Marshfield Clinic

Convened IRB Meetings: Preparation, Conduct, and Follow-up

1. SCOPE

1.1. MCRF Office of Research Integrity and Protections (ORIP) and Institutional Review Board (IRB)

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. Review Committee Coordinator (RCC) – an ORIP staff member

2.2. Presenting primary reviewer (PPR) – an IRB member assigned by the RCC to review an agenda item for a convened IRB meeting

2.3. Contributing primary reviewer (CPR)- an IRB member assigned by the RCC to review an agenda item for a convened IRB meeting along with the PPR

2.4. Expert Guest Reviewers (EGR) – an individual who is not an IRB member however requested by the RCC/IRB Administrator or Chair to review an agenda item when no IRB member has the expertise to evaluate

3. RESOURCE GUIDE BODY

Purpose: To document the procedures used to ensure efficient, effective, compliant convened meetings of the Institutional Review Board (IRB)

3.1. Setting the Agenda

a. Convened IRB Meetings are held on the first and third Tuesday of every month, except when there is a lack of submissions for an agenda or a quorum is not available.

- An Initial (new) study IRB submissions to be reviewed at a convened meeting is requested to be submitted at least 3 weeks prior to the anticipated IRB scheduled meeting date that the PI would like to have it reviewed, in order to allow ample time for processing, primary review, responses from investigator (if applicable) and review by convened board members prior to the meeting.
- Initial (new) IRB submissions are scheduled for review on a first-come, first served basis
- Other items are scheduled to meet review deadlines, such as in the case of continuing review reports. These items are requested at least 2 weeks prior.

b. Up to 15 items are generally allowed per agenda, no more than 3-4 of them being new protocols. This has proven to allow adequate time for review in a 90 minute meeting. A lower limit may be placed at the discretion of the Chair or IRB Administrator based upon complexity of the items to be reviewed.

c. The following items may be included on a convened IRB agenda:

- Initial (new) IRB submission
  - Application

- Consent Documents
- Recruitment Materials
- Protocol

□ Continuing Review Reports

□ Changes to Approved Research

□ Unanticipated Problems Involving Risk to Subjects or Others

□ Report or Serious or Continuing Non-Compliance

□ Emergency Use or Expanded Access

□ Expedited Review Summaries (which include all actions taken)

□ Information/Educational items

□ Previous Minutes

3.2. Pre-Review Procedures and Distribution of Materials

a. Submissions to the IRB are checked to ensure all required fields are completed. This is done by an ORIP Review Committee Coordinator (RCC). Incomplete submissions are returned with instructions for completion.

b. The following materials (if applicable) must be submitted to ORIP to initiate IRB initial review:

□ Completed IRB Application

□ Final research protocol

□ Informed Consent documents or waiver requests

□ Information sheets

□ Recruitment materials

□ Investigational Drug Brochures

□ Investigational Device User manual or Instructions

□ Grant applications for federally funded research

□ HIPAA authorization waiver requests

□ Curriculum vitae or other documentation demonstrating PI qualification to conduct the proposed research

□ DHHS approved consent document

c. The following protocol tools require IRB review, and any and all subsequent revisions must be submitted for review as amendments.

□ Surveys

□ Interview Questions

□ Phone scripts

□ Letters to participants and

□ Newsletters

- Case report forms that capture information that was not specifically described in the protocol

d. All IRB submission materials are made available to members via the electronic IRB system, iRIS. iRIS is web-based and so members may access their IRB materials from any machine and location where they have internet access seven days prior to the convened meeting. Members were and will continue to be polled to ensure they have this access readily available.

e. Primary Review (PR) assignments are made by a RCC after consultation with the IRB Administrator and/or Chair.

