study activity in eResearch Regulatory Management, the University of Michigan IRBs and many human subjects research administration units are adopting one standard definition of "**enrolled**." *(The term is used differently for clinical research billing purposes: please see **NOTE** at the bottom of this page.)*



"**Enrolled**" as reported in eResearch generally means "*consented and screened, with eligibility verified*." Study teams should answer questions about subjects "*enrolled*" (including estimates reported at initial application in section 08 and actual numbers reported in continuing review application section 02-2) 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.*



This definition should be usable for most prospective studies. Screening procedures may not involve interaction or intervention, and may happen before or after consent. A few examples:

- A study may post public advertisements asking potential subjects to phone the study team for a one-time survey. Subjects who call in are first asked a non-sensitive eligibility questions, such as age, race, or primary news source for current events; those who meet certain criteria give verbal consent to participate in the survey, and are enrolled.
    - Eligibility is verified before consent is given, so little if any difference is expected between the "consented" and "enrolled" numbers.
    - A subject who chooses not to complete all the questions might be counted as a withdrawal.
- A sample repository study may review clinical charts to identify potential subjects from patients with an upcoming appointment at a UMHS clinic. Patients are approached for participation by a study team member at the time of their appointment; those who agree sign a consent form, and at the same appointment a vial of blood draw is drawn for research banking.
    - Eligibility is verified before consent is given, so little if any difference is expected between the "consented" and "enrolled" numbers.
    - A subject who later asks that their sample be removed from the repository might be counted as a withdrawal.
- A study may want to interview HIV-negative adults about behavior that may put them at risk for HIV infection. Potential subjects are asked to come for a "screening visit" at which blood is drawn to confirm their HIV status. Subjects sign a consent form for the interventional screening procedure. Any potential subjects who are HIV-positive are "screen failures" who are not enrolled. Depending on the study design, there may be another separate consent process before the interview.
    - Consent is given before eligibility is verified, so some potential subjects may consent but *not* be enrolled.

Some studies, especially multi-site trials with outside sponsorship, use a protocol-specific definition of "enrolled." Most of these *are* compatible with the standard definition, "*consented and screened, with eligibility verified*." When protocol-specific definitions depart from the standard – as in example #3 below – your IRB regulatory staff can help you determine the most appropriate ways to answer eResearch questions about "enrollment."

Examples of "enrollment" definitions from clinical trial protocols:

1. Prior to enrollment of a subject, the following must occur:
    - Confirm patient signed informed consent.
    - Confirm patient meets all of the inclusion and none of the exclusion criteria....
    - Due to the inclusion/exclusion criteria, not all subjects that consent to the study will be enrolled. ... Enrollment will occur only if the patient meets all inclusion criteria and does not meet any exclusion criteria and has been assessed by the Screening Committee as being an appropriate candidate....
    - Subjects will be considered enrolled into the study at the time of the assignment of a patient identification number.
2. Once written consent is obtained and subject eligibility assessed, eligible subjects will be enrolled.... All screening assessments must be completed before enrollment at Visit 2.
3. The point of enrollment is defined as the time at which a patient has signed and dated the CF [consent form].

NOTE: Contact Calendar Review & Analysis Office (CRAO) for questions about Clinical Research Billing process, *including* "enrolling" and "disenrolling" for the purposes of MBECT. Clinical trials billing is managed through MBECT, a separate system from eResearch. An MBECT "Subject Enrollment" record is required for *each consented participant* to manage research billing of items/services.