HANLDING AND REPORTING OF SUBJECTS INQUERIES OR COMPLAINTS

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

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

PURPOSE: To define the procedures for handling and reporting of inquiries and/or complaints regarding the conduct of the project as received from individuals who are involved or are associated with an individual who is involved in a human subject research project conducted by a Medical College of Wisconsin (MCW) faculty/staff.

DEFINITIONS:

Human Research Protection Program Research Subject Advocate (HRPP RSA): Individual identified by the Human Research Protection Program (HRPP) to receive inquiries and/or complaints regarding the conduct of a project as related to the rights and responsibilities of the subjects involved in studies conducted by MCW faculty/staff. The HRPP RSA or designee is responsible for the handling and reporting of the received inquiries and/or complaints regarding the conduct of a project.

Quality Improvement (QI) Specialist: A staff member of the Quality Assurance/Quality Improvement Unit which is a component of the Human Research Protection Program. The role and responsibility of the QI Specialist includes post approval review of human subject research and human subject research education.

PROCEDURE:

1. The Investigator is responsible for notifying the IRB of any complaint regarding human subject research received from a subject, the subject's legally authorized representative or other individual associated with the subject.
   a. The Investigator may learn of the complaint via direct contact with the subject, the subject's legally authorized representative or other individual associated with the subject, OR
   b. The Investigator may learn of the complaint via the HRPP RSA or QI Specialist who has had contact with the subject, the subject's legally authorized representative or other individual associated with the subject.

2. The Investigator may report the complaint to the IRB using the continuing progress report SmartForm providing that the complaint does not represent an increased risk to the subject, and does not change the risk/benefit ratio.

3. In the event the complaint represents either an increased risk to the subject or changes to the risk/benefit ratio, the Investigator must report the complaint to the IRB within 5 calendar days.

4. The Investigator's submitted information will be reviewed by the IRB Chair/committee.

5. Upon review of the submitted information, the IRB Chair/committee may request one, several or none of the following actions:
   a. PI to provide additional information regarding the complaint...
b. PI to provide a corrective action plan to reduce or eliminate future occurrence of the event

c. PI to implement changes to the conduct of the project

d. QI review/audit of the project

6. The IRB’s review and determination regarding the reported complaint will be recorded in the meeting minutes.

REFERENCES:
N/A

SUPPORTING DOCUMENTS:
N/A

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Approved By

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