

 Office of Research Integrity - Human Subjects			SOP #: ORI(HS)-11.06
			Revision #: 1.0
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Approved By: ORI Executive Director	*Signature on file	Date:	Date First Effective: February 25, 2014
Approved by: Biomedical Chair	*Signature on file	Date:	
Approved by: Social Behavioral Chair	*Signature on file	Date:	Revision Date:

SOP 11.06 - Managing Research Concerns and Complaints

1. Objective

The purpose of this SOP is to describe how research related concerns and complaints are managed by ORI-HS.

2. General Description

ORI-HS has mechanisms in place to provide current, prospective, and past research participants or their designated representatives with safe, accessible, and confidential means for asking questions, obtaining information and discussing concerns related to a research study, their participation or both. Concerns and complaints about research may also be reported by graduate students, faculty, classified staff, and professional staff.

Participants in a research study receive documents about the study (e.g., informed consent forms, information sheets, comprehensive recruitment materials). These documents specify that individuals may contact ORI-HS to report concerns or complaints about the conduct of the research study.

The ORI-HS website, found through the main UNLV website, includes a section entitled “Information for Research Subjects” that provides information about participating in research studies, including participants’ rights as research subjects. The main page of the website also contains a link to file an anonymous complaint or to report a concern about a specific study. The “Report a Concern” page indicates that individuals may also contact the ORI Executive Director where a direct telephone number is provided.

3. Roles & Responsibilities

Execution of SOP: Principal Investigators (PI)/Study Personnel (SP), IRB Chair, IRB, Office of Research Integrity – Human Subjects (ORI-HS) Staff.

ORI-HS – The Executive Director, Office of Research Integrity is responsible for responding to research participant concerns and complaints, or for delegating response to another appropriate person.

Principal Investigator Responsibilities – participant complaints received by a PI must be reported using the process for reporting problems (see SOP 11.01).

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4. Procedures

Concerns reported by potential, current or past research subjects are treated with respect and confidentiality, regardless of the sender, recipient or content of the communications. Contact not directed towards a specific individual (e.g., telephone call placed to the main office) will be fielded by ORI-HS staff and then forwarded to the Executive Director, or other appropriate person such as the IRB Chair.

Upon receipt and depending on the circumstances of the contact, the Executive Director has multiple options for responding, including, but not limited, to:

- Corresponding with the claimant to identify or clarify the specific issues.
- Obtaining additional information from other sources if needed to assess the validity of the stated concerns and to determine if the matter may be due to a misunderstanding. It may be necessary to contact the PI or other appropriate parties.
- Determining the best course of action for addressing the concern or complaint. As necessary, a new Incident Intake Form will be created and the event, where associated with an existing study, will be processed in a manner similar to, but modified as needed, a reviewable study action (i.e. study modification or continuing review) and maintained with the associated study file.

The Executive Director or designated representative may review the protocol file, and may contact the Principal Investigator or research staff to obtain additional information to substantiate or further assess the claim. In the latter case, the identity of the person making the complaint will be protected to the greatest degree possible.

The privacy and confidentiality of a claimant will be considered paramount during investigation and event resolution. The resolution of such an event may take many forms and is extremely dependent on the circumstances surrounding each case. However and as appropriate, the resolution of an issue will seek to gain consensus from the ORI Executive Director, the IRB Chair or Chairs, the IRB, and/or any relevant UNLV authority or department. Where an issue is thought to be associated with possible researcher noncompliance, SOP 11.02 will also be followed.

5. References

SOP 11.01 Problems and Adverse Events, Record and Report
SOP 11.02 Researcher Noncompliance: Investigation, Reporting, and Corrective Action
ORI-HS Incident Intake Form (draft)