

 <b>Office of Research Integrity - Human Subjects</b>		SOP #:	ORI(HS)- 5.10
		Revision #:	4.0
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Approved By: ORI Executive Director	*Signature on file	Date:	Date First Effective: 11/12/2013
Approved by: Biomedical Chair	*Signature on file	Date:	
Approved by: Social Behavioral Chair	*Signature on file	Date:	Revision Date: 01/21/2019

## SOP 5.10 - Continuing Review and Project Completion

### 1. Objective

To describe the procedures for conducting continuing review (CR) of previously approved protocols.

### 2. General Description

The Institutional Review Board (IRB) conducts substantive and meaningful CR at intervals appropriate to the degree of risk and not less than once per year. The research protocol must satisfy the criteria set forth in 45 CFR 46.103 for the IRB to approve continuation of the study. Continuing review of research previously determined to be exempt follows a different process; see SOP 5.04 for additional information.

The IRB may use expedited review procedures only under the following circumstances:

- x The study was initially eligible and continues to be eligible for expedited review procedures; OR
- x The research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects; OR
- x Where study personnel have enrolled no subjects and no additional risks have been identified either at UNLV or at any study site if the research involves a multi-site study; OR
- x a



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9. If the approval might lapse before completion of the CR, the expedited reviewer can make a determination to allow subjects currently participating to continue in accord with procedures described in the section below on lapses of approval.
10. ORI-HS staff lists expedited CRs on the IRB agenda to advise the IRB of the expedited CRs.
11. A decision to re-approve a study and associated documents will be documented in the study file, database, and a formal notification sent to the PI (See SOP 5.11).

The IRB Chair or IRB may procure, for the purposes of providing expertise or special knowledge surrounding a topic or issue of concern, an outside consultant(s) to advise an IRB review of protocol or IRB related request. The consultant will serve in an advisory role only. Any

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4. For full board CR, the date of the start of the approval period is the date of the convened meeting if approved. When the outcome of the IRB requests revisions (approved pending submission of minor revisions), the ORI-HS issues approval after the IRB Chair and/or Co-Chair reviews and approves the revisions. The approval period begins on the date on which the IRB Chair and/or Co-Chair approves the revisions. For expedited CR, the date of the start of the approval period is the date the expedited reviewer approves the study.
5. If the PI has concerns regarding the IRB decision or recommendations for changes in the study, he/she may submit his/her concerns to the IRB in writing with a justification for appealing the IRB decision. The IRB reviews the request using standard IRB review procedures.

## 5. References

- 45 CFR 46.103(b)(4)
- 45 CFR 46.108(b)
- 45 CFR 46.109(e)
- 45 CFR 46.110
- 45 CFR 46.111
- 45 CFR 46.115(a)(3)&(7)

UNLV Rules and Procedures for Conducting Human Subject Research, 5.4.1