

N	<b>SOP: Consultation</b>		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HRP-051	Executive Director, IRB Office Northwestern University	11/01/2024
			PAGE
			Page 1 of 2

## 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 PREVIOUS VERSION

- 2.1 Revised from previous version 05/18/2021.

## 3 POLICY

- 3.1 The IRB invites consultants with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. Such expertise may include scientific and scholarly expertise and knowledