GW Policy on Approved IRB Study Expiration

It is the responsibility of the PI to submit an application for continuing review at least 30 days prior to expiration of the IRB approval date. OHR staff provides two notices to the PI as an alert of this requirement. If approval expires, the study must stop. It is the Principal Investigator’s (PI’s) responsibility to submit to the IRB a continuing review application for all active expedited and full-board studies on at least an annual basis or those studies will expire. Investigators should be aware of the following information concerning common scenarios pertaining to expiration:

1. The PI submits the continuing review application to the GW IRB prior to its expiration date, but approval expires prior to the IRB’s approval for continuation (lapse of approval)

OHRP and FDA place specific limitations on the conduct of research studies that have been submitted for IRB continuing review, but for which IRB approval lapses during the review process. In general, no research activity may occur until the IRB approves the continuing review application. It is the policy of GW that new enrollment must stop when IRB approval lapses in this circumstance. The IRB, however, may take an action permitting continuation of study procedures with enrolled participants under certain limited circumstances as is consistent with federal guidance:

- OHRP’s “Guidance on Continuing Review” holds that study activity may continue for a brief time during this lapse in approval if it is in the “best interest” of the study participants.

- FDA’s “Guidance for Institutional Review Boards and Clinical Investigators” expresses the same basic concept where the investigator is actively pursuing renewal with the IRB and the IRB believes that an over-riding safety concern or ethical issue is involved. In such cases the IRB may permit the study to continue for the brief time required to complete the review process.

The PI will be notified by the IRB if it determines that the study activity with enrolled participants may continue once approval has lapsed, including the length of time the activity may continue. If IRB approval of a study will lapse after the continuing review application is submitted, but before the continuing review application will be reviewed by the IRB, the IRB Chair may determine whether continued study activity will be permitted. The PI will be notified of the IRB Chair’s decision.

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II. **The PI fails to submit the continuing review application to the IRB prior to the expiration date**

*The study is expired/closed.* No study activity, including non-interventional activity such as data analysis, may occur after the expiration date. GW does not grant to the IRB the authority to “extend” the approval period for a study, nor may it provide a “grace” period.

A *new research application must be submitted to re-initiate the study.* A continuing review application will not be accepted once approval has expired. Submission of a new application is required to obtain GW IRB approval.

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