THE UNIVERSITY OF ARIZONA
Research
Innovation & Impact

Enrollment and Accrual of Study Participants

Guidance

The number of participants in a study directly relates to the Belmont Report concept of Justice, whether or not subject selection is equitable, and whether the risks to participants are reasonable in relation to the anticipated benefits of the study. As such, investigators must estimate the projected enrollment of participants when seeking IRB approval.

Recognizing that enrollment of participants is a process, the following definitions are used to clarify the point at which a participant is considered to be enrolled in human research:

***Enrolled Participants*:** individuals who are eligible for participation (i.e., meet the inclusion criteria for the study), have given informed consent and participated in some or all of the study procedures (excluding screening procedures where applicable).

- For observational studies all subjects whose data is being observed, in anyway, even if they are not participating in all study procedures are considered 'Enrolled.'

Screened Participants: individuals who have given informed consent and participated in screening procedures to determine eligibility. Note that informed consent is required before any data can be collected for screening purposes. A screening process where persons are simply informed of inclusion/exclusion criteria and allowed to self-identify as eligible for enrollment does not require informed consent because no data about the individuals are collected.

- ***Screen Failures***: individuals who have given informed consent and participated only in screening procedures to determine eligibility, but who were determined to be ineligible to take part in the study. Screen failures are not considered to have enrolled in a study.
    - For projects in which data is collected and kept on screen fail subjects, those subjects should be included in the total enrollment number as they now meet the definition of an 'enrolled participant." This is applicable only if the subject consented to having their data kept.

***Withdrawals*:** individuals who have given informed consent and participated in some study procedures, but who withdrew or were withdrawn from the study.

- If an individual is considered as withdrawn, they may still be counted as an enrolled participant as the data that was collected up until point of withdrawal may still be used.

Investigators may not enroll more participants than the number specified in the application currently approved by the IRB unless an amendment to increase enrollment is approved.

As part of the annual continuing review process, investigators must provide information about accrual of participants during the course of the study including:

- total number enrolled to date

Enrollment and Accrual of Study Participants

- where the project involves a formal screening process to determine eligibility, total number of screen failures
- total number of participants who withdrew or were withdrawn and the reasons for all active withdrawals.