I. Purpose

The purpose of the George Washington University Medical Center (GWU) Committee on Human Research Institutional Review Board (IRB) (hereinafter referred to as the GWU IRB) continuing review (CR) policy is four-fold. First, the CR policy describes the scope and frequency of continuing reviews and what will occur if there is a lapse in continuing review. Second, the CR policy describes the categories of continuing review and how each protocol is reviewed based on a study’s category of continuing review. Third, the CR policy identifies the information the Principal Investigator (PI) must include in a Continuing Review Data Collection Form (Attachment 1) and supporting information, if applicable, when requesting continuing review of a study. Lastly, the policy explains how the Office of Human Research (OHR) calculates a continuing review date.


III. Scope of Continuing Review

Continuing review of research protocols extends to protocols in which human subject enrollment is ongoing as well as to protocols in which human subject enrollment has been closed and the research interventions completed, but the data from the subjects continue to be collected and analyzed.

III. Frequency of Reviews

Continuing review of approved research protocols generally occurs on an annual basis; however, the GWU IRB has discretion to require protocols to be reviewed/renewed more frequently than annually when warranted. The following is a non-exhaustive list of protocols requiring more frequent than annual continuing review:

A. Studies approved pursuant to FDA regulations regarding Waiver of Informed Consent in Emergency Research;
B. Use of Humanitarian Use Devices (every 6 months);

1 Please note that if a PI does not request continuing review of his/her study at the time his/her study is due to expire, the PI must still complete the Continuing Review Data Collection Form to reflect the reason why the PI is not seeking continuing review, i.e., the PI is requesting closure of the file or that the study be terminated.
C. Studies overseen by a Data Safety Monitoring Board (DSMB) in which the DSMB requires continuing review to occur on a less than annual basis;
D. Studies involving a Recombinant Advisory Committee (RAC);
E. Studies in which the GWU IRB or PI requests that CR be conducted more frequently than annually.

IV. Categories of Continuing Review

The continuing review category of a research protocol is dependent on the protocol’s initial review category (expedited or full committee) and the level of risk associated with the study. As a general rule, continuing review is conducted by the full IRB unless the research is found to be appropriate for expedited review (see section IV.B. below).

A. Full Committee Continuing Review

1. What to Submit. In order for a study to be considered for full committee review, the PI must submit 1 copy of the following:

(i) The Continuing Review Cover Sheet;
(ii) A completed Continuing Review Data Collection Form, with supporting documentation, as applicable; and
(iii) An unmarked version of the most recently approved Informed Consent/Assent Form, as applicable or
(iv) For studies in which the PI is asking for approval of modifications at the same time s/he is seeking continuing review. Proposed modified informed consent form(s), assent form(s), recruitment material, data-gathering material (e.g., surveys, questionnaires, etc.) and/or protocol, as applicable. If modifications are being proposed for any of the above referenced documents, please include a copy(ies) of the old version(s) with the changes highlighted and a copy(ies) of the new version(s) without highlights. Whenever changes are made to any of these documents, please include a new version date for each modified/revised document.

2. What IRB Members Review and Review. All IRB members receive and review the following:

(i) A protocol summary;
(ii) A Continuing Review Data Collection Form which includes the following:
   • The number of subjects accrued;
   • The number of subjects withdrawn/dropped from the study. The phrase withdrawn/dropped from study includes all enrolled subjects who are subsequently taken off of the study either voluntarily, e.g., subject sees his/her participation in the study as an inconvenience, or involuntarily, e.g., due to subject noncompliance or in accordance with the study protocol.
   • A summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
• A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
• Any relevant multi-center trial reports; and
• Any other relevant information, especially information about risks associated with the research.

(iii) A copy of the current informed consent document and any newly proposed consent document. When reviewing the current informed consent document, the IRB should ensure that:
• The currently approved or proposed consent document is still accurate and complete; and
• Any significant new findings that may relate to the subject’s willingness to continue participation are provided to the subject.

In addition, when conducting continuing review of research not eligible for expedited review the primary reviewer will also receive a copy of, or be provided access to, the complete protocol including any modifications previously approved by the IRB.

3. Full Committee Continuing Review of Multi-Center Trials Monitored by a DSMB, Other Similar Body, or Sponsor

When conducting continuing review of research not eligible for expedited review and which involves multi-center trials monitored by a DSMB, other similar body, or a sponsor, the GWUMC IRB may rely on a current statement from the DSMB/sponsor indicating that the DSMB/sponsor has reviewed study-wide adverse events, interim findings, and any recent literature that may be relevant to the research, in lieu of requiring that this information be submitted directly to the IRB. Nevertheless, please keep in mind that the GWUMC IRB must still receive and review reports of local, on-site adverse events and unanticipated problems involving risks to subject or others and any other information needed to ensure that its continuing review is meaningful and substantive. See OHRP Guidance on Continuing Review, July 11, 2002.

B. Continuing Review of Research Eligible for Expedited Review

1. Studies Eligible for Expedited Continuing Review. The types of studies outlined below are eligible for expedited continuing review.

