	IRB SOP: Use of Consultants		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HSR-132	IRB Chair, IRB Office Campbell University	10/08/2019

1 PURPOSE

- 1.1 This procedure establishes the process for the IRB to obtain consultants.
- 1.2 The process begins when the IRB Office staff or IRB member has identified the need for consultation.
- 1.3 The process ends when the consultant has provided additional expertise to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 POLICY


- 3.1 The IRB invites consultants with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.
- 3.2 Consultants with a Conflict of Interest (financial or other) related to the protocol under review may not provide information to the IRB.

4 RESPONSIBILITIES

- 4.1 IRB Office staff members carry out these procedures.

5 PROCEDURE

- 5.1 Identify a consultant with the required expertise who can provide a review. Identify individuals as follows:
 - 5.1.1 Other employees of the institution
 - 5.1.2 External consultants
- 5.2 Contact the consultant and determine availability for review.
- 5.3 Determine whether the consultant has a Conflicting Interest as defined in *IRB SOP: Definitions*. If so, obtain another consultant.
- 5.4 Use *Review Materials Worksheet* to determine which documents to make available to the consultant so the IRB can obtain the additional expertise needed, and make these documents available to the consultant. At a minimum the consultant must be sent the *Consultant Checklist*. If the additional expertise needed does not require review of any materials, no materials need be provided.
- 5.5 For review by the convened IRB:
 - 5.5.1 Make the consultant's written comments available to the IRB members attending the meeting by including them with meeting documentation.
 - 5.5.2 Consultants may attend the IRB meeting to present their findings and be available to answer questions from IRB members or they may have their written findings presented by the primary reviewer. Consultants may not vote.
- 5.6 For Expedited Review:
 - 5.6.1 Directly obtain the information in writing from the consultant.
 - 5.6.2 Document information received in the protocol record.

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6 MATERIALS

- 6.1 IRB SOP: Definitions
- 6.2 IRB SOP: IRB Meeting Conduct
- 6.3 Review Materials Worksheet
- 6.4 Consultant Checklist

7 REFERENCES

- 7.1 45 CFR 46.107(e)
- 7.2 21 CFR 56.107(f)
- 7.3 28 CFR 512.11(a)(2)
- 7.4 34 CFR 356.3
- 7.5 DoD Directive 3216.02 paragraphs 3.a.(2), 4.b.(2)
- 7.6 ICH-GCP: 2.4, 2.5, 2.13, 3.2.6