Completion and Closure to Subject Entry

Definitions:

Human Subject (DHSS definition): a living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individuals, and uses, studies or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Human Subject (FDA definition): an individual who is or becomes a participant in research, either as a recipient of the test article or as a control and/or an individual on whose specimen a device is used. Under the FDA regulations and guidance, a human subject may include individuals whose de-identified tissue specimens are used in in vitro diagnostic medical device research. Private Information: Includes information about data or behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving no subjects. This may include identifiable private information obtained from a primary subject about a third party.

Relying Institution: the institution that has assigned an external Institutional Review Board (IRB) to serve as the Reviewing IRB under an IRB Authorization Agreement.

Completion of a research protocol

A continuing review application is required as long as the research uses identifiable data, thus posing a risk of breach of confidentiality to the participants. If the investigator is not using identifiable data, the protocol can be closed and no further IRB oversight is required. As long as human subjects research is ongoing, including analysis of collected data that contains identifiable private information or identifiable biospecimens, the study must maintain IRB approval and should not be submitted for completion. The study may be submitted as completed when the study is:

- permanently closed to subject entry
- completed with analysis of data and investigators have concluded that no new information needs to be provided to enrolled subjects;
- concluded to the point that there is no need to re-contact enrolled subjects to obtain additional research information.

If the research is prematurely completed or terminated for any reason, the completion should be reported to the IRB with the rationale for early completion.

How to submit a completion

Completion of research studies should be reported to the Woman's Health Research Center using a Continuing Review / Revision application and checking the box marked "Completion". Completion of studies may be acknowledged by the Woman's Health Research Center and the IRB will be notified at the next meeting. The Principal Investigator (PI) should submit the application and a statistical and/or progress report summarizing the results of the study thus far.

When IRB oversight is limited to Woman's IRB, the investigators must report study completion to the Woman's Health Research Center when either of the following conditions are met:

(a) When individually identifiable data and biospecimens are no longer being collected and all identifiable private information has been removed from the data set and biospecimens that will be used for analysis purposes.

(b) When the investigator will not be involved in data management and analysis (e.g., multi-center clinical trials), when all data collection is completed and the study sponsor has completed all closeout activities, even when human subjects research activity is ongoing at other study sites.

When Woman's IRB oversight includes at least one Relying Institution, the Woman's investigators may not submit study completion until human subjects research activities are complete at each Relying Institution.

After a study is completed, no subjects may be enrolled and no data may be collected. The Principal Investigator will be notified of acknowledgement the completion via letter. The Woman's Hospital Research Center will retain the records for three years after the study is completed. After three years the PI will be contacted via letter and asked if he/she would like to have the IRB file. If there is no reply after 30 days, the record will be destroyed.

Completion of an exempt study

Studies that have been approved as exempt from IRB review do not require a completion submission to the IRB; however, annual status updates will be sought from the investigator, and the investigator should notify the IRB that the study is completed at this time.

Temporary closure to subject entry

Studies may be temporarily closed to subject entry to allow for data analysis and a determination if the study should continue and/or progress to the next stage of accrual. The IRB should be notified of the temporary closure by submitting a Continuing Review / Revision application. A request for re-opening the study to subject entry must be approved by the full board prior to implementation. The PI will be notified via letter of acknowledgement of the closure to subject entry by the IRB. The study will remain in active status and will still be subject to continuing review, if applicable. Temporary or permanent closure to subject entry may be reviewed and acknowledged via expedited review.

Permanent closure to subject entry

Studies may be permanently closed to subject entry if there are no plans to enroll additional subjects and the study is being kept open for data analysis and long-term follow-up only. The IRB should be notified of the permanent closure via submission of a Continuing Review / Revision application. The PI will be notified via letter that the IRB has acknowledged the closure. The study will remain in active status and will still be subject to continuing review, if applicable. A request for re-opening the study to subject entry must be approved by full IRB review prior to implementation. Temporary or permanent closure to subject entry may be reviewed and acknowledged via expedited review.