MCW Office of Research
Standard Operating Procedure

OBSERVATION OF RESEARCH ACTIVITIES

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

Applies to: Faculty and Staff involved in human research

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

Observation of the consenting process may also occur in conjunction of Routine Review of a research project that remains open to enrollment.

DEFINITIONS:
N/A

PROCEDURE:
IRB REQUEST

1. The MCW IRB can request observation of a research activity, including the informed consent process, if it has determined that an activity or project is either associated with a high degree of risk or 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 research activities or review of a reportable event and will be documented in the meeting minutes and notification letter to the Principal Investigator (PI).
2. The IRB will provide a written request to the QI regarding observation of research activity.
3. The QI Specialist will contact the Investigator/member of project team to discuss the IRB's request, learn of dates, times and locations of research activities and arrange for observation of the IRB's requested research activities.
4. The project team and QI will establish and implement a communication plan regarding notification of research activities for observation.
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 observation, the QI Specialist will obtain permission from the subject/legally authorized representative prior to observing any research activities including potential consenting discussions. (A member of the project 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.)

a. No observation will take place if the subject does not agree/give permission.
b. In the event permission to observe is obtained from the legally authorized representative, assent from the subject will be obtained whenever possible.
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 completion of each observation experience the QI Specialist will provide feedback to the project team member involved in the consenting process
9. Upon completion of observation of all the requested research activities, the QI Specialist will provide a written summary of the observations, and if applicable recommendations, to the requesting IRB.
    a. The Investigator will receive a copy of the written summary of observations.

ROUTINE REVIEW OBSERVATION OF THE CONSENTING PROCESS

1. Observation of the consenting process may be included in the Routine Review of research projects that remain open to enrollment.
2. The QI Specialist will explore the potential for observation of the consenting process with the project team.
    a. The initial or follow up consenting process conversation/activities or reconsenting may be considered for observation.
3. On the day of observation, the QI Specialist will obtain permission from the subject/legally authorized representative prior to observing any research activities including potential consenting discussions. (A member of the project 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.)
    a. No observation will take place if the subject does not agree/give permission.
    b. In the event permission to observe is obtained from the legally authorized representative, assent from the subject will be obtained whenever possible.
    c. In the event permission to observe is obtained from the legally authorized representative, assent from the subject will be obtained whenever possible.
4. Upon completion of each observation experience the QI Specialist will provide (oral) feedback to the project team member involved in the research activity.
5. Upon completion of Routine Review activities, the QI Specialist will provide a written summary of all the Routine Review findings including the observed research activities.

REFERENCES:

N/A

SUPPORTING DOCUMENTS:
N/A

Effective Date:	06/15/2018
Version number:	2.0
Previous Version/date:	1.0; 11/20/2010
Responsible Office:	HRPP Office
Approval Date:	06/07/2018

Approved By
HRPP Authorized Official: David Clark, PhD, Director, HRPP
Human Research Protections Program (HRPP)
Office of Research
Medical College of Wisconsin