(i) A research protocol initially approved via expedited review unless the protocol has changed or will change, such that expedited review would no longer be permitted for continuing review;

(ii) A research protocol initially approved by the full committee when:
• the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; OR
• no subjects have been enrolled and no additional risks have been identified; OR
• the remaining research activities are limited to data analysis.
Under either of the situations noted above, the IRB chair or his/her designee will perform the continuing review. The IRB chair/designee can re-designate the protocol to full committee continuing review dependent upon proposed modifications to the protocol or the occurrence of events that challenge the minimal risk status of the research.

2. **What to Submit.** In order for a study to be considered for expedited continuing review, the PI must submit 1 copy of the same information outlined above under full committee continuing review – what to submit.

3. **What the IRB Chair/Designee Receives and Reviews.** When reviewing research under an expedited review procedure, the IRB Chair (or designated IRB members) received and reviews the same information referenced above under full committee continuing review – what IRB members receive and review.

V. **How To Determine Continuing Review Date**

A. **For Studies Approved/Renewed Under Full Committee Review (FCR).** The CR date for studies approved/renewed under FCR is calculated based on the date the full committee/IRB convened and reviewed the study for initial or last continuing review. In order to ensure that studies do not expire due to lapse in continuing review, OHR shortens the IRB approved continuing review period, which is always 12 months or less. OHR shortens the continuing review date by taking into consideration the date the full IRB considered the above referenced study for initial/continuing review, adding the IRB approved continuing review period to that date (usually 12 months), and then choosing the last day of the month proceeding that date. This is the reason why, depending on when a particular protocol is approved/renewed by the IRB, a particular study’s next expiration/renewal date may be shorter than 12 months even though the IRB final approval memorandum/continuing review form refers to a 12-month approval period. For example, assume a PI is informed of IRB approval of his/her study via an IRB final approval memorandum dated September 15, 2002 for a study that was before the full IRB on September 10, 2002. The full IRB approved the study for a period of 12 months, i.e., September 10, 2003. In this instance, the expiration/renewal date would be recalculated to August 31, 2003, in order to ensure against study expiration due to a lapse in continuing review.

B. **For Studies Approved/Renewed under Expedited Review.** The CR date for studies approved/renewed under expedited review procedures must occur within 1 year of the date the IRB Chair or his/her designee gave final approval/renewal to the studies. OHR applies the same procedures noted above in order to ensure that studies do not expire due to lapse in continuing review.

VI. **Lapse in Continuing Review**

Continuing review of all non-exempt research protocols is mandatory. Protocols automatically expire after one year (or less) unless reviewed and re-approved by the IRB. See 45 CF4 46.109(e) and/or 21 CFR 56.109(f). If a study expires as a result of a lapse in continuing review, the study must stop unless the IRB finds that it is “in the best interest of
individual subjects” to continue participating in the research. Moreover, enrollment of new subjects cannot occur once IRB approval has expired. If a study expires due to lapse in continuing review and the GWU IRB does not make an “in the best interest of individual subjects” determination, the study cannot proceed until the protocol, informed consent/assent forms (as applicable) are re-reviewed and re-approved by the GWU IRB.

The PI will be initially informed of the expiration date of his/her protocol via a final IRB approval memorandum that is generated following final IRB approval. The PI will again be informed of the expiration date of his/her protocol via an OHR reminder letter that will be sent out 60 days and again 30 days prior to the expiration date of the research protocol. A Continuing Review Data Collection Form will accompany the reminder letters.

Although OHR has implemented an administrative procedure intended to assist the PI in avoiding study expiration due to lapse in continuing review, please keep in mind that it is the PI’s responsibility to make sure that the protocol is renewed prior to the study’s expiration date. It is also the responsibility of the principal investigator to complete the continuing review data collection form, including the submission of required supporting information.

VII. What to do if A Study Expired Due to A Lapse in Continuing Review

As stated above, if a study expires due to lapse in continuing review the study cannot proceed until the protocol, informed consent/assent forms (as applicable) are re-reviewed and re-approved by the GWU IRB. The full GWU IRB or IRB Chair/designee will re-review such expired studies depending on when the PI finally submits the requested continuing review information. The general rule regarding IRB re-review of studies that have expired due to a lapse in continuing review is as follows. For those studies in which the PI has submitted a Continuing Review Data Collection Form along with accompanying information (when applicable) within 30 days of his/her study having expired, the full GWU IRB or IRB Chair/designee will re-review the study based on the information the PI has submitted to OHR to date. However, for those studies in which the PI has submitted a Continuing Review Data Collection Form along with accompanying information (when applicable) more than 30 days after his/her study has expired, the full GWU IRB or IRB Chair/designee will re-review the study only after the PI has submitted a new protocol and informed consent/assent form (as applicable).

Attachments:

Attachment 1 – Continuing Review Data Collection Form

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2 The GWU IRB could make such an “in the best interest of individual subjects” determination when it is determined that the halting of a study medication/medical device would result in additional risks to subjects.