**Guidance:**

The number of participants in a study relates to required determinations of 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 provide an estimate of the number of participants to be enrolled in the study when seeking IRB approval.

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 the total number enrolled to date, and, where the project involves a formal screening process to determine eligibility, the total number of screen failures. The total number of participants who withdrew or were withdrawn must also be reported. The reasons for all active withdrawals must be provided.

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

1. **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).

2. **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.

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individuals who have given informed consent and participated in some study procedures, but who withdrew or were withdrawn from the study.