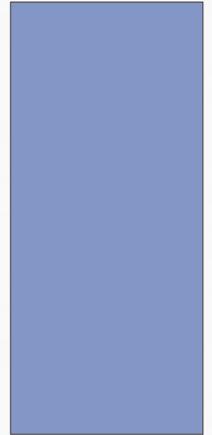


OHR 2015: UPDATES TO POLICIES AND STAFF

IRB FORUM
JANUARY 2015



POLICIES

OLD, NEW, AND UPDATED

GW POLICY ON PRINCIPAL INVESTIGATORS

The following may not serve as PI:

- GW Staff not holding a Faculty appointment
- Limited service Faculty
- Lecturers
- Adjunct
- Professor Emeritus
- Residents
- Fellows
- Clinical Professors
- Students
 - Undergraduate students
 - Masters students
 - Doctoral candidates

- GW requires that individuals who will serve as the principal investigator (PI) of human subjects research studies meet certain criteria.
- Only the following individuals may serve as PIs of HSR studies reviewed by the GW IRB:
 - Full Professor
 - Assistant Professor
 - Associate Professor
 - Research Scientists
 - Research Professors

GW POLICY ON PRINCIPAL INVESTIGATORS

- PI exceptions are permitted on a case-by-case basis.
- A PI Eligibility Exception Form must be completed and submitted to the OHR for review.
- These exceptions must be submitted for per study, not per PI.

OHR POLICY ON SUBMISSION REQUIREMENTS

It is the policy of the Organization that applications submitted to the GWU IRB for review must contain sufficient information to allow the IRB to make the determinations required by DHHS and FDA regulations. Application materials submitted to the OHR are reviewed by staff to determine that:

- a) All required regulatory information has been provided.
- b) All GWU required information has been provided.

The principal investigator (PI)/study contact will be notified when an application does not contain required material. The PI/study contact is responsible for submission of all requested information.

There is a 30 day period in which the PI/study contact must respond to requests for additional information required to initiate IRB review. The PI may request a one-time 30 day extension period to provide requested information. An application for which a response has not been received within the 30 day response period, or the 30 day response extension period, will be withdrawn from consideration. In cases where an application is withdrawn due to lack of response to a pre-review request, a new application with complete material must be submitted to initiate the review process. No exceptions will be made.

OHR POLICY ON SUBMISSION REQUIREMENTS

- What does this mean?
- Submit all applicable documents. Use current versions of applications and other OHR documents- otherwise they will be returned;
- Make sure to respond to preliminary reviews in a timely fashion;
- Don't shortcut when providing study details;
- This includes modifications and continuing reviews!

OHR POLICY ON HUMAN SUBJECTS RESEARCH TRAINING

Human Subjects Research (HSR) Training is required for all GW research investigators (who conduct research on human participants) and their research staff, IRB Chairs, IRB Co-Chairs, IRB members, OHR management, and OHR staff.

The approved HSR training site for GW is CITI. If the GW required CITI training courses have not been completed by the PI and all study team members prior to submission of an application to OHR, the application will be returned to the PI as incomplete.

GW requires continuing HSR Training. All investigators involved in human subjects research must complete recertification (renewal) of their initial HSR training in order to remain compliant with GW policy.

OHR POLICY ON HUMAN SUBJECTS RESEARCH TRAINING

- This means....
- Ensure all research team members have current CITI and have completed the appropriate trainings applicable to the study;
- It is the responsibility of the PI to maintain these trainings;
- OHR does not maintain trainings and cannot provide you with copies of trainings.

OHR 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 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:

OHR POLICY ON APPROVED IRB STUDY 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.

OHR POLICY ON APPROVED IRB STUDY EXPIRATION

2. 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. GWU 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 IRB approval.

OHR POLICY ON APPROVED IRB STUDY EXPIRATION

- How does this impact the study?
- If situation 1, some subjects may be allowed to continue for safety reasons.
- If situation 1, the PI submits a renewal with sufficient time to review and approve the study, but the lapse of approval is on the IRB, the study must stop for the lapse of approval but new documents need not be submitted.
- If situation 2, all research must stop, a closure form must be submitted, and should the PI wish to continue the study, new documents must be submitted for review and approval.
- The new submission will not be granted priority review.

OHR POLICY OF IRBS OF RECORD (RELIANCE)

- An IRB of Record or IRB Authorization Agreement (IAA) is a special agreement between two institutions who are engaged in human subjects research.
- These agreements help to economize on the IRB review and approval process by limiting the IRB review to one institution.
- IAAs are sometimes referred to as IRB of Records, but mean the same thing.
- When signing the IAA, one institution is designated the lead IRB or IRB of Record.
- After obtaining an IAA you will need to do the following:
 - If GW is the IRB of Record, you should continue to correspond with the GW IRB as you would normally do, such as submitting renewals, modifications, or closure requests.
 - If the other institution has been designated the IRB of Record, you should correspond with the other institution and submit renewals, modifications, and closure requests in accordance with their local procedures. You must contact the GW IRB if any of the following are true:
 - Change in risk level for the study;
 - Subject complaint;
 - Unanticipated problem involving risk to subjects or others;
 - Suspension or termination of the research by the investigator, IRB, or sponsor;
 - Change in PI;
 - Change in funding arrangements;
 - Change in GW staff roles and responsibilities;
 - Closure of the study.

OHR POLICY OF STUDY FILES

Study files are to include the following information when it exists:

- Correspondence and submissions to and from the IRB related to the study
- Protocols or research plans
- Approved sample protocol
- Investigator brochure
- Scientific evaluations, when provided by an entity other than the IRB
- Recruitment materials
- Consent documents
- DHHS-approved sample consent document and protocol
- Progress reports submitted by investigators
- Reports of injuries to subjects
- Records of continuing review activities
- Data and safety monitoring reports
- Modifications
- Unanticipated Problems Involving Risks to Subjects or Others
- Documentation of Noncompliance
- Significant new findings and statements about them provided to subjects
- Any findings required by law

OHR POLICY OF STUDY FILES

- This means:
- It is not the responsibility of the IRB to maintain study files for your research;
- The PI and research team must maintain all current and legacy documents related to the research;
- These documents must be made available to the IRB for auditing purposes in a timely fashion.

QUESTIONS?

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