

Approved By:	Signature	Date:	Notes
ORI Executive Director	*Signature on File		Date First Effective: 01/23/2023
Biomedical Chair	*Signature on File		
Social Behavioral Chair	*Signature on File		Revision Date: N/A

SOP 5.11 - Use of Consultants in IRB Review

1. Objective

The purpose of this SOP is to outline the process for the use of consultants during IRB review. IRB chairs, members, and HRPP staff are encouraged to seek consultation with relevant experts where appropriate.

2. General Description

The IRB may procure, for the purposes of providing expertise or special knowledge surrounding a topic or issue of concern, a consultant(s), from within or outside UNLV, to advise on an IRB review or an IRB related request. When doing so, care must be taken to ensure the confidentiality of the content reviewed by the consultant. Any consultant(s) will be free of conflict of interest and will be asked to provide acknowledgment that the review of study or study related materials are of a private nature, and that confidentiality of any shared information will be maintained. If a consultant is not available, IRB review may be postponed pending inclusion of an appropriate consultant.

3. Roles & Responsibilities

Execution of SOP: Principal Investigator (PI)/Study Personnel (SP), Office of Research Integrity – Human Subjects (ORI-HS) Staff, IRB Members

4. Procedures

The 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 on an IRB review or an IRB related request.

To assess the need for additional expertise, the HRPP will take into consideration current IRB membership and the members’ current areas of expertise, as outlined in the official IRB roster. Consultants may be approached by an IRB chair or by HRPP staff to initiate a consulting relationship.

Consultants act in an advisory capacity. They may participate in the deliberations and make recommendations on the project, but may not vote, and are not counted towards quorum. A consultant may not participate in the IRB’s review of any project in which the consultant has a conflicting interest, except to provide information requested by the IRB. Consultants are considered to have a conflict of interest as outlined in the [UNLV Conflicts of Interest policy](#).

The use of a consultant in IRB review follows the procedures outlined below:

- Payment of consultant fees, if applicable, are arranged through the ORI Executive Director
- The consultant should sign or agree to any confidentiality agreements as necessary as they engage in their consulting work with the IRB
- Consultants should be provided with relevant review materials in a timely manner, and a timeline for review should be established, to ensure timely completion of consultant reviews
- Consultants may attend IRB meetings (in-person or remotely) to provide information relevant to IRB deliberations

- Written comments provided by the consultant will be entered into the IRB minutes as part of the IRB deliberations as deemed appropriate and necessary for the specific review
- If the IRB uses a consultant and the consultant is present at the convened meeting, the minutes must include the name of the consultant (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)), a brief description of the consultant's expertise, and a summary of the information provided during the discussion.
- When a consultant is used during an exempt or expedited review, the consultant's written comments will be included in the documentation of the review
- HRPP staff or an IRB member may request that the consultant provide written comments as an alternative to or in addition to attending the IRB meeting.
- The IRB is not obligated to follow consultant recommendations; however, the input from the consultant should be presented to the IRB during relevant deliberations.

In addition to securing additional scientific or contextual consultation, the IRB reviewer, together with the HRPP staff, Chairperson and/or ORI Executive Director, may determine the necessity for consultation by legal counsel. In such cases, the UNLV General Counsel may be consulted directly by the IRB leadership for information and/or clarification regarding matters of state law applicability or to request a legal opinion pertaining to an IRB review. The opinion and/or information offered by legal counsel will be entered into the IRB minutes as a part of the IRB deliberations for the specific review during full board review, and included in the documentation of the review for exempt and expedited research.

5. References