CONTINUING REVIEW POLICY
FOR MEDICAL AND NON-MEDICAL RESEARCH

I. Policy

The George Washington University, Committee on Human Research, Institutional Review Board (GWU IRB) is required to conduct continuing review of human subject research protocols at intervals appropriate to the protocols’ degree of risk, but not less than once per year. At a minimum, research projects must be reviewed and re-approved by the GWU IRB before the study’s one-year expiration date. The GWU IRB determines a study’s expiration date at the time of initial IRB approval or continuing review approval. If a study is not reviewed and re-approved by the GWU IRB prior to the study’s expiration date, IRB approval of the study automatically expires.

There is no grace period for extending the continuation of research related activities beyond the study’s expiration date. Thus, if a study expires due to lapse in continuing review the following steps are taken:

A. Subject accrual/enrollment is suspended pending re-approval of the research by the GWU IRB;
B. Continuation of research interventions or interactions in already enrolled subjects continues pending re-approval of the research by the GWU IRB, but only if the IRB finds that it is in the best interest of individual subjects to do so;
C. The GWU IRB addresses, on a case-by-case basis, those rare instances when failure to enroll a new subject pending re-approval of the research by the GWU IRB would seriously jeopardize the safety or well being of a prospective subject.

II. Purpose

The GWU IRB Continuing Review (CR) policy:

A. Describes the scope and frequency of continuing review approvals and what will occur if there is a lapse in continuing review of research protocols;
B. Describes the categories of continuing review and how protocols are reviewed based on the continuing review category, i.e., Expedited Review or Full Committee Review;

C. Identifies the documentation required for continuing review approval via the Continuing Review Data Collection/Project Termination Form (available at www.gwumc.edu/research/forms.htm) and the supporting documentation, (as applicable) which is required to conduct continuing review, and

D. Explains how the GWU Office of Human Research (OHR) calculates the continuing review date.

A. Scope of Continuing Review Approval

Continuing review must be substantive and meaningful. The criteria for continuing review are the same as those for initial review. Therefore, in order for the GWU IRB (or the reviewer for protocols reviewed under expedited review procedures) to re-approve a study, the GWU IRB must be able to conclude:

1. Risks to subjects continue to be minimal and reasonable in relation to anticipated benefits;
2. Selection of subjects continue to be reasonable in relation to anticipated benefits;
3. Informed consent/assent/research subject authorization continue(s) to be appropriately documented, if applicable;
4. There are:
   a. Provisions for safety monitoring of data;  
   b. Protections to ensure the privacy of subjects and confidentiality of data; and  
   c. Appropriate safeguards for vulnerable populations.

Continuing review of research protocols applies to:

1. Studies in which human subject enrollment is ongoing; and
2. Studies in which human subject enrollment has closed and the research interventions completed, but data from subjects continues to be collected and analyzed.

Continuing review of research protocols is no longer required once all research-related activities have been completed at GWU.

B. Frequency of Continuing Review Approval

The frequency of continuing review approval for research protocols generally occurs on an annual basis; however, the GWU IRB has discretion to require protocols to be reviewed more frequently than annually. The following is a non-exhaustive list of the types of research protocols requiring more frequent than annual continuing review:

1. Studies approved pursuant to FDA regulations regarding Waiver of Informed Consent in Emergency Research;
2. Studies overseen by a Data Safety Monitoring Board (DSMB) in which the DSMB requires continuing review to occur on a less than annual basis;
3. Studies involving a Recombinant Advisory Committee (RAC); or
4. Studies in which the GWU IRB or Principal Investigator requests that continuing review approval be conducted more frequently than annually.
C. Categories of Continuing Review

The continuing review category of a research protocol is dependent upon the protocol’s initial review category (expedited or full committee) and the level of risk associated with the study. As a general rule, the full IRB conducts the continuing review of a research project that was initially approved by the full IRB, unless the protocol has been modified such that expedited review would be appropriate or the status of the study at the time of continuing review is such that the study now qualifies for expedited review.

1. Studies Eligible for Expedited Continuing Review. The following studies are eligible for expedited continuing review:

   a. Any study initially approved via expedited review unless the study has changed or will change, such that expedited review would no longer be permitted for continuing review;
   b. A study initially approved by the full IRB, but at the time of continuing review the IRB finds that:
      i. The research is permanently closed to 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
      ii. No subjects have been enrolled and no additional risks have been identified; OR
      iii. The remaining research activities are limited to data analysis.
   c. A research protocol, not involving an IND or IDE where certain expedited review categories do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Studies eligible for expedited continuing review are reviewed and re-approved by the IRB Chair or designee on behalf of the full IRB Committee. The expedited review determination is reported to the full IRB via the agenda of the next scheduled full committee meeting.

2. Studies Eligible for Full Committee Continuing Review. All other studies not meeting the criteria outlined above are eligible for full committee continuing review.

Studies eligible for full committee continuing review are assigned to one member of the IRB, i.e., the primary reviewer. The primary reviewer conducts continuing review on behalf of the full IRB. Following the primary reviewer’s critique of the study, the full IRB discusses the protocol and makes a re-approval determination with recorded vote.

