1. POLICY:

The closure of a protocol is a change in the status of an approved research activity from active to closed. Protocol closure must be reported to the IRB by the Investigator. The Closure Date establishes the record-keeping period of 3-years (or more, as applicable) post closure, and allows the IRB to collect pertinent information as needed, as well as close its files.

These procedures apply to all human subject research reviewed by the IRB, and exempt research.

2. DEFINITIONS

2.1 *Exempt Research.* Research that qualifies for one of the exemption categories specified at 45 CFR 46.104 and/or 21 CFR 56.

2.2 *IRB Reviewed Research.* Human subject research that does not qualify for an exempt determination (or which requires limited IRB review as a condition of an exempt determination) must be reviewed and approved by the IRB before it can be undertaken. While the research study is open, it remains under the oversight of the IRB.

2.3 *Protocol Closure.* The point at which research activities cease and the study is reported as "closed" to the IRB.

2.4 *Closure Date.* The date the study status is changed to "closed" with the IRB.

3. PROCEDURES

3.1 Requirements to Close a Protocol

3.1.1 No further interventions/interactions with subjects, no follow-ups, nor access to personally identifiable information for research purposes are occurring; and

3.1.2 All data analysis involving the research site(s) under this study is complete[1]; or data have been de-identified and no direct identifiers or code keys (if data are coded) exist that would allow for the potential identification of subjects; and

3.1.3 Grant funds associated with the protocol are no longer being accessed; or an associated grant remains active, the human subjects research activities have ended.

[1] Note that identifiable data may be stored securely for future research purposes if authorized by the IRB-approved data collection protocol and/or appropriate consent has been obtained from subjects.

3.1.4 Alternatively, an Investigator separating from Purdue may:

(a) identify a Purdue Investigator to oversee the study, or

(b) transfer oversight to an IRB at another institution, thereby closing the study with the Purdue IRB.

3.2 Procedure to Close a Protocol

3.2.1 Investigators can close a protocol for IRB reviewed research by submitting study closure materials through the electronic system. This must be submitted prior to the expiration of IRB approval.

3.2.2 Protocols that are transferred to another IRB are closed when the new IRB assumes jurisdiction.

3.2.3 HRPP Support Staff record the closure in the data management system and notify the Investigator of the closure by issuing a closure notice.

3.2.4 HRPP Support Staff archive the closed protocol. The protocol is retained for a minimum of three (3) years. If other regulations and policies apply to a particular protocol, the protocol is retained in accordance to the applicable record retention requirements (e.g., a minimum of six (6) years for research covered by HIPAA). At the end of the record retention period, the protocol is destroyed.

3.3 Administrative Closure of Protocols

3.3.1 Approved protocols that pass their designated "end date" may be closed administratively by the IRB if the Investigator fails to renew the protocol following established renewal procedures relevant to the given protocol.

3.3.2 Investigators who separate from Purdue with open protocols will have the active protocols at Purdue closed administratively.

3.4 Reactivation of a Closed Protocol

3.4.1 The IRB recognizes that occasionally Investigators or the IRB may inadvertently close a protocol that was intended to remain in approved status.

3.4.2 An Investigator has up to 60 days after the date of closure to notify the IRB Office of the mistaken closure and request reactivation.

3.4.3 Once an Investigator requests reactivation, continuing review is conducted on the protocol. To facilitate this process, the investigator must submit

any continuing review materials requested for the IRB to complete continuing review.

3.4.4 Protocols expired longer than 60 days cannot be reactivated. The Investigator must submit a new protocol application.

3.5 Investigator Duties After Protocol Closure

3.5.1 Investigators must retain research records pertaining to a research protocol for a period of three (3) years after the closure date. If other regulations and policies apply to a particular protocol, the protocol is retained in accordance to the longest applicable record retention requirements (e.g., a minimum of six (6) years for research covered by HIPAA). Such research records include, but are not limited to, signed informed consent forms, the approved protocol, and correspondence with the IRB.

3.5.2 Such records may be preserved in hardcopy, electronic or other media form and must be accessible for inspection and copying by authorized representatives of the HRPP, the Department of Health and Human Services, the Food and Drug Administration (FDA), and research sponsors.

3.5.3 Once a research protocol has been closed, Investigators may keep the data they collected, including identifiable private data, in a manner consistent with the IRB- approved protocol and subject consent. Investigators must continue to honor any confidentiality protections of the data.

3.5.4 Investigators must honor any other commitments that were agreed to as part of the approved research, for example, providing information about the study results to research subjects, or honoring commitments for compensation to research subjects for research participation. Additionally, if an Investigator becomes aware of risks to subjects from their participation in the research for which the subjects have not been informed, the investigator must notify the IRB via the submission of an Unanticipated Problem and/or Adverse Event Report.

3.5.5 Investigators who leave the Institution must deposit their research records with their Department Head prior to their departure from the institution.

4. RESPONSIBILITY

HRPP Support Staff are responsible for recording Investigator initiated protocol closures and administrative closures in the data management system, sending Closure Notices to Investigators, archiving closed protocols, and destroying protocols at the close of the applicable record retention period.

The IRB Administrator is responsible for supervising and advising the HRPP Support Staff.

The IRB Chair or designee is responsible for reviewing the final Continuing Review or Closure Report and confirming closure of the protocol.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.108(a)(3); 21 CFR 56.109(f)

45 CFR 46.103; 45 CFR 46.109; 45 CFR 46.115(b)

6. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.