Department: **UAMS Institutional Review Board**
Policy Number: **14.5**
Section: **Recruitment Practices**
Effective Date: **August 12, 2004**
Revision Date: **August 19, 2015; February 15, 2016; July 21, 2020**

SUBJECT: Subject Enrollment Defined

POLICY
Subject enrollment shall be defined as described in this policy. Study submissions shall include planned accrual goals.

DEFINITIONS

Accrual goal - The number of subjects anticipated to enroll in the study. This includes subjects who fail screening, subjects who begin, but do not complete study participation, and those who complete the study.

Enrolled subject – A volunteer who gives informed consent to participate in a study. The IRB considers subjects enrolled after they've given their consent to participate, regardless of subsequent screen failures or a subject changing their mind prior to any study procedures. NOTE: This may differ from the sponsor's definition of enrollment.

Screen Failure/Ineligible subject – A volunteer evaluated for participation but who did not meet the criteria for study participation described in the protocol. This evaluation may involve direct subject contact or may occur before the subject is aware of being considered for participation, e.g., through a screening chart review. The person may or may not have given informed consent for this screening, depending on study specifics.

PROCEDURE

A. 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.
B. 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.
C. 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 enter the screening portion of a project count towards the approved accrual goal. If the PI anticipates that the study will require screening of more subjects than will actually continue in a trial, the requested accrual goal should be large enough to include all screened subjects, and not only the subjects who continue in the trial.
D. During the course of the study, all proposed changes in the accrual goal must be submitted to the IRB for approval, through the modification process in the IRB e-system, with an accompanying justification. Any increase in the accrual goal cannot be implemented until IRB approval has been obtained.