



Tracking and Calculating “Enrollment” Information for the “Renewal Application for Continuing Review”

(updated 10/2007)

The HSIRB requires the reporting of study enrollment numbers at the time of Continuing Review. This is important information which the IRB uses to ensure that the number of subjects enrolled has not exceeded the number approved in the protocol and that the study is progressing at a reasonable rate so as to be completed in a timely fashion according to the study design. If there is little or no progress toward study completion due to inadequate subject enrollment, the likelihood of benefit is reduced and the risk/benefit balance is negatively altered, placing those subjects enrolled at risk (no matter how minimal those risks might be), without any anticipated benefit.

DEFINITIONS:

A. Enrolled:

Adult: A signed consent document was obtained **AND** the subject participated in study procedures.

Minor: A signed “Parental Permission” with matching signed “Assent of the Minor” were obtained (in most cases both “Parental Permission” and “Assent” of the minor is required) **AND** the minor participated in study procedures.

B. Screen Failure:

This term applies to studies that include screening procedures in their protocols. Screen Failures are NOT included in the “Total Enrollment Number.” “Screen Failures” are reported on a separate line on the “Renewal Application for Continuing Review.”

For studies that have screening procedures in their protocol: The individual signs a consent document **AND** participates in screening procedures, **AND** based on the screening, **does not** meet eligibility requirements, **AND** therefore does not continue to participate in the study.

***Example :** The individual is thought to meet the general inclusion criteria which are: non-pregnant female between the ages of 18-35. The individual reports for a study visit and, as part of the protocol’s screening procedures, the subject has a urine test to rule out the possibility of pregnancy. The subject is found to be pregnant (i.e., does not meet eligibility criteria) and therefore does not continue participation in the study. She is considered to be a “Screen Failure.”*

***Example of when the term “Screen Failure” DOES NOT apply:** An individual calls in response to a recruitment ad. After a brief phone screen to determine if eligibility requirements are met, it is determined that the individual does not meet eligibility requirements. The individual does not sign a consent document or participate in study procedures. This individual is a respondent to a recruitment ad who was “not enrolled” — the term “screen failure” DOES NOT apply in this instance.*

C. Enrolled but Later Withdrew: (NOTE: “Enrolled” subjects who later withdraw **are included** in the “Total Enrollment Number.”)

Self-Withdrew: The consent or parental permission/assent documents were signed **AND** the subject participated in study procedures **BUT** later “self-withdrew” from the study for any reason. The withdrawal should be documented and the reason for the self-withdrawal should be specified.

Withdrawn from Study by Investigator or Sponsor: The consent or parental permission/assent documents were signed **AND** the subject participated in study procedures **BUT** was later withdrawn from the study by the investigator or study sponsor. The withdrawal should be documented and the reason for the withdrawal should be specified. Reasons for such withdrawals may include, but are not limited to:

- By the Investigator because it has been determined that it was in the subject’s best interest to discontinue participation in the study
- By the Investigator because subject was non-compliant with protocol
- Because the Sponsor closed the study

HOW TO CALCULATE THE “TOTAL ENROLLMENT NUMBER”

1. Start with the **Total Number of Individuals Who Signed Consent or Parental Permission/Assent Documents AND participated in study procedures**
2. Subtract any/all **“Screen Failures”** (See definition **“B”** on page 1)
3. The remaining number is the **“Total Enrollment Number”** (which includes any “withdrawals” described in definition **“C”** on page 1)

EXAMPLES OF ENROLLMENT TRACKING LOGS

In order to assure accurate enrollment reporting, the HSIRB suggests that you create and maintain an “Enrollment Log.” You may find the following examples helpful:

For studies involving ADULTS (**please refer to definitions on page 1*)

ID#	Male	Female	Date Consent Signed	*Subject “Enrolled”		**“Screen Failure”		**“Withdrawn”	
				Yes	No	Date	Reason	Date	Type/Reason
001	X		2/5/05		X	2/6/05	Meets exclusion criteria: urine test positive for pregnancy		
002		X	5/4/05	X				1/25/06	Withdrawn by investigator because subject’s non-compliance with study procedures increased risk to subject’s health.
003	X		8/9/05	X					
004		X	9/2/05		X	9/2/05	Did not meet inclusion criteria: scored below required number on test		

For studies involving MINORS (**please refer to definitions on page 1*):

ID#	Male	Female	Date Parental Permission signed	Date Assent Signed	*Subject “Enrolled”		**“Screen Failure”		**“Withdrawn”	
					Yes	No	Date	Reason	Date	Type/Reason
001	X		2/5/05	2/5/05		X	2/6/05	Meets exclusion criteria: Wears contact lenses (missed during initial screening)		
002		X	5/4/05	5/4/05	X				1/25/06	Self-Withdrew: moved out of area
003	X		8/8/05	8/9/05	X					
004		X	9/2/05	9/3/05		X	9/3/05	Did not meet inclusion criteria: scored below required number on test		

*Comments and suggestions for future “HRPP Topics” are welcome and should be submitted to:
Dorothy Wright at: dswright@research.buffalo.edu*

