



MCW Office of Research Standard Operating Procedure

IRB APPROVAL DOCUMENTS

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:

The MCW IRB reviews a variety of activities in the course of human subject research. These activities are given approval dates per the *Approval Date Guidelines*. IRB approval/effective dates inform an Investigator when they may begin enrolling subjects or use the approved documents and clarify the IRB approval timeframe.

In addition, the HRPP Office monitors the IRB process and workflow to ensure submissions are reviewed in a timely manner and Investigators receive approval documents according to the expectations of the HRPP Office.

DEFINITIONS:

Approval date: The date that the IRB Committee finds that all regulatory criteria for approval are satisfied and the majority of a convened committee (or a designated Expedited Reviewer) vote to “approve,” with or without the requirement for additional modifications.

Effective date: When the majority of a convened committee vote to approve with a requirement for additional modifications, the effective date is the day that the IRB Chair or designated Committee member verifies that all required modifications have been satisfactorily completed.

PROCEDURE:

IRB Approval/Effective Dates:

1. IRB Letters are the official correspondence from the IRB to Investigators. All IRB decisions will be conveyed to Investigators via a written letter.
2. IRB letters for submissions reviewed by a convened IRB or via expedited review will be signed via the electronic signature of the IRB Chair or designee and be issued to the Investigator and designated project team members via the eBridge system.
3. IRB letters will be issued in conjunction with IRB actions as described in *IRB SOP: IRB Actions*. IRB approval letters will include the following information (as applicable):
 - i. Protocol, version, date
 - ii. Amendment, version, date
 - iii. Investigator’s Brochure, version, date
 - iv. Device Manual, version, date
 - v. Advertisement/Recruitment Materials, version, date
 - vi. Consent Form(s)
 - vii. Waiver of Consent

- viii. Waiver to Document Consent
 - ix. Waiver of HIPAA authorization
- 4. The *Staff: Approval Date Guidelines* outline the approval dates given to various IRB reviews and approval process as noted below:
 - a. The following IRB submissions and activities may be “approved” by the IRB and cite “IRB Approval Date” and/or “IRB Expiration Date”
 - i. Initial Application: except in cases where the review has been determined to meet exemption criteria, qualify for FLEX review or not human subjects research.
 - ii. Amendments: these documents will only include an IRB approval date. If the amendment includes a revised consent form, the consent form will receive an effective date.
 - iii. Continuing Progress Reports (CPR)
 - iv. Expanded Access of an investigational drug, device or biologic
 - v. Humanitarian Use Devices
 - vi. Final or Completed Continuing Progress Reports (CPR)
 - b. The following IRB submissions and activities will be “acknowledged” by the IRB and will not cite an IRB approval date or expiration date.
 - i. Reportable Events
 - ii. Emergency Use of a drug or device
- 5. Convened Committee Activities: The “IRB Approval Date” is the date of the IRB meeting date, and the “IRB Expiration Date” is the last date of the IRB approval period. The “IRB Effective Date” is the date the IRB Chair or designated reviewer indicated approval of required changes. The “IRB Expiration Date” indicates the last day when a project is active and approved. For example, if a project is approved from 10/02/2007 to 10/01/2008, the project may use its approved documents such as the consent form or conduct procedures until midnight on 10/01/2008.
- 6. Expedited Review Activities: The “IRB Approval Date” is the date the IRB Chair or designated reviewer indicated approval and the “IRB Expiration Date” is the last date of the IRB approval period. The “IRB Expiration Date” is the last day when a project is active and approved. Project activities may occur until midnight on the “IRB Expiration Date”.

Stamping IRB Approved Documents:

- 1. An IRB “Effective Date” stamp is applied to the following documents once they have been reviewed and approved by the IRB for use in a project:
 - Consent Forms
- 2. MCW IRB approved consent forms for projects reviewed by a convened IRB or via expedited review contain an approval date and expiration date. The consent approval date will be the same date as the IRB project approval date. The approval date will be the same as or earlier than the effective date (see Definitions, above). The consent expiration date is the last day when a consent form may be used. For example, if a consent form is stamped or indicates an approval period from 10/02/2007 to 10/01/2008, the project may use the consent form until midnight on 10/01/2008.
- 3. When the majority of a convened committee or a designated reviewer votes to “approve” with no requirement for additional modifications, the effective date is the same as the approval date.
- 4. Thus, when additional modifications are required, there can be a gap of days or weeks between the approval and effective dates.

Timeframe for Communication of IRB Determinations:

1. The HRPP office has established timeframes in which approved documents should be processed and forwarded back to Investigators and project team. These guidelines also indicate the turnaround time to forward documents to the appropriate HRPP staff, IRB Chairs, Institutional Officials, and/or regulatory agencies.
2. IRB decisions will be sent to Investigators within 5 business days after a convened meeting or final determination by a designated reviewer. All IRB-approved stamped documents will be posted within 5 business days once IRB approval has been granted.

REFERENCES:

N/A

SUPPORTING DOCUMENTS:

IRB SOP: IRB Actions

Staff: MCW IRB Approval Date Guidelines

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