IRB Study Closure Policy

1.0 Purpose

The purpose of this policy is to define Wright State Institutional Review Board (hereafter referred to as IRB) requirements pertaining to closure of IRB-approved studies.

2.0 Scope

This policy applies to all human subject research that is conducted by Wright State University faculty, staff and students and human subject research for which the WSU Institutional Review Board (hereafter referred to as "IRB") acts as the IRB of record for an external entity (e.g., Premier Health, Dayton VA Medical Center).

3.0 Definitions

3.1 **Closure** means an action that occurs when research-related interventions or interactions with human subjects have been completed and all identifiable private data or specimen collection and utilization/analysis as described in the IRB-approved research plan have ceased.

3.2 **Principal Investigator (PI)** means the primary individual responsible for the preparation, conduct, and administration of a human subject research study.

4.0 Policy

The principal investigator (PI) is responsible for formally closing an IRB-approved study when it is completed or discontinued. Study closure is considered a change in study status and therefore requires IRB review and approval per federal regulations and guidance. After a study has been closed by the IRB, it will not accept further submissions related to that study unless the submission impacts the rights and welfare of the locally enrolled subjects.

5.0 **Procedures**

An IRB-approved study can be formally closed by submitting the Study Closure form in the electronic submission system when:

5.1 The research was never initiated and there are no longer plans to open the study; or

5.2 The study PI plans to leave Wright State or local hospital relying on IRB and not transfer study to alternate local PI; or

5.3 The research is permanently closed to enrollment, with no further interaction/intervention with subjects or access to their personally identifiable information, all identifiable data analysis is complete and all sponsor/other data queries are completed and the sponsor has "locked" the data.

For multisite industry or cooperative sponsored research where the research is ongoing at other sites, the Wright State PI may close the local study when:

5.4 The Wright State site is no longer collecting, receiving, or analyzing identifiable data; and

5.5 If applicable, the sponsor does not have any outstanding queries or pending data analysis requests related to Wright State-approved study/site.

It is important to understand that if a Continuing/Administrative Review or Study Closure Form is not approved by the study expiration date, approval for the study has lapsed and **all research activities must stop**. However, expiration of IRB approval is not considered suspension or termination of research and is not subject to the *Human Subject Research Mandatory Reporting Policy.*

If the IRB does not receive a Continuing/Administrative Review or Study Closure Form within 30 days after the study expiration date, the HRPP Office will administratively close the study and notify the investigator in writing of this administrative closure. To resume research activities for a closed/administratively closed study (e.g., finish analyzing identifiable data), the PI must receive IRB review and approval of a new Initial Review Form and related new submission documents.

If a study has been open for a period of three or more years and the PI has not enrolled subjects in the study, the IRB requires study closure unless there are extenuating circumstances for keeping the project open (e.g., the study is about a rarely seen

condition). The documentation of any extenuating circumstances must be submitted to and approved by the IRB at the time of continuing/administrative review.

Once a Study Closure Form has been approved by the IRB, the study status in the electronic submission system will be changed to "Closed."

Repeated failure by an investigator to properly close studies may be reviewed by the IRB as potential non-compliance in accordance with the *Human Subject Research Non-Compliance Policy.*

6.0 **Responsibilities and Authorities**

6.1 PI Responsibilities

The Principal Investigator must:

6.1.1 Continue to protect the confidentiality of the data after study closure.

6.1.2 Destroy all subject identifiers connected with the research data, if the study was approved with a HIPAA Authorization Waiver and the investigator indicated in the IRB application would be destroyed upon completion of the research.

6.1.3 Retain research records in accordance with applicable Wright State requirements.

6.1.4 Ensure that all research-related activities, interventions, or interactions with human subjects have been completed at the site(s) approved under the PI's IRB application at the time the Study Closure Form is submitted to the IRB.

6.1.5 Submit a Study Closure Form or an Amendment Form transferring study to another eligible PI when terminating employment or affiliation with Wright State University. Amendments to change the study PI must be submitted and approved by the IRB prior to the departure of the original PI as he/she will lose access to the electronic submission system immediately after date of termination.

6.2 IRB Responsibilities

The IRB will review Study Closure Forms via full or expedited review and if

needed, request additional information from the study team. When IRB review is completed and study closure approved, a study closure letter will be sent to the PI. All IRB members will be notified of study closures approved via expedited review at the next convened meeting.

7.0 **Records**

All records related to this policy will be stored and maintained in accordance with any Wright State Policy, federal regulations, and sponsor requirements associated with the human subject research under review.

8.0 **References**

8.1 45 CFR 46
8.2 21 CFR 50
8.3 21 CFR 56
8.4 38 CFR 16