

Responsibilities After Initial IRB Review for Expedited and Full Board Studies/FAQ

After a study is initially approved by the IRB, there are additional forms and information that need to be submitted to the Office of Human Research in order to keep your study active, modify your study, or close your study. These additional steps are as important as the initial approval, and are required by federal and University policies that regulate human subjects research.

1. When a study is approved by Expedited or Full Board review, additional forms and information must be submitted to:

- Renew the study
- Modify the study
- Close the study
 - <http://www.gwumc.edu/research/human/inside/forms/expedited.html>

2. What does the study expiration date mean?

- For Expedited and Full-board reviews, approval is granted for 365 days. This means that the IRB must re-review the study each year in order for the study to continue.
- You will find the expiration date stated in approval letter.
- If IRB approval of a specific study expires before it is renewed or closed by the IRB, investigators must stop all research activities involving human subjects related to that study.

3. What is required to continue a study beyond the expiration date?

- If research is to continue past the initial 1- year approval the Renewal Request Form must be submitted to the Office of Human Research, and the IRB must approve the continuation of the study.
- The Renewal Request Form should be submitted within 30 days **before** the study expiration date for Expedited studies and about 45 days for Full Board studies.
- *Link to Renewal Request Form: (Includes checklist)*
 - http://www.gwumc.edu/research/human/inside/forms/files/Renewal_Request_Form.doc

4. What is required to modify an IRB-approved study?

- For any proposed change to a study that was approved by Expedited or Full Board IRB review, a Modification Request Form must be submitted to the Office of Human Research, and approved by the IRB **before** implementing the change.
- Changes that require IRB approval include (but not limited to):
 - adding/deleting or changing questions
 - increasing accrual ceiling
 - adding investigators, sites
 - changing consent forms, etc.
- *Link to Modification Request Form: (Includes checklist)*
 - http://www.gwumc.edu/research/human/inside/forms/files/Modification_Request_Form.doc

5. Do I need to close an IRB-approved study once it has been completed? If so, what is required?

- All studies approved by Expedited or Full Board review need to be closed by the IRB. The Study Closure Form should be submitted to the Office of Human Research, and approved by the IRB.
- If a study has been completed, a Study Closure Form must be submitted before the expiration date, otherwise the study will expire.
- *Link to Closure Request Form: (Includes checklist)*
 - http://www.gwumc.edu/research/human/inside/forms/files/Study_Closure_Form.doc

6. What notices will be sent regarding the expiration of IRB approved studies?

- OHR's first communication of your expiration date is found on the approval letter.
- You will also receive a 60/30 day notice asking you to submit 30 days prior to your expiration date to ensure the study is re-approved before expiring.
- If the study renewal or closure is not approved by the IRB before the expiration date, you will receive an expiration notice, and all research activities must stop.
- If the study Renewal Request Form or Study Closure Form is not approved by the IRB by 60 days after expiration date, then the study will be administratively terminated by the IRB.

7. What if there is an unanticipated problem or procedure conducted without IRB approval during the study?

- Please consult with Office of Human Research regarding the possible submission of a Problem Report
 - *Link to the Form:* http://www.gwumc.edu/research/human/inside/forms/files/Problem_Report_Form.doc

Please contact the Office of Human Research for any questions regarding IRB submissions at 202-994-2715 or ohrirb@gwumc.edu

<http://www.gwumc.edu/research/human/inside/forms/index.html>