

 Office of Research Integrity - Human Subjects			SOP #: ORI(HS)-7.05
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Approved By: ORI Executive Director	Signature on file	Date:	Date First Effective: March 26, 2015
Approved by: Biomedical Chair	Signature on file	Date:	
Approved by: Social Behavioral Chair	Signature on file	Date:	Revision Date:

SOP 7.05 - UNLV Students as Research Subjects

1. Objective

The purpose of this SOP is to describe additional considerations for research involving students enrolled at UNLV as research subjects.

2. General Description

College students are often participants in research studies. Many of the issues related to participation are the same for college students as for other populations. However, there are two issues that are of concern with this population: 1) coercion/undue influence and 2) confidentiality/privacy. Care should be taken to reduce coercion/undue influence by faculty and other figures that may have an authoritative role over students, and the risk of breaches in confidentiality.

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/IRB - The IRB will carefully examine the proposed inclusion of this participant population and will seek to ensure that special protections for this population are in place to minimize the potential for coercion/undue influence and protect confidentiality/privacy where necessary.

Principal Investigator Responsibilities - If an investigator wishes to recruit participants from within their laboratory, office, class, or subject pool, the protocol proposal form should discuss:

- The nature of the professional relationship between the investigator and the prospective participants.
- Justification of the need to recruit participants from the investigator's laboratory, office, or class.
- Description of the method of participant recruitment and how situational coercion/undue influence will be minimized to the greatest extent possible. *Note: The investigator should consider alternate methods for recruiting, and obtaining informed consent from students, and not engage in one-on-one solicitation; and 2) use of an individual to obtain consent that does not have any supervisory or instructional role relative to the prospective participant.*

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4. Procedures

The IRB will take into account the following considerations when reviewing research that involves UNLV students as research subjects.

Considerations for Reducing Coercion/Undue Influence

- To reduce coercion for research participation for course credit or course requirements, alternatives should be provided that are comparable in time, effort, educational benefit, and fulfillment of course requirements such as research papers, research seminars, book reports, attendance at research talks by faculty, or special projects.
- When research activities to be done by the students are not part of the required class activities or participation in the subject pool, the investigator or instructor should arrange to have the data collected by a third party, so that the investigator or instructor does not know who participated and does not have access to the identifiable data or identity of participants for any purpose until grades have been assigned and entered. For an investigator or instructor using pre- and post-tests to determine efficacy of a particular curriculum, a colleague or third party should obtain the consent forms and distribute the tests when the investigator or instructor is not present (a graduate teaching assistant in the class in which the student/subject is enrolled does not qualify as a third party for collecting the data on behalf of the instructor). If an Investigator is also the professor of the class where students will be recruited from, it is highly recommended that someone not affiliated with the class conduct the consent process, and make any recruitment announcements.
- Participants must be able to withdraw from the study at any time without penalty. College student participants who withdraw from a research study prior to completion should receive research credit for participation commensurate with their level of participation, or full research credit.
- Faculty should not recruit subjects by direct invitation to particular students to avoid coercion/undue influence. Subjects should be recruited by a general announcement, central posting, or announcement mechanism and should include a clearly written description of the project.
- Where research credit is provided as compensation for participation, it is highly recommended that the consent form clearly state that research credit is still awarded even if the subject chooses to withdraw their participation.

Considerations for Maintaining Confidentiality

- Since there are special risks to confidentiality in the close environment of the university, special attention should be given to full disclosure of these risks during the consent process. The plan for handling research data should also be designed to minimize the risk that confidentiality will be breached. When possible, data should be collected in a manner that minimizes the chance of one participant learning the response of another.

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5. References

45 CFR 46.111(b)

45 CFR 46.116

34 CFR 97

Institutional Review Board Management and Function, Bankert & Amdur – Chapter 9