Marshfield Clinic

Determining Which Projects Require Review More Often than Annually

1. SCOPE

1.1. System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1. None

3. PROCEDURE BODY

This document sets forth the procedures for the Marshfield Clinic Research Foundation Institutional Review Board (IRB) to determine which research studies will require IRB review more often than annually.

3.1. Full Board Review:

a. At a study's initial approval and with each subsequent continuing review, the IRB will determine an interval for the next IRB review. The primary reviewers of the new study or its continuing review report will be responsible for recommending a timeframe for conducting continuing review. All IRB members are given the opportunity at the meeting to give input to this decision. The time frame for conducting continuing review may be not more than one year.

b. The IRB should consider whether more frequent reviews are required based on the following factors:

- Nature and degree of risk posed by the research project;
- The degree of uncertainty regarding the risks involved;
- Vulnerability of the subject population;
- Projected rate of enrollment;
- IRB approval granted by a slim margin;
- Investigator history of non-compliance or complaints made by subjects;
- Investigator inexperience;
- Whether the research project involves novel interventions or therapies; and
- At the discretion of the IRB.

3.2. Expedited Review:

If an expedited reviewer believes a new study or continuing review report merits IRB review more often than annually, the item should be deferred by the expedited reviewer to the convened board for consideration and review

4. ADDITIONAL RESOURCES

Live
PROCEDURE

4.1. None

5. DOCUMENT HISTORY

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1.0	New Document in Document Control transferred from Policy & Handbook Library - #889.2 (no changes made)
2.0	
3.0	

Live

6. DOCUMENT PROPERTIES

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PROCEDURE