Marshfield Clinic®

Projects Needing Verification from Sources other than the Investigator

1. SCOPE

1.1.   System Wide

2. DEFINITIONS & EXPLANATIONS OF TERMS

2.1.   **Material Change** – A change from what was approved by the IRB, having the potential to affects the rights, safety or welfare of subjects, or having the potential to affect the soundness of protocol in what was approved by the IRB as well as a change form.

3. PROCEDURE BODY

To outline procedures to be followed by the IRB in determining which projects require verification from sources other than the investigator that no material changes have occurred since previous IRB review.

3.1.   Background

   a. Federal regulations 45 CFR 46.103(b)(4)(ii), 21 CRF 56.108(a), and our institution's Federal-Wide Assurance require our IRB to maintain a written procedure for determining which research projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review.

3.2.   Document Body

   a. MCRF staff may report the need for potential verification from other sources other than the investigator. Primary reviewers, at initial and subsequent reviews, will be responsible for making known when they believe verification is needed from sources other than the investigator that no material changes have occurred since the previous IRB review. A study may be identified for additional verification at continuing review time or any time an IRB member or IRB staff person suspects it may be necessary. The request to require verification will be made by IRB staff or member at a convened IRB meeting. At that time, all IRB members will have the opportunity for input into the decision to require this verification. The chair will then request a vote and a simple majority in favor of verification is required to initiate the process. Obtaining verification will be the responsibility of IRB staff. The results of the verification will be presented to the requesting IRB upon its completion. Any non-reported material changes will be followed up on according to the IRB's

Non-Compliance with Federal Regulations, Institutional Policies and IRB-Approved Applications and Protocols policy.

Criteria to be considered when considering verification include:

1. Complexity of the research
2. Risk level of the research
3. Investigator history of non-compliance
4. Concerns being raised about possible material changes occurring without IRB approval

 In addition, standard verification will take place as directed in the IRB Internal Auditing/Quality Improvement Plan.

The processes used to conduct the verification include but are not limited to: Interviews with research support staff or co-investigators, and IRB requesting audit by the Research Compliance Dept.

4. ADDITIONAL RESOURCES

4.1. References:
- none

5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control in transferred from Policy & Handbook Library - #890.2 Revise sect. 3.2 to allow for all MCRF staff to report the need for additional verification also for IRB to request audit by Research Compliance Dept.
2.0	
3.0	

6. DOCUMENT PROPERTIES

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