



## Monday Morning Practice Pearls #40

### What does it mean to close a study with the IRB?

Study closure occurs when research-related interventions or interactions with human subjects have been completed **AND** all data or specimen collection **AND** analysis is completed. Study closure is an action taken by the PI and may occur for a variety of reasons. The types of study closures are:

- **Completed:** The study has been concluded as described in the protocol.
- **Premature Closure:** The study has permanently stopped earlier than anticipated by the protocol.
- **Study is withdrawn:** A study is stopped prior to enrollment of the first participant.

For more information on study closure and the PI and IRB's responsibilities see the Human Research Protection Program (HRPP) [SOP 11A](#). **NOTE:** The SOP changed the closure terminology from terminated to one of the 3 types of closures.

### How is the IRB notified of study closures?

An "Intramural Clinical Protocol Study Closure Application" must be completed and submitted to the IRB. The application is found in iRIS and includes:

- Type of closure
- Reason for closure
- Description of the research results including an AE table
- Information about the specimens collected on this trial (e.g., used, destroyed, transferred)
- Information about the data collected on this trial (e.g., data coded or de-identified)
- List of abstracts and publications that resulted from the protocol.

### What are the responsibilities of the research nurse related to study closure?

- Ensure that all participating basic science laboratories have completed all the data analysis per the protocol.
- Ensure that there is documentation in the medical record for each patient as to the off study date and the off study reason.
- Ensure that all patients have been taken off study with the CRO.
- Work with your protocol support office and PI to ensure that all the data required for the study closure application is accurate. The PI will ultimately sign-off on the closure in iRIS.
- Maintain all research-related documents and consider storing off-site.