

Department: UAMS Institutional Review Board
Policy Number: 14.5
Section: Recruitment Practices
Effective Date: August 12, 2004
Revision Date: N/A

SUBJECT: Subject Enrollment Defined

Definitions:

Accrual goal - The proposed total number of subjects that are to be screened and/or enrolled in a research study.

Enrolled subject – A volunteer who gives informed consent to participate in a study.

Human subject - An individual who is or becomes a participant in research, either as a recipient of the test article/treatment or as a member of a control group, or who is a participant on whom identifiable data is being collected. A subject may be either a healthy individual or a patient.

Ineligible subject - A volunteer who gives informed consent to participate in the study, but who is found to be ineligible to participate in the study (e.g., based on study-required screening tests, revised laboratory report, etc.) and whose participation was terminated.

Screen Failures – Subjects who were evaluated for participation in a study but did not meet the criteria found in the study protocol. This subject may or may not have signed a consent form depending upon the specifics of the IRB approved protocol.

IRB Review

A new IRB application must state the number of subjects to be accrued, *i.e.*, the accrual goal. When initial IRB approval is issued, approval is granted to accrue only the number of subjects listed in the application.

If the accrual goal is reached, subsequent accrual must cease. Accrual of subjects beyond the initially approved number is considered non-compliance with the terms of the project approval. Careful records of subject accrual, screening and/or enrollment should be kept to avoid inadvertent non-compliance.

If the Principal Investigator (PI) anticipates that a portion of the subjects will not be eligible to continue in the study after a screening process, the accrual goal should be estimated accordingly. Subjects who are entered in the screening portion of a project count towards the approved accrual goal. If the PI anticipates that the study will require screening of twice as many subjects as will actually continue in a trial, the requested accrual goal should take this into account.

During the course of the study, all proposed changes in the accrual goal must be submitted to the IRB for approval, through the modification section in ARIA, with an accompanying justification. Any increase in the accrual goal cannot be implemented until IRB approval has been obtained.

If the PI wishes to amend the accrual goal at the time of continuing review, he/she should clearly indicate this request as part of the continuing review and await the final decision of the IRB before proceeding with additional accrual beyond the original accrual goal. All requests for increased enrollment must be accompanied by a justification for the increase.