f. PRs are assigned to each agenda item. For initial submissions, both a presenting primary reviewer (PPR) and a contributing primary reviewer (CPR) are identified. Submission materials will be available to them, the IRB Chairperson and the IRB Administrator approximately two weeks prior to the IRB meeting where the materials will be reviewed. The designated PPR is always an MD, PhD or RPh. The CPR is not. Prior to the meeting the primary reviewers are expected to review their assigned items and identify any questions or concerns that may affect approvability of the study, utilizing the Reviewer checklist as a guide. PRs should relay questions or concerns that require follow-up to the RCC, who will coordinate the flow of information between the study team and the IRB. Any member is allowed to use this process, as well, in the conduct of their reviews. All IRB members receive all submitted materials for each agenda at least one week prior to the scheduled meeting. This includes alternate members if they are scheduled to attend and participate in the meeting.

g. A system of Expert Guest Reviewers (EGR) is in place to supplement IRB review in the event that no member has the needed expertise to evaluate an initial IRB submission. At the time the RCC consults with the IRB Administrator and /or Chair, the need for an EGR will be discussed. In general, if the IRB Chair determines an expert consultation is in order, the RCC will facilitate it. Also, a PR may contact the IRB Administrator or Chair to request and EGR, if the PR receives an initial IRB submission that they do not feel entirely qualified to evaluate. EGR may also be consulted on changes to approved research or continuing review reports as necessary.

h. When assigned, an EGR will be consulted in addition to the review conducted by the IRB Primary reviewers. The PR will conduct their normal review. The EGR will be provided with the completed IRB Application, protocol and consent documents. The EGR will contribute expert knowledge by answering questions about local standard care and making risk benefit analysis. (See EGR Evaluation form) The information on this form is returned to the RCC who in turn makes it available to IRB members. Should the IRB Chair have an additional phone conversation with the EGR, he or she will write a brief summary that will be shared with the IRB and become part of the IRB file.

3.3. Conduct of the IRB Meeting

a. Members attend convened IRB meetings in person and via teleconference. Members who attend by teleconference are provided with the toll-free call in number. Prior to the meeting, the RCC sets up the teleconference system and the RCC or IRB Administrator will generally acknowledge members when

they call in and give them a status update of when the meeting will begin. Members will have laptop computers available to them at convened meetings so that they may access the iRIS electronic agenda and supporting materials. They may also choose to bring and utilize their own devices. Quorum for the meeting consists of 50% of the membership plus one. The quorum must include a member who is a non-scientist, a member who is not affiliated with Marshfield Clinic or St. Joseph's Hospital and a member who has personally enrolled in a research study. One individual may fulfill more than one role on the IRB. No vote may be taken if a quorum is not met or is lost during the course of the meeting. MCRF IRB routinely reviews research involving the vulnerable population, children, therefore research involving children will be reviewed while a member who specializes in pediatrics, child psychology or family medicine is in attendance. The RCC is responsible for noting when members join the meeting, for letting the Chair know when an initial quorum has been achieved, and for monitoring the maintenance of the quorum during the meeting. The RCC will also document via the minutes that quorum was maintained.

b. The role of the IRB Chair is to lead the Convened IRB meeting, ensuring adequate and fair discussion of all agenda items. If discussion continues on an agenda item, but in the estimation of the Chair, no substantive information is being exchanged, the Chair may truncate discussion and call the question.

c. The Chair will call the meeting to order once quorum is attained and adjourn the meeting upon completion of the agenda or exhaustion of the ninety minutes allotted for the meeting.

d. The Chair is responsible for verbally asking the membership to declare any conflicts of interest (See procedure, "IRB Consideration of Conflict of Interest: Member and Investigator.") If any conflicts are identified, that member will recuse him or herself by leaving the room during the final discussion and vote on the particular item. Teleconferenced members recuse themselves by walking away from the phone for a time and checking back to see if they may rejoin. Whenever possible, the Chair will rearrange the agenda to move items involving teleconference members with conflicts to the very end of the agenda so that they may simply leave the meeting before those items are discussed.

e. It is the responsibility of the Chair to maintain orderly discussion at the meeting by recognizing members who wish to speak. The Chair will call the motions and seconds, and facilitate and take part in the vote. A verbal vote will be taken on all motions. After the verbal vote of members in the room, the Chair will ask members on the phone for their individual votes. If it sounds like a close vote, the Chair will ask for a show of hands from members in the room and another verbal vote from members on teleconference. For a motion to be approved, it has to receive the approval of a majority of members present at the convened meeting. The RCC is responsible for documenting the votes cast.

f. If the Chair has a conflict of interest pertaining to a particular agenda item, then the Vice Chair or designee will conduct that portion of the meeting while the Chair steps out during the discussion and vote.

