1 Purpose

1.1 This procedure establishes the process for obtaining and responding to complaints, concerns and other feedback about the conduct of specific human research studies at the UM, at Jackson Health Services (JHS), or about the UM Human Research Subject Protection Program at the University of Miami (UM).

1.2 The process begins when the HSRO is aware of the complaint or feedback. The process ends when the evaluation is complete and an HSRO Team Members (HTM) responds appropriately.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 Complaints, concerns and suggestions about the conduct of specific human research studies or about the UM Human Research Protection Program are taken very seriously.

3.2 The UM and HSRO will handle all complaints, concerns and feedback as confidential as possible within the law.

3.3 The HSRO and the UM Hotline provide safe, confidential and reliable methods for research participants and their LARs, and research teams to discuss problems, concerns, and questions, or offer input with a knowledgeable person who is not part of the research.

3.4 HTM and/or the IRB will work with the participant, their LAR, the PI, other research team members, and other UM departments to resolve the issue(s).

3.5 The IRB will review the issue(s) and make appropriate determinations when the issue(s) involves an unanticipated problem involving risks to subjects or others or serious or continuing non-compliance.

3.6 An HTM will report to the subject/LAR the outcome of HSRO’s efforts to resolve the issue(s).

4 RESPONSIBILITIES

4.1 The HTM and/or IRB members carry out this procedure

5 PROCEDURES

5.1 The HSRO must provide a phone number and email address for research team members, and research participants or their LARs to use when they report issues about human subject research conducted at the UM or JHS. The HSRO is responsible for ensuring this contact information is included:

5.1.1 In consent UM IRB-approved research informed consent documents;
5.1.2 On the HSRO webpage for participants; and
5.1.3 On the HSRO webpage with contact information.

5.2 When an issue(s) is conveyed anonymously, the HSRO will provide a code number to the informant to use during future communications.

5.3 When an HTM receives a report of an issue regarding human subject research at the UM or JHS, the HTM will obtain the following when the informant elects to provide it:

5.3.1 Date of contact
5.3.2 The individual’s name;
5.3.3 The individual’s relationship to the subject, if applicable;
5.3.4 The individual’s contact information;
5.3.5 The study name and protocol number, if available;
5.3.6 Sufficient information about the issue to understand and respond.

5.3.7 Whether the informant has contacted the PI, a research team member, or anyone else about the issue(s).

5.3.8 A description of the informant’s proposed resolution of the issue(s), if the informant has such a proposal.

5.4 The HTM will resolve the issue during the initial call, whenever possible, and determine whether the issue(s) may meet the definition of non-compliance that may be serious or continuing or an unanticipated problem involving risks to subjects or others.

5.5 The HTM will promptly forward the information to the Executive Director and Director when the information appears to meet the definition of non-compliance that may be serious or continuing or an unanticipated problem involving risks to subjects or others or when the issue is otherwise complex requiring review by a senior level HTM. The Executive Director and/or the Director will take one or more of the following actions:

5.5.1 Conduct an initial inquiry that consists of a detailed review of the protocol documents to confirm and/or substantiate the issue(s) and determine the best outcome;

5.5.2 Contact the PI or study team to advise them of the issue(s) and obtain information;

5.5.3 Contact the person who initially reported the issue(s) to obtain more information;

5.5.4 Develop a corrective and preventive (CAPA) plan if the issue(s) involves HSRO or IRB non-compliance;

5.5.5 Report the issue(s) to the RCQA if a formal compliance investigation is warranted or if the issue(s) involve a pattern of non-compliance and a quality review may be warranted.

5.5.6 Report the issue(s) to the Research Compliance Officer if the issue(s) involve research misconduct;

5.5.7 Report the issue(s) to the Risk Manager if the issue(s) involve a research-related injury;

5.5.8 Report the issue(s) to the AVP for Regulatory Affairs and Assessment and the Vice Provost for Research and Scholarship.

5.6 The HTM will promptly notify the IRB via an RNI when the issue(s) involves potential risks to participants or others, negatively impacts the rights of participants or others, or may meet the definition of non-compliance that may be serious or continuing.

5.6.1 The IRB will review the information and make the appropriate determination(s)

5.6.2 The IRB may direct the PI or HSRO to take specific actions to help resolve the issues(s).

5.7 If the issue(s) is of the nature that participants’ safety, rights and/or welfare are at immediate risk or hazard, the Executive Director or Director will notify an IRB Chair or Vice Chair who will contact the PI to establish an interim measure to protect participants pending a formal inquiry and IRB full committee review. This measure may include a suspension of some or all of the study.

5.8 The Executive Director or Director will consider issue(s) involving the HRPP or IRB’s action or non-action that do not involve possible risks to participants or others on a case-by-case basis. They may implement suggestions that will improve systems or procedures to the overall program.

5.9 If the issue(s) involve general or specific complaints about the IRB, HSRO or the HRPP that involve risks to participants or others, the HSRO will follow HRP-024 SOP: Reports of New Information
5.9.1 The Executive Director or Director will share the information in the report with the Associate Vice President, Regulatory Affairs and Assessment.

5.10 Either the Executive Director or the Director will contact the informant to discuss the outcome of the HSRO’s and/or IB’s actions.

6 REFERENCES

6.1 HRP 001 SOP Definitions
6.2 HRP 024 SOP New Information