

## When and How to Report a Completed Research Study

### *Why is it necessary to report a completed research study?*

There are several reasons why it is necessary to report a completed research study:

- The HSIRB must be informed of study activity since last approval to ensure that subjects were properly protected during that period.
- According to the Code of Federal Regulations, 45 CFR 46.115, the IRB is charged with maintaining adequate documentation and records of continuing activity. If a study is completed, closed or discontinued, the HSIRB must be informed so that appropriate records documentation can be made.
- PIs are responsible for maintaining study records for at least 3 years after closure. An HSIRB closure date serves as the starting point for this time requirement.

### *When is a study considered to be “completed”?*

A study is considered “**completed**”:

- when subjects are no longer being recruited, no longer being followed, **AND** data analysis has been completed.

A study is considered “**active**”:

- as long as subjects are being recruited, being followed, and/or data are being analyzed.
- even though it may be “closed to enrollment.” As long as study participants are undergoing intervention or follow-up OR data analysis is taking place, the study is considered to be “active.”

### *When must HSIRB be notified?*

A Completed Notification: Final Report Form must be submitted to HSIRB when the study:

- has been completed (this would include when a study is discontinued because the PI left the institution without provision for continuation of an HSIRB-approved study), or
- has been denied funding, or
- has not been conducted, or
- was closed by the study sponsor

If any of the above situations apply, the HSIRB should be notified as soon as possible, in any case no later than at the next renewal. If the study is sponsored and a close-out visit is conducted, the Completed Notification: Final Report Form should be submitted to the HSIRB when the close-out visit has been completed.

Once a study is completed/closed, no further collection or analysis or data is permitted and all study activity must cease.

### *Who is responsible for notifying the HSIRB?*

The Principal Investigator (PI) is responsible for closing out a study with the HSIRB.

### *What if a PI has left the institution?*

When a PI leaves the Institution, their study should be terminated and the Completed Notification: Final Report Form sent to the HSIRB. Alternatively, the study may be transferred to another investigator who will take responsibility for the research. In either case, the HSIRB **must** be notified. Refer to the HSIRB website for guidance on transferring responsibility for a study to another investigator.

### *What are some common errors to avoid when completing the form?*

While the revised Completed Notification: Final Report Form (last revised 1/2007) provides improved instructions regarding the information requested, a few suggestions are provided below to help you to avoid some common errors.

#### **To avoid the top 5 errors ... BE SURE THAT ...**

1. ... the entire form has been completed and **all questions have been answered**.
2. ... your responses match the time frame requested:  
i.e., “**since the start of the study**” OR “**during the past year**”
3. ... your enrollment numbers have been calculated properly.
4. ... your response provides complete information regarding the **repository** for the study’s human subjects documentation, (e.g., consent documents, HSIRB documents, etc.). Regulations require that study documentation be retained for a minimum of 3 years after the closing date. The complete address for where this documentation will be stored for during that retention period must be provided. (Note: Be sure to notify HSIRB of any change in the location of those files during the retention period.)
5. ...the Principal Investigator (PI) or the designee of the PI, **signs and dates** the form.

