The purpose of this worksheet is to provide support for HSRO Team Members who receive reports of complaints, concerns, allegations, 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). This worksheet also creates a record of the issue and the actions taken. HSRO Team Members must use this worksheet when they receive a report of a complaint, concern, allegation or other feedback.

### Section 1 – Description of Issue

1.1 Date of contact

1.2 The informant’s name

1.3 If the informant wants to remain anonymous, assign a code using the date of call (ex. 01012021) and provide this number to the informant

1.4 The informant’s relationship to the subject:  
- Subject
- Spouse
- Parent
- Child
- Other

1.5 The informant’s contact information*

1.6 The study name and protocol number, if available

1.7 Has the informant discussed the issue with PI, team member or other UM person?  
- Yes
- No

1.9 Description of complaint, problem, concern or feedback

1.10 What solution does the informant want (propose)?

1.11 Was issue resolved?  
- Yes. If yes, provide description of resolution:  
- No. If no, go to Section 2

### Section 2 – Check the applicable statements

- This issue involves non-compliance that is not serious or continuing. *(If checked, the following must be checked before closing this Worksheet. You will need to work with the appropriate parties to develop/obtain the CAPA plan)*

- Root cause analysis and CAPA plan completed. *(When completed and implemented. Go to Section 4)*

This issue involves:

- Risk to subjects that was previously unknown *(If checked, promptly discuss with IRB Chair)*
- An allegation of non-compliance that appears serious or continuing
- An unanticipated problem involving risk to subjects or others
- A complex situation requiring input from a Director.

*(If any of the above are checked forward to Executive Director or Director for recommendation who will research issue, notify appropriate parties and follow HRP SOP 024)*
WORKSHEET: Complaints and Feedback about the Human Research Protection Program

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### Section 3 – Executive Director/Director Review

**Actions taken:**

- ☐ Reported to PI/Study Team
- ☐ Reported to RCQA
- ☐ Reported allegation of research misconduct (fabrication, falsification, plagiarism) to Research Compliance Officer
- ☐ Reported possible research related injury Risk Manager
- ☐ Reported the issue(s) to the AVP for Regulatory Affairs and Assessment and the Vice Provost for Research and Scholarship.
- ☐ Submitted to IRB.

**Is issue resolved?**

- ☐ Yes
- ☐ No

**Additional Notes on outcome:**

### Section 4  Feedback to Informant

- Informant was notified of outcome ☐ Yes ☐ No
- Informant’s response