3.4. Review of Agenda Items

a. The Chair will ask the PPR to provide a 5-10 minute overview of an agenda item. This will include a summary of the research activities. The Chair will then ask the CPR to add any comments. If a PR must be absent from the meeting, the Chair will read his or her available written comments to the Board. Finally, the item will be opened up for discussion to any member who has an additional question or comment. Finally, one of the PR will step through the Primary Reviewer's Guide and comment on the approvability of the study. The Chair will then call for a motion. Acceptable actions are: Approve, Approve Contingent, Table and Disapprove. Motions for approval will include a timeframe for the conduct of the next review. PR will provide their completed Reviewer Guides to the RCC so they may become part of the IRB file.

3.5. Convened IRB Meeting Minutes

a. The RCC is responsible for taking IRB minutes. Minutes will include the following:

- Time the meeting is called to order and adjourned
- Name of members in attendance, including when an alternate member replaces a member
- Notation if a member leaves the meeting due to a conflict of interest and documentation that conflict was the reason for the recusal
- For each review item on the agenda:
  - Summary of the discussion that took place, including controverted issues, and their resolution, if available
  - Motions made
  - Actions taken by the IRB
  - Results of voting documented as numbers for, against and abstaining
  - Description of an modifications required to secure approval of the item, and the basis for requiring modification
  - The approval time period, if applicable
  - Basis for any disapproval of research and
  - Outcome of any of the following determinations, as applicable: (waiver or alteration of informed consent or authorization, research involving pregnant women, fetuses, neonates, or children).
  - The rationale for significant risk or non-significant risk determinations in device research
- All regulatory citations upon which the IRBs decisions are based

3.6. In Follow-Up to the Meeting

a. Correspondence regarding reviews conducted at the convened IRB meeting will be sent to the Principal Investigator, with copies to his or her research staff as indicated in the IRB application

b. Approval letter(s) will contain as applicable:

- Study Title:
- SP Code or IRB Reference Code
- Approval Period/Expiration date
- List of materials reviewed
- Documentation of Convened IRB Review
- Outcome of the review
- Informed Consent or waiver determination
- Contingencies, if any and their basis
- Required actions, if any
- How to respond to the IRB and by what date.

c. In addition, to the relevant information above, Disapproval letters will contain specific reasons for disapproval and how the Principal Investigator may appeal the decision.

d. Researcher responses will be reviewed by the IRB Chairperson or Administrator, depending upon the status of the item under review. The responsive materials will be processed via expedited review in order to finalize a contingency or added to the next available IRB agenda to re-consider a tabled or disapproved item, or for review of a contingency requiring re-review by the convened IRB.

3.7. Notification of IRB Actions to the Institutional Official for Research

a. Finalized IRB meeting minutes are provided after each meeting to the Executive Director, Marshfield Clinic Research Foundation

4. ADDITIONAL RESOURCES

4.1. References: None

4.2. Supporting documents available: None

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control System transferred from the Policy & Handbook Library - # 5296.1 Added definitions (2); added agenda timeline submission (3.1a) and Clarified 3.2(f) regarding time for processing & review. Addition (3.3 (f))coverage of Vice Chair or designee if Chair has COI.

2.0	Add hyperlink to other application policies in this document
3.0	Revised section 3.1(c) to add potential agenda items such as Emergency Use & Expanded Access; Sect. 3.6 (b) Add additional contents within approval letter as applicable.

6. DOCUMENT PROPERTIES

Primary Author: Scheller, Lori A
Co-Author(s):
Approver(s): This document has been electronically signed and approved by: Ziemba, Steven J PHD on: 3/1/2016 9:44:45 AM