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Approved By: ORI Executive Director	*Sgnature on File	Date:	Date First Effective: July 1, 2013
Approved by: Biomedical Chair	*Sgnature on File	Date:	
Approved by: Social Behavioral Chair	*Sgnature on File	Date:	Revision Date: 10-12-2018

11.02 - Researcher Noncompliance: Investigation, Reporting, and Corrective Action

1. Objective

S Department of Health and Human Services; UNLV, through the UNLV Office of Research Integrity Human Subjects , has established written procedures for ensuring prompt reporting to appropriate entities of any unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with the applicable U.S. federal or state regulations, UNLV Policies governing research with human subjects, or the requirements or determinations of the IRB(s).

Additional goals to keep in mind while reading this SOP include: minimizing risk to research subjects, maintaining privacy for involved parties, ensuring a fair process for investigation, maintaining effective documentation, determining appropriate corrective action(s), and referring and reporting events to appropriate parties.

2. General Description

Noncompliance Failure through behavior, action, or omission to follow or comply with UNLV policy or UNLV rules and procedures that govern research with human subjects, and/ or failure to follow the requirements or determinations of the reviewing IRB.

Serious Noncompliance l Noncompliance that, in the judgement of the IRB or designee, has been determined to:

Affect the rights and welfare of participants and others; Increase risks to participants and others, decrease potential benefits or otherwise unfavorably alter the risk/ benefit ratio; Compromise the integritys Tc[No)]TJET60.0000092 0 612 79 reW* nBT/F2 11.04 Tf1 0 0 1 126.0e

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Suggests a likelihood that noncompliance will continue without intervention, or Involves repeated or frequent instances of minor noncompliance.

This procedure is specific to handling the investigation, reporting, and corrective action of acts and allegations of researcher noncompliance. All acts and allegations of researcher noncompliance are first handled by the ORI Executive Director, ORI-HS staff, or an IRB chair, for which this procedure is most relevant.

Researcher noncompliance may lead to or be the result of an unanticipated problem involving risk to subjects or others. The reporting of unanticipated problems is addressed separately in SOP 11.01.

Acts and allegations of research noncompliance as it may apply to non-researchers (i.e. ORI-HS staff, the IRB, etc.) is addressed separately in SOP 11.03.

3. Roles & Responsibilities

ORI - It is primarily the responsibility of ORI to investigate and facilitate the conclusion of any act or allegation of researcher noncompliance. Facilitation includes, but is not limited to, reporting to appropriate parties in a timely manner, maintaining clear records of all correspondence and decisions, and issuance of ORI or IRB corrective action decisions as may be required. In an instance where an event involves an IRB approved protocol, the ORI may request or recommend additional corrective action, and/ or impose additional restrictions. Such decisions are approved by the IRB. In instances where an event is not directly related to an IRB approved protocol, the ORI may remove a pending study from IRB review, request or recommend corrective action, and/ or impose restrictions. Such decisions are approved by the IRB, or IRB chairs. Additional recommendations, such as investigating possible research misconduct, may be made to the Vice President of Research for further consideration.

IRB/IRB Chairs - In an instance where the act or allegation of noncompliance involves an IRB approved protocol, the convened IRB or IRB chair(s) will be notified. The IRB or IRB chair(s)

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