Marshfield Clinic

# IRB Approvals with Conditions

## 1. SCOPE

1.1. System Wide

## 2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. None

## 3. PROCEDURE BODY

The Marshfield Clinic Research Foundation Institutional Review Board (MCRF IRB) may approve research activities contingent upon conditions that must be subsequently met by the Principal Investigator (PI). This is referred to as "contingent approval" or "approval with conditions."

3.1. Convened IRB

a. Research activities may be approved on a contingent basis, provided that the specific information or action required to satisfy the contingency does not jeopardize the IRB's ability to determine whether the item satisfies the approval criteria established at 45 CFR 46.111 and 21 CFR 56.111. These criteria include:

- Risks to subjects are minimized;
- Risks to subjects are reasonable in relation to the anticipated benefits;
- Selection of subjects is equitable;
- Informed consent will be sought;
- Informed consent will be documented;
- Adequate data safety monitoring plan is in place;
- Provisions to protect the privacy of subjects and maintain confidentiality of subjects; and
- The rights of vulnerable populations are protected.

b. In the course of initial review, continuing review, or review of proposed changes or amendments to previously approved research, the convened IRB may require the following conditions of approval of research:

- Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted;
- Submission of additional documents;
- Specific language changes to the protocol, informed consent document(s), or advertisements for recruitment; or
- Substantive changes to protocol, informed consent document(s), or advertisements for recruitment, along with clearly stated parameters that the changes must satisfy.

c. If the IRB requires additional explanations, or responsive materials or revisions that do not fall within one of the categories delineated in Section 3.2 further IRB review of the item must be tabled and brought back to the convened IRB for a final decision. Contingent approval is not permitted in this situation. When an item is tabled, any responsive materials are reviewed by the IRB Chair.

d. The OHRP Guidance on IRB Approval of Research with Conditions requires the IRB to verify that all contingencies are met as part of IRB approval.

- Unless otherwise specified in the IRB minutes, the IRB designates the IRB Chair as the individual who will review responsive materials from the PI via expedited review procedures. The IRB Chair must review the materials before finding that the required contingencies have been satisfied before granting IRB approval. When the convened IRB designates someone other than the IRB Chair, the IRB will identify an individual who has the appropriate expertise or qualifications to review the responsive materials and communicate with the IRB Chair, who will then determine whether the required contingencies have been satisfied.

e. The IRB may approve some components of a proposed research study and allow a PI to initiate research activities related to the approved components, while deferring approval on other components until contingencies are met. The IRB must ensure the approved components are scientifically valid and satisfy all criteria for IRB approval even if other components are never conducted.

3.2. Expedited Review

a. Research activities may be approved on a contingent basis, provided that the specific information or action required to satisfy the contingency does not jeopardize the IRB's ability to determine whether the item satisfies the approval criteria established at 45 CFR 46.111 and 21 CFR 56.111. These criteria include:

- Risks to subjects are minimized;
- Risks to subjects are reasonable in relation to the anticipated benefits;
- Selection of subjects is equitable;
- Informed consent will be sought;
- Informed consent will be documented;
- Adequate data safety monitoring plan is in place;
- Provisions to protect the privacy of subjects and maintain confidentiality of subjects; and
- The rights of vulnerable populations are protected.

b. In the course of initial review, continuing review, or review of proposed changes or amendments to previously approved research, the IRB expedited reviewer may require the following conditions of approval of research:

- Confirmation of specific assumptions or understandings on the part of the IRB expedited reviewer regarding how the research will be conducted;
- Submission of additional documents;

- Specific language changes to the protocol, informed consent document(s), or advertisements for recruitment; or
- Substantive changes to protocol, informed consent document(s), or advertisements for recruitment, along with clearly stated parameters that the changes must satisfy.

c. If the IRB expedited reviewer requires additional explanations, or responsive materials or revisions that do not fall within one of the categories above further review of the item must be tabled and brought back to the expedited reviewer for a final decision.

d. The OHRP Guidance on IRB Approval of Research with Conditions requires that all contingencies are met as part of IRB approval.

e. The expedited reviewer will review responsive materials from the PI. The IRB expedited reviewer must find that the required contingencies have been satisfied before granting IRB approval.

f. The IRB expedited reviewer may approve some components of a proposed research study and allow a PI to initiate research activities related to the approved components, while deferring approval on other components until contingencies are met. The IRB expedited reviewer must ensure the approved components are scientifically valid and satisfy all criteria for IRB approval even if other components are never conducted.

## 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 transferred from Policy & Handbook Library - #778.7 (no changes made) |
| 2.0 | |
| 3.0 | |

## 6. DOCUMENT PROPERTIES

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