



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



SBSIRB requires the reporting of study enrollment numbers in order to assess whether it will be possible for the study to be completed in a timely manner so as to prevent unnecessary risk exposure to participants -- no matter how minimal those risks may be. Specific information regarding “non-enrollments” and “withdrawals” (see definitions below) assists SBSIRB in this process.

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. Not Enrolled: (NOTE: This term applies to studies that include screening procedures in their protocols.)

For studies that have screening procedures: The individual signed a consent document **BUT** did not meet screening procedures **AND** therefore, did not continue their participation in the study.

Example : Based on a brief telephone screening, an individual is found to meet the 2 general inclusion requirements (is male between the ages of 18-35) and reports for the study visit. After signing the consent, the individual takes an aptitude test as part of the protocol’s screening requirement. If the subject does not meet the protocol-specified score for participation, the subject should not proceed with any further study procedures and is considered “Not Enrolled.”

Example of when the term “Not Enrolled” DOES NOT apply: An individual calls in response to a recruitment ad and does not meet inclusion/exclusion criteria based on the phone screening.

C. Enrolled but Later Withdrew:

Self-Withdrew: The consent/parental permission/assent document(s) were signed **AND** the subject participated in study procedures **BUT** later “self-withdrew” from the study. Document the withdrawal. If known, indicate the specific reason for self-withdrawal.

Withdrawn from Study by Investigator/Sponsor: The consent/parental permission/assent document(s) were signed **AND** the subject participated in study procedures **BUT** was later withdrawn from the study. Document the withdrawal. Also document the specific reason for withdrawal. 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/Parental Permission/Assent Documents**
2. Subtract any/all “**Not Enrolled**” (See definition “**B**” above)
3. The remaining number is the “**Total Enrollment Number**”
(NOTE: the “Total Enrollment Number” **INCLUDES** “Withdrawals” as described in “**C**” above.)

See Page 2 for ways to track “Enrollment” Information

TRACKING SUBJECT ENROLLMENT

In order to assure accurate enrollment reporting, SBSIRB 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”		**“Not Enrolled”		**“Withdrawn”	
				Yes	No	Date	Reason	Date	Type/Reason
001	X		2/5/05		X	2/6/05	Meets exclusion criteria: Wears contact lenses missed during initial screening)		
002		X	5/4/05	X				1/25/06	Self-Withdrew: moved out of area
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”		**“Not Enrolled”		**“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	9/2005	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:
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