

Office of Research Integrity - Human Subjects			SOP #:	ORI-HS(HS)5.06
			Revision #:	2.0
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Approved By: ORI-HS Executive Director	*Signature on file	Date:	Date First Effective: 10/13/2016	
Approved by: Biomedical Chair	*Signature on file	Date:		
Approved by: Social Behavioral Chair	*Signature on file	Date:	Revision Date: 7/12/20	

UNLV Office of Research Integrity- Human Subjects and Institutional Review Board
Standard Operating Procedures

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Meeting Administration

1.

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4. Disapproved. The submission does not meet the criteria for approval in 45 CFR 46.111 as written. The IRB sends the PI documentation describing the reason for the disapproval. The study is closed, but the PI may resubmit the proposal for reconsideration. This new submission is treated as a new study.

If the protocol is approved, the IRB decides on the risk level of the study. They also consider whether any requests made by the PI (e.g., request for waiver of informed consent, documentation of consent, waiver of HIPAA authorization, etc.) is acceptable with respect to meeting federal requirements.

The IRB determines the approval period, as appropriate to the degree of risk but not less frequently than once per year. The IRB may set a shorter approval period for high risk protocols or protocols with high risk/low potential benefit ratio. The study expiration date is one year minus one day from the approval date of the protocol. For example, a study that is approved on 2/20/16 has an expiration at 11:59 pm on July 1, 2017.

If the research involves prisoners, ORIS staff check to determine whether the PI submitted the protocol for funding to any DHHS agency. If this is the case and the protocol involves prisoners, ORI HS staff, with input from the PI, prepares and submit a prisoner certification report to the Office for Human Research Protection (OHRP) in accordance with OHRP requirements and the Mandated Reporting to External Agencies SOP.

Once the IRB approves a protocol, ORI HS staff send an approval letter to the PI, which includes the approval period, a reminder to use only the approved consent/assent form, and a reminder that the IRB must approve any changes to the protocol prior to initiation of the changes.

All IRB findings are documented in the IRBNet system where the UNLV Office of Research Integrity (ORI) Executive Director and Associate Vice President of Research and may review as needed. Other UNLV officials may contact the UNLV ORI Executive Director for information.

If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit them to the IRB via a written document that includes a justification for changing the IRB decision.

5. References

45 CFR 46.111
21 CFR 56.111
38 CFR 16.111

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