OBSERVATION OF RESEARCH ACTIVITIES

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: MCW/FH Faculty and Staff involved in human research

PURPOSE: In accordance with federal regulations, the MCW/FH IRB has the discretion of requesting a third party observe the informed consent process and the research. The request may be based upon the degree of risk associated with the research activities, the need for protection and/or a concern related to noncompliance. While members of the IRB can observe the consenting process or other research activity for themselves, this activity is often delegated to the MCW Quality Assurance/Quality Improvement staff (QI Specialist).

DEFINITIONS: N/A

PROCEDURE:

1. A request for the observation of a research activity, including the informed consent process, will be initiated by the IRB if it has determined that an activity is either associated with a high degree of risk, need for additional protections, or the IRB has a concern regarding noncompliance.
   a. This determination may result from the IRB’s initial or continuing review of project activities or review of a reportable event.

2. The IRB will describe their determination in the IRB Decision letter to the Investigator and will provide a copy of the letter to the QA/QI Manager.

3. When a project has been identified for observation of research activities, including the consenting process, the QI Specialist will contact the Investigator/Coordinator to learn of dates, times and locations of research activities.

4. The QI Specialist will issue a reminder email 1-2 working days prior to the scheduled observation to the Investigator and Coordinator.

5. The QI Specialist will be available to observe the research activity, including informed consent at the designated date, time and location.

6. On the day of the observation, the QI Specialist will obtain permission from the subject/legally authorized representative prior to observing any research activities including potential consenting discussions.
   a. A member of the study team may inform the subject/legally authorized representative of the request to observe prior to the QI Specialist’s conversation with the subject/legally authorized representative.
   b. No observation will take place if the subject does not agree/give permission.
   c. In the event permission to observe is obtained from the legally authorized representative, assent from the subject will be obtained whenever possible.
7. The QI Specialists activities may include:
   a. Observation of the initial discussions associated with the consenting process, or
   b. Observation of follow up discussions including documented informed consent, or
   c. Observation of both initial and follow up discussions including documented informed consent which take place on separate occasions, or
   d. Observation of entire consenting process which takes place at one time
   e. Observation of another specified research related activity
   f. Brief interview with subject/legally authorized representative post observed activity

8. Upon IRB request, the QI Specialist will observe the consenting process to determine whether the conditions were met as listed in the informed consent observation checklist.
   a. Upon completion of each observation experience the QI Specialist will provide feedback to the study team member involved in the consenting process

9. Upon IRB request the QI Specialist will observe research activity other than the consenting process to determine whether the safety, rights, welfare of the subjects are safeguarded in the conduct of the project activity as described in the IRB approved protocol.
   a. Upon completion of each observation experience the QI Specialist will provide feedback to the study team member involved in the observed research activity

10. Upon completion of observation of all of the requested research activities, the QI Specialist will provide a written summary of the observations.
    a. The Investigator will receive the written summary of observations and, if applicable, recommendations regarding the research activity.
    b. A copy of the written summary and applicable recommendations will be forwarded to the IRB Chair and IRB Coordinator of the overseeing committee for review and inclusion in the IRB project file.

REFERENCES:
45 CFR 46.108
21 CFR 56.108

SUPPORTING DOCUMENTS:
Informed Consent Observation Checklist
Research Activity Observation Checklist

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Human Research Protections Program (HRPP)
Office of Research
Medical College of Wisconsin