D. Documentation Required for Continuing Review Approval

1. Full Committee Review. The Principal Investigator (PI) must submit 15 copies of the following:
   a. The Continuing Review Notice;
b. A completed Continuing Review Data Collection/Project Termination Form (which is available at [http://www.gwumc.edu/research/forms.htm](http://www.gwumc.edu/research/forms.htm)) with supporting documentation (as applicable);

c. For those studies in which subjects are still being enrolled, an unstamped version of the most recently-IRB approved Informed Consent/Assent/Research Subject Authorization Form(s), all of which are available at [http://www.gwumc.edu/research/forms.htm](http://www.gwumc.edu/research/forms.htm), as applicable. When reviewing the current informed consent/assent/research subject authorization document, the IRB ensures that:

i. The currently approved or proposed consent/assent/research subject authorization document is still accurate and complete; and

ii. Any significant new findings that may relate to the subject’s willingness to continue participation are provided to the subject.

d. For studies in which the PI is seeking approval of modifications at the time of continuing review approval, the PI must include the information outlined above plus 15 copies of the new version document(s) and 15 copies of the existing document(s) with the proposed changes highlighted. Whenever changes are made to documents, a new version date must be added in the footer section of each modified document(s).

IRB members receive a copy of all of the documents noted above as well as a copy of the protocol summary. The primary reviewer receives a copy of all the documents noted above and a copy of, or is provided access to, the complete IRB-maintained file, which includes all modifications previously approved by the GWU IRB.

**Full Committee Continuing Review of Multi-Center Trials Monitored by a Data Safety Monitoring Board (DSMB), Other Similar Body, or Sponsor.** When the full IRB conducts continuing review of a multi-center research project monitored by a DSMB, other similar body, or a sponsor, the GWU IRB may rely on the DSMB/sponsor report indicating that the DSMB/sponsor has reviewed study-wide serious 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 GWU IRB. Even if the GWU IRB receives such a statement from the DSMB/sponsor, the GWU IRB must still receive and review reports of local, on-site reportable events, and any other information needed to ensure that its continuing review is meaningful and substantive. (See OHRP Guidance on Continuing Review, July 11, 2002)

2. **Expedited Review.** The PI must submit one (1) copy of the information outlined above under section [D1. Full Committee Review](#). The IRB Chair or designee receives all of the information noted above, including access to the complete IRB-maintained file.

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

1. **For Studies Approved/Renewed Under Full Committee Review (FCR).**

   The continuing review date for studies approved/renewed under FCR is calculated based on the date the full committee convened and approved the study as submitted or approved...
it pending submission of additional information (i.e., conditional approval). In order to ensure that studies do not expire due to lapse in continuing review approval, the GWU IRB shortens the IRB approved continuing review period, which is always 12 months or less, by considering the date the full IRB reviewed and approved the study (as submitted or conditionally), adding the IRB approved continuing review period to that date (e.g., 12 months), and then selecting the last day of the month preceding that date. This explains why, depending on when a particular protocol is approved/renewed by the GWU IRB, a particular study’s next expiration/renewal date may be less than 12 months despite the final approval memorandum/continuing review form referring to a 12-month approval period.

Example. The IRB conditionally approved a study for a period of 12 months at its September 10, 2002 meeting, i.e., September 10, 2003. In a memorandum, dated September 15, 2002, the PI is informed of the conditional approval and the request for additional information. On October 5, 2002, the PI submits the requested additional information to the IRB. The expiration/renewal date of September 10, 2003 (12 months from the date the full committee conditionally approved the study) is recalculated to August 31, 2003, in an effort to prevent study expiration due to a lapse in continuing review approval. Note that the continuing review date has nothing to do with the date the IRB received the requested additional information, i.e., October 5, 2002.

2. For Studies Approved/Renewed under Expedited Review.

The continuing review date for studies approved/renewed under expedited review procedures is calculated based on the date the IRB Chair or designee renders 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 approval.

III. Communicating Continuing Review Date

The PI is initially informed of a study’s expiration date via the initial IRB approval memorandum. Again, the PI is informed of the study’s expiration date by way of a 60-day and 30-day Continuing Review Notice. Although the Office of Human Research (OHR) has implemented an administrative process intended to assist the PI in avoiding study expiration due to lapse in continuing review approval, it is the Principal Investigator’s responsibility to ensure the protocol is renewed, i.e., reviewed by the IRB and re-approved prior to the study’s expiration date, regardless of whether the PI received a continuing review notice.

The PI is also responsible for completing the Continuing Review Data Collection/Project Termination Form in its entirety and include required supporting documentation; submitting an incomplete Continuing Review Data Collection/Project Termination Form will cause a delay in the continuing review process that may ultimately result a lapse in IRB approval.

IV. Lapse in Continuing Review

Continuing review of all research protocols approved via the expedited and full committee review process is mandatory. GWU IRB approval of all such protocols automatically expires after one year (or less) unless reviewed and re-approved by the IRB prior to the study’s
expiration date. Simply submitting a Continuing Review Data Collection/Project Termination Form to the GWU IRB, without receiving IRB approval of the study prior the study’s expiration date results in a lapse in IRB approval for the study. Thus, in order to avoid a lapse in IRB approval, the PI must submit the requested continuing review information to the GWU IRB within a time frame that allows the study to be **reviewed and re-approved by the IRB prior to the expiration date**.

If GWU IRB approval of a study expires as a result of a lapse in continuing review approval, all study related activities must cease, unless the IRB determines that it is “in the best interest of individual subjects” to continue participation in the research pending re-approval of the research by the IRB. An “in the best interest” determination will only be granted if the Principal Investigator requests the GWU IRB to make such a determination. Such a determination allows the study to remain active pending re-approval of the research by the IRB, but only for those subjects identified in the request; all study activities related to other subjects must cease during the lapse in continuing review. Moreover, enrollment of new subjects is generally prohibited once IRB approval has expired.

As a general matter, if a study expires due to lapse in continuing review approval and a request for an “in the best interest of individual subjects” determination is not received by the GWU IRB, the study cannot proceed until the protocol and all supporting documents are reviewed and re-approved by the GWU IRB.

An official memorandum entitled “Administrative Termination Due to Lapse in Continuing Review” is generated the day after a study expires if no continuing review information has been submitted to the IRB prior to the study expiration date. This memo is sent to the Principal Investigator of such a study and informs the Principal Investigator of the requirements necessary to proceed with the research activities related to the expired study at GWU.

V. IRB Review of a Study Due for Continuing Review Approval

The GWU IRB will review continuing review information for a study that is due for continuing review approval as follows:

A. **Continuing Review Information Submitted to the IRB Prior to or on Study Expiration Date**

The GWU IRB will accept all continuing review data collection forms and accompanying information that is submitted to the IRB prior to or on the study expiration date. The GWU IRB will consider this continuing review data collection form along with the information already contained in the IRB-maintained study file.

A full committee review example. On March 29, 2003, a PI submits to OHR continuing review information for a full committee review study that is due to expire on March 31, 2003. The next scheduled IRB meeting is April 14, 2003. During that meeting, the IRB votes to approve the study for an additional 12 months pending receipt of minor modifications as requested by the full

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2 The GWU IRB can 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.
committee. The modifications are submitted to and approved by the IRB on April 30, 2003. In this scenario, the IRB continuing review approval date is the date the full committee convened to review the study and conditionally approved it, i.e., April 14, 2003. In this scenario, the study experienced a short lapse in IRB approval (April 1, 2003 – April 13, 2003).

In this scenario, the Continuing Review Notice will include a stamp that reflects GWU IRB approval from April 14, 2003 through March 31, 2004. The Continuing Review Notice will also inform the PI: (1) of the period in which there was a lapse in continuing review approval (April 1, 2003 – April 13, 2003); (2) that all research-related activities should have ceased during the lapse in continuing review; and (3) if research activities were conducted during the lapse in continuing review approval, no data generated from those activities can be used for the study as the data was collected without IRB approval.

An expedited review example. On July 29, 2003, a PI submits to OHR a Continuing Review Data Collection & Study Termination Form for an expedited review study that is due to expire on July 31, 2003. An OHR staff member reviews the Continuing Review Data Collection & Study Termination Form and determines that information is missing, e.g., an ICF for a study that is currently enrolling subjects. On July 30, 2003, the OHR staff member notifies the PI of the missing information and informs the PI that the IRB Chair cannot approve the study for an additional approval period until the IRB Chair reviews the ICF. Subsequently, on August 20, 2003, the PI submits the requested ICF document. The IRB Chair reviews and approves the study on the same day for an additional 12 months. In this scenario, the study experienced a short lapse in IRB approval the continuing review approval (August 1, 2003 - August 19, 2003.)

In this scenario, the Continuing Review Notice will include a stamp that reflects GWU IRB approval from August 20, 2003 through July 31, 2004 (12 months from the date the IRB Chair/designee approved the study, August 20, 2004, truncated to the last day of the month prior to August 20, 2004). The Continuing Review Notice will also inform the PI: (1) of the period in which there was a lapse in continuing review approval (August 1, 2003 – April 19, 2003); (2) that all research-related activities should have ceased during the lapse in continuing review; and (3) if research activities were conducted during the lapse in continuing review approval, no data generated from those activities can be used because the data was collected without IRB approval.

Please note that the GWU IRB reserves the right to administratively terminate any studies in which the PI has failed to respond to an IRB/OHR continuing review - requests for additional information, or other similar additional information requests, within 30 – 60 days from the request.

B. Continuing Review Information Submitted to the IRB After Study Expiration Date

As a general rule, the GWU IRB will NOT accept continuing review information that is submitted to the IRB after a study has expired. The GWU will only review such a study if the PI submits a new IRB submission package, including a new IRB submission form, protocol, informed consent/assent form(s) (if applicable), research subject authorization form (if applicable), and all associated documents are reviewed and approved by the GWU IRB as a new study with a new IRB number.