

A guide to completing the CCIR Pilot Study Report for PIs

2. Study Sample

Total subjects consented _____ * *Total subjects still active* _____
Total women consented _____ * *Total screen failures* _____ *
Total minorities consented _____ * *Total withdrawals* _____ *
 *Indicates cumulative total from start of study

Include subjects who are in follow-up.

“Screen failures” signed the consent form, but later proved not to qualify for the study during screening procedures.

“Withdrawals” signed the consent form, but later withdrew from the study, either before or after receiving study drug, device or intervention.

Approximate ethnic makeup of population **consented**:

<i>Black:</i> _____%	<i>Asian:</i> _____%	<i>Pacific Islander:</i> _____%
<i>Hispanic:</i> _____%	<i>Caucasian:</i> _____%	<i>Middle Eastern:</i> _____%
<i>Native American/ Native Peoples:</i> _____%	<i>Other: (specify)</i> _____%	

Federal regulations require IRBs to gather information about the ethnic make-up of the subjects in the study. Estimate the ethnic breakdown of subjects consented at your site. Total should not exceed 100%.

3. Have there been any other unexpected study-related adverse events or unanticipated study-related problems which have not previously been reported?

See attached IRB Problem/Event form.

Unanticipated problems are issues outside the Adverse Event reporting system which may involve risk to the subject, or affect others in the research study. They include, but are not be limited to:

- Breach of confidentiality
- Destruction of study records
- Study drug unaccounted for

Unanticipated study-related problems might also be IND safety reports not previously reported to WIRB or other updates to risk or benefit information related to the study