

 Office of Research Integrity - Human Subjects			SOP #: ORI(HS)-3.12
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			Page #: Page 1 of 2
Approved By: ORI Executive Director	*Signature on file	Date:	Date First Effective: 10/22/2015
Approved by: Biomedical Chair	*Signature on file	Date:	
Approved by: Social Behavioral Chair	*Signature on file	Date:	Revision Date:

SOP 3.12 - Coordination between the IRB and the Institutional Biosafety Committee

1. Objective

The purpose of this SOP is to describe procedures for coordination between the Institutional Review Board (IRB)/Office of Research Integrity (ORI) and the Institutional Biosafety Committee (IBC).

2. General Description

Both the IBC and the IRB are committed to ensuring the protection of human subjects involved in research. At UNLV, approval from both the IRB and the IBC is required prior to engaging in any human subjects research involving infectious agents, or the use of human blood, body fluids, or tissue.

3. Roles & Responsibilities

Execution of SOP: Principal Investigator (PI)/ Study Personnel (SP), Office of Research Integrity – Human Subjects (ORI-HS) Staff, IRB Members, Biological Research Program (BRP) Staff, Institutional Biosafety Committee (IBC) Members

IRB

The biomedical IRB reviews all research involving human subjects. If ORI-HS staff receives an IRB application, which in their judgment may require IBC approval, ORI-HS staff contacts the Manager, Biological Research Programs for assistance in determining whether IBC review is required.

Institutional Biosafety Committee

The Institutional Biosafety Committee reviews all research involving infectious agents, or the use of human blood, body fluids, or tissue. If the Manager, Biological Research Programs receives an IBC application that may require IRB approval, then the Manager, Biological Research Programs contacts ORI-HS staff for assistance in determining whether IRB review is required.

Principal Investigator

The PI must obtain IRB approval and IBC approval prior to beginning any research activities. Protocols may be submitted simultaneously to the IRB and the IBC. Once approvals have been received, any changes to the protocol require modification submissions to both the IRB and the IBC.

UNLV Office of Research Integrity - Human Subjects and Institutional Review Board Standard Operating Procedures		
SOP #:ORI(HS)-3.12 Revision #:	TITLE: Coordination Between the IRB and the IBC	Page 2 of 2

4. Procedures

When a research project requires both IRB and IBC approvals, human research administrators (ORI-HS) and the Manager, Biological Research Programs will communicate directly with each other to ensure that all regulatory requirements are met.

If ORI-HS becomes aware of a project in which IRB approval was required but not received, they will communicate with the Manager, Biological Research Programs and alert the Executive Director, Office of Research Integrity. The IRB chair and the IBC chair will make the determination on whether or not the project should be temporarily halted.

5. References

UNLV Institutional Biosafety Committee Policies and Procedures, 5.1
(<http://www.unlv.edu/assets/research/policies/Research-InstitutionalBiosafetyPolicy.pdf>), link last updated: 09-04-2015