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

Applies to: Faculty and Staff involved in human research

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In accordance with federal regulations, the MCW IRB has the discretion to request a

- a. No observation will take place if the subject does not agree or give permission.
  - b. If permission to observe is obtained from the LAR, 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 and/or their LAR post observed activity
8. Upon completion of each observation of consent 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. Investigators will receive a copy of the written summary of observations and/or any recommendations.
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 and/or their LAR prior to observing any research activities including potential consenting discussions. A member of the project team may inform the subject and/or their LAR of the request to observe prior to the QI Specialist's conversation with the subject and/or their LAR.
- a. A member of the project team may inform the subject and/or their LAR of the request to observe prior to the QI Specialist's conversation with the subject and/or their LAR.
  - b. No observation will take place if the subject does not agree and/or give permission.
  - c. If 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.

N/A

N/A

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Effective Date: 07/01/2023