MCW Office of Research
Standard Operating Procedure

HANLDING AND REPORTING OF SUBJECTS INQURIES OR COMPLAINTS

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

Applies to: Faculty and Staff involved in human research

PURPOSE:
Federal regulations identify required elements for informed consent, one element is an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. MCW IRB requires IRB approved consent forms to include the contact information for the Principal Investigator and the Research Subject Advocate consent. This procedure describes a research team's steps for handling and reporting of inquiries and/or complaints regarding the conduct of the project as received from research subjects, the subject's legally authorized representative or other individual associated with the subject, and/or the Research Subject Advocate.

DEFINITIONS:
Research Subject Advocate (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 projects conducted by 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.

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 through direct contact with the subject, the subject's legally authorized representative or another individual associated with the subject, OR
    b. The Investigator may learn of the complaint via the RSA or QI Specialist who has had contact with the subject, the subject's legally authorized representative or another individual associated with the subject
2. The Investigator may report the complaint to the IRB with their Continuing Progress Report (CPR) 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. *See IRB SOP: Requirements for Reporting to the IRB*
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 determination letter and meeting minutes.

REFERENCES:
N/A

SUPPORTING DOCUMENTS:
IRB SOP: Requirements for Reporting to the IRB

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