James Madison University Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
TITLE: Subject Concerns/Complaints			
SOP # 10	**Revision # 1**	**Effective Date: 9/22/2023**	**Page 1 of 3**

OBJECTIVE

To provide guidance in handling concerns, complaints, or questions received regarding a research study involving human subjects.

GENERAL DESCRIPTION

The right of research subjects to lodge a concern (e.g., allegation), complaint, or question and to be assured that the concern, complaint, or question is taken seriously and resolved in a timely manner is of prime importance. The Director of the Office of Research Integrity (ORI) is responsible for investigating concerns, complaints, and questions from subjects and any improprieties involving investigators or their staff. The ORI Director handles these issues in a timely manner, assuring protection of human subjects, and the IRB holds any violators accountable to the applicable regulation. A research subject (past, current, or prospective), a designated spokesperson, family member, or anyone with a concern about a human research study may raise concerns, complaints, or questions about a research project by telephone, in writing, anonymously online through the ORI website, or in person to the ORI Director or the IRB Chair. Each IRB approved informed consent document includes the contact information of the IRB Chair [45 CFR 46.116(a); JMU Policy # 1104].

RESPONSIBILITY

Execution of SOP: Director of ORI, ORI Staff, IRB Chair, Principal Investigator (PI)/Study Personnel

PROCEDURES

Concerns/Complaints/Questions

1. A research subject or anyone with a concern, complaint, or question regarding a research study involving human subjects may raise the concern, complaint, or question with the ORI. Upon receipt of a concern (e.g., allegation), complaint, or question, the ORI Director gathers the following information from the complainant as appropriate:
   - Subject's (or complainant's) name and contact information (This information is NOT MANDATORY, and an individual may report an incident anonymously through the ORI website.);
   - Study protocol title, protocol number, and the name of the PI;
   - Date(s) of the incident, and;
   - An explanation of the concern, complaint, or question.

2. The ORI Director assures the individual (or complainant) that he/she will inquire into the circumstances and that the IRB/ORI will take appropriate measures to address the issue.

Furthermore, the ORI Director informs the individual that a response to him or her will be forthcoming as rapidly as possible provided that contact information is given (e.g., if possible, within 2 to 3 weeks if the issue is a complaint). The ORI Director also explains to the individual the limits to confidentiality.

3. The ORI Director handles the concern, complaint, or question in a confidential manner to the extent allowed by law. The ORI limits access to information concerning the contact to employees with responsibilities that require knowledge of the concern, complaint, or question.

4. The ORI Director conveys the information regarding the concern, complaint, or question to the PI of the study at issue and the IRB Chair in a timely manner.

5. The ORI Director promptly investigates the concern, complaint, or question; evaluates the alleged impropriety on a case-by-case basis; and makes every effort to correct the issue(s) at the administrative level.

6. If the alleged impropriety involves potential harm to subjects or others, the ORI Director notifies the IRB for immediate action pending formal inquiry**.** The ORI Director reports concerns, complaints, or questions involving serious issues immediately to the IRB Chair, the Updated title of Vice Provost for Research, Economic Development and Innovation (VPREDI), the Institutional Official, and, if appropriate, Legal Counsel.

7. The ORI Director manages the inquiry, preparing related correspondence, and maintaining documentation of the review for up to five years from completion of the inquiry or close out of the IRB file, whichever is longer.

8. The IRB Chair, in collaboration with the ORI Director, ensures appropriate response to each concern, complaint, or question and reports the action(s) taken to the IRB. If the complaint, concern, or question is of a minor nature such as a payment issue, the IRB Chair or ORI Director may resolve the issue without bringing it forth for an IRB committee vote. The IRB Chair or ORI Director refers major issues such as failure to obtain signed informed consent from potential subjects (if required) to the IRB committee, and the IRB votes on any actions the IRB takes. All actions taken are by the IRB, are appropriate for the circumstances, and the final course of action is dependent on the nature, severity, and seriousness of the findings.

9. Depending on the nature of the event or circumstances, the IRB may take the following actions but is not limited to:
   - Further inquiry;
   - Administrative action;

- Details and recommendations forwarded to the appropriate committee chairs (e.g., IRB, Biosafety Committees) for consideration in their committees;
- Details and recommendations forwarded to the appropriate department chair for action as appropriate;
- Details and recommendations forwarded to the VPREDI, the Institutional Official, and/or University Legal Counsel for action;
- Details and recommendations forwarded to the appropriate officials at affiliated institutions for notification, action, and/or follow-up, if applicable, and;
- Other actions as deemed appropriate.

10. The ORI and IRB monitor any concerns, complaints, or questions that an individual may lodge for issues of noncompliance. The ORI Director brings issues involving noncompliance to the attention of the IRB Chair and the IRB. (See the Noncompliance SOP.)

REVISION HISTORY

Version No.	Brief Description of Changes	Created on Date
00	Creation of SOP	7/20/2015
01	Updated title of Vice Provost for Research, Economic Development and Innovation (VPREDI) and hyperlinks	9/22/2023

SIGNATURE HISTORY

Name and Title	Signature	Date

REFERENCES

45 CFR 46.116(a)
JMU Policy # 1104