Marshfield Clinic

Expedited Review

1. SCOPE

1.1. System-Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. Minimal Risk Research

- The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a healthy individual or during the performance of routine physical or psychological examinations or tests.

2.2. Minimal Risk to Privacy:

- The investigator has presented to the IRB for consideration at least the following:
  - ◊ (1) a plan to protect identifiers from improper use and disclosure;
  - ◊ (2) a plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
  - ◊ (3) adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the HIPAA Privacy Rule.

2.3. Minor:

- With respect to changes to approved research, means that the allowable risk associated with the change is either no more than minimum, or that the proposed change does not increase risk to subjects.

3. PROCEDURE BODY

The objective of this document is to outline the types of human subjects research, or minor changes in research previously approved by the Marshfield Clinic Research Foundation Institutional Review Board (MCRF IRB), that may be processed through expedited review. This policy also summarizes the responsibilities of MCRF Office of Research Integrity & Protections (ORIP) staff and the IRB reviewer.

3.1. Federal Regulations and Guidance

a. Department of Health and Human Services (DHHS) regulations at 45 CFR 46.110 and Food and Drug Administration regulations at 21 CFR 56.110 allow for the use of an expedited review process for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

b. HIPAA Privacy Rule regulations at 45 CFR 164.512(i)(2)(iv)(c) allow an IRB to use an expedited review procedure to waive the requirement to obtain

authorization from research subjects to use and/or disclose their Protected Health Information, or to approve an alteration to the authorization requirements, if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the Protected Health Information for which use or disclosure is being sought.

3.2. MCRF IRB conducts review of human subjects research projects and their related materials in two manners: convened IRB and expedited review. An expedited review process is allowed by federal regulations for certain types of research involving no more than minimal risk, for minor changes in previously approved research, and for waiving the requirement to obtain authorization for use or disclosure of Protected Health Information (PHI), or to approve alteration of the authorization requirements. In order to be reviewed via expedited review, the item must be one of the following:

a. A new study that meets the definition of "minimal risk" noted above, and is an activity that is listed in 63 FR 60364-60367, "Research Which May be Reviewed through Expedited Review Procedures."

   If the project meets 63 FR 60364-60367 1-8 and includes genetic analysis, the study may only be reviewed via the expedited review process if

   - No results will be given to subjects.
     - Investigators must submit all materials for review as required in the document, "Initial Review."

b. Continuing review of research previously approved by the convened IRB as follows:

   - Where (i) the research is permanently closed to enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   - Where no subjects have been enrolled and no additional risks have been identified; or
   - Where the remaining research activities are limited to data analysis.
     - Investigators must submit all materials for review as required in the document, "IRB Continuing Review."

c. Continuing review of research, not conducted under an IND or IDE where categories 2-8 of 63 FR 60364-60367 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

   - Investigators must submit all materials for review as required in the document, "IRB Continuing Review."

d. The item is a change to a project previously approved through expedited review, and the proposed change does not pose more than minimal risk to subjects, and does not remove the project from within categories 1-7 of 63 FR 60363-60367.

   The item is a minor change in research previously approved by the convened IRB during the period for which approval is authorized.

e. The following minor changes in previously approved research may be processed by expedited review:

- New or revised correspondence, primarily recruitment materials;
- Consent form changes that do not involve an increase in risk to subjects;
- Protocol changes that do not involve an increase in risk to subjects;
- Addition/removal of co-investigators approved for the study;
- Changes in Principal Investigator for studies approved through expedited review, including those originally approved by the convened IRB but transitioned to expedited continuing review;
- Adverse event reports submitted to meet ICH GCP requirements after IRB approval, which should also be reported on the "IRB ICH GCP Adverse Event Report." These will receive review by the IRB Chair or designee and be stamped "IRB-No Further Review Required," or if deemed appropriate, the Chair or designee may request additional information from the reporting investigator. Upon completion of review, the stamped original form will be returned to the investigator.
- Addition of performance sites;
- Recruitment brochures and advertisements for studies originally approved;
- Proposed subject compensation or incentives that require prior approval per the Recruitment of Subjects policy; and
- Telephone scripts used for recruitment.

f. Investigators must submit all materials for review as required in the document, "Changes/Amendments to Approved Research."

3.3. Expedited review will normally be carried out by the MCRF IRB Chairperson. In the Chairperson's absence, the Chair may delegate the authority to conduct expedited review to the Vice Chairperson, another IRB member selected by the Chair or the ORIP IRB Administrator, who is also an IRB member. Before conducting review, the expedited reviewer will consider whether he or she has a conflict of interest precluding review of the item consistent with the document, "IRB Consideration of Conflict of Interest: Member and Investigator."

a. The new research application or change to approved research or continuing review will be made available via the iRIS system. This, along with the appropriate reviewer guide, and evidence of the P.I.'s qualification via curriculum vitae, will be provided to the expedited reviewer. The criteria for approval are the same as for by the convened IRB:

- 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. The expedited reviewer may then:

- ☐ Approve
- ☐ Table
  - The item will receive further review once the expedited reviewer receives the requested responsive material from the investigator
- ☐ Defer to the convened IRB for review

c. Disapproval is not allowed via expedited review.

d. The written expedited review summaries will be provided to MCRF IRB members monthly, which include summaries of all approvals by expedited review procedures, including initial review, continuing review, and review of changes.

4. ADDITIONAL RESOURCES

4.1. References:

- None

4.2. IRB Request Forms for submission: (located in Policy & Handbook Library [Forms])

- IRB Application – New Research
- Changes/Amendments to Approved Research
- IRB Continuation Request
- IRB ICH GCP Adverse Event Report

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control System transferred from Policy & Handbook Library – 785.15. Add IRB Request forms under Additional Resources section (4.2)
2.0	Added hyperlink to applicable policies and IRB submission forms

6. DOCUMENT PROPERTIES

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