

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 ~~when appropriate~~

2. General Description

The IRB may procure, for the purposes of providing expertise or special knowledge surrounding a topic or issue



- o 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
- o 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 information provided during the consultation. RI WKH
- " : KHQ D FRQVXOWDQW LV XVHG GXULQJ DQ H[HPSW RU H[SHGLWLRQ. RI WKH information provided during the consultation is included in the documentation of the review
- " HRPP staff or an IRB member may request that the consultant provide 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 of additional consultation. RI WKH