

# Series 410 Study Closure | Institutional Review Board

## Study Closure from Series 410 of the Standard Operating Procedures

### I. Closure of Active Studies

Principal Investigators are responsible for ensuring the timely closure of a completed human subjects research project. Human subjects research is complete when the aims of the study have been reached, analyses are complete, and the study no longer involves a human subject. Closure is timely when a Closure Request is submitted within 60 days of the study becoming eligible for closure. See Chapter 10 of the Investigator Handbook for detailed guidance on eligibility for closure.

### II. Expiration of Active Studies

Studies that are not renewed, closed, or resubmitted prior to their continuing review or expiration date will expire. No human subjects research is permitted to take place under an expired protocol. Expired protocols cannot be renewed; they must be closed, or a new protocol must be filed while study procedures are halted once the protocol has become expired.

Principal Investigators with expired studies may not submit new protocols for review, except in the case where the new protocol is intended to take the place of the expired protocol and the PI has confirmed that study procedures have halted.

A pattern of permitting protocols to expire absent the circumstances for closure eligibility may constitute continuing noncompliance. Noncompliance procedures are detailed in Series 800 of these Standard Operating Procedures.

### III. Data & Specimens

Data, specimens, intellectual property, and other outputs resulting from a completed human subjects research project are often retained beyond the closure of the protocol. Principal Investigators are responsible for ensuring that the data are managed and stored in a manner that complies with USU Policy 588, Research Data, and that all appropriate security measures are followed as outlined in USU Policies 550-559 regarding Information Technology.

Sponsored research that proposed a Data Management Plan must ensure that the Data Management Plan:

1. Appropriately adheres to human subjects research requirements; and
2. Is followed, even if it is appropriate to close a human subjects research project prior to award closeout.