MWMC IRB

Handbook for IRB Submissions

All forms for IRB submissions can be found on the MWMC website through the following link: http://www.mwmc.com/healthcare-professionals/IRB

The forms are broken down into the following categories

- Pre-Approval
- Post Approval
- Renewal/Continuation and Completion Forms

Enrollment of subjects into an investigational trial shall not commence until written IRB approval is received

- Submission Timelines:
  - Deadline for full board review is one full week before the scheduled meeting (fourth Wednesday of each month)
  - Submissions for expedited review are ongoing
  - All submission forms must be fully completed. Failure to complete and sign may result in a delay of IRB review.

Types of Study Review

- **Full Board Review:** A full board review requires a quorum of board members. If a research study is not classified as exempt or expedited, it requires review by the full IRB in a convened meeting which occurs on the fourth Wednesday of each month.

- **Expedited Review:** An expedited review consists of a review of research involving human subjects by the IRB chairperson. The FDA has established and published in the Federal Register, a list of categories of research that may be reviewed through an expedited review procedure. http://www.fda.gov/ohrms/dockets/98fr/110998b.txt

- **Exempt Research Review**: In order for a study to be considered exempt, the investigation must meet certain criteria. If a study is determined to be exempt, the IRB will inform the investigator. The letter of determination will include one or more references to the exempt categories under which the exemption is granted.

Determination of IND or IDE Requirement

Upon receipt of an IRB submission The MWMCIRB will review the submission to determine if an Investigational Device Exemption (IDE) or an Investigational New Drug (IND) Application is necessary.

- **Investigational New Drug (IND**) : MWMCIRB will ascertain that a proposed investigation involving investigational drug will have a valid IND number.

- **Investigational Device Exemption (IDE)** There are three types of studies described in the regulations at 21 CFR Part 812: significant risk (SR) device studies, non-significant risk (NSR) device studies, HDE.

On the review of the studies involving the use of medical devices on a human subject the board will determine if the device poses significant or non- significant risk to subjects.

A significant risk device means a device that:

- Is intended as an implant and presents potential risk to the health, safety or welfare of the patient.
- Is purported or represented to be used for supporting or sustaining human life and presents potential for serious risk to the health, safety or welfare of the patient.
- Is for use of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise preventing impairment of human health.

A non-significant risk devise is any devise that does not meet the criteria mentioned above

Forms for Initial Submission

- All forms can be accessed through the following link: *http://www.mwmc.com/healthcare-professionals/IRB/Forms*
- Submissions must be fully completed, failure to submit completed packages with all required documents may result in a delay of IRB review.
- Please refer to the last page of each form for a checklist of required documents for submission

- **Submission for Investigational Drug/Biologic Studies:**
  - Site Submission Form
  - Additional Research Location Form (if applicable)
  - Disclosure of Financial Conflict of Interest

- **Submission for PI/ Resident Studies (Not Chart Reviews):**
  - Site Submission Form
  - Protocol Submission Form
  - Protocol Summary Non-Industry Form
  - Disclosure of Financial Conflict of Interest (if applicable)

- **Submission for Chart Review**
  - Site Submission Form Chart Review (see checklist for required documents)
  - Chart Review Protocol

- **Submission for Humanitarian Device Study (HUD)**
  - Humanitarian Device Study Form
  - Site Submission From

- **Study Transition Form (for studies being transitioned to MWMC IRB from another IRB)**
  - Study Transition Form

After a protocol is approved, the site will receive a letter of IRB approval along with other approved documents as they relate to the study. After study has been approved, Investigators or Investigator designee have the following obligations:

- Report any changes in research activities
- Obtain IRB approval before initiating changes to approved research
- Obtain IRB approval for any changes in Research Sites or Staff
- Obtain IRB approval for recruitment materials
- Report unanticipated problems including major protocol deviations within 5 days of becoming aware of the deviation
- Report serious adverse events within 48 hours of becoming aware of the event as required by Tenet policy CQ 2.03

If the conditions of MWMCIRB's approval are violated, the IRB may take action to see that these violations are resolved and not repeated. These actions could result in a site visit or suspension of study enrollment.

Forms for Proposed Study Modifications after IRB Approval

**All changes will require IRB approval prior to the implementation of the change, unless the requested change is necessary to reduce immediate risks to human subjects.*

- **Amendment to Protocol, ICF, Investigator Brochure**
  - Use for changes in protocol, ICF or Investigator Brochure

- **Informed Consent Revision Request**
  - Use this form if submitting changes only to the ICF, changes in research staff or location

- **Miscellaneous Research Submission Form**
  - Use for subject materials, diaries, questionnaires etc.

- **Report of an Unanticipated Problem**
  - Unanticipated problems must be reported within 5 days of site becoming aware of them
  - If reporting an SAE please complete an SAE Report Form and submit with this report
  - If filing a protocol deviation, a Protocol Deviation Form must be submitted (see below)

- **SAE Reporting Form**
  - All SAEs must be reported to MWMC within 48 hours of site becoming aware of them

- **Protocol Deviation**
  - MWMCIRB does not require that protocol deviations be reported, unless they constitute an Unanticipated Problem. An Unanticipated Problem is defined as any unforeseen event or events that may involve risks or affect the safety or welfare of subjects or others, or that may affect the integrity of the research. However, if you are required by sponsor, CRO or site policy to report a protocol deviation to MWMCIRB, please use this form

- **IND Safety Report**
  - On this form list all of the IND Safety Reports which the sponsor requires you to submit to the MWMC IRB

- **Additional Research Location Form**
  - Complete a separate form for each Additional Location.

- **Change to investigative site or staff**
  - If adding a new PI or Sub-I please include revised ICF and complete ICF Revision Request if applicable.

Continuing Review

During the course of the study, the investigator will be required to submit a Continuing Review Form at least annually to provide MWMCIRB with information regarding the progress of the study. These forms can be located through the following site:
http://www.mwmc.com/healthcare-professionals/IRB/Forms

- Beginning two months before expiration, investigators will be notified by e-mail, phone and/or fax by the IRB of upcoming study expiration. (this is a courtesy of the MWMC, ultimately it is the Investigator's responsibility to renew studies prior to expiration)

- Reminders will be sent out in advance of a study expiration date; however, it is the responsibility of the investigator to monitor the research study to ensure obtaining continuing review before expiration.

- The submission of the Continuing Review Form must include complete copy of the Informed Consent for the last subject enrolled at your site.

- In the event that an investigator fails to submit a continuing review report prior to the study expiration date, MWMCIRB may inform the investigator that IRB approval of the research study being conducted at this site has expired.

- Completion Report MWMCIRB will require all investigators to complete a final report utilizing the IRB Closure Form when an approved study is completed or closed by the sponsor. In the event a Study Completion Form is not received, the study will be reported to the appropriate authorities (as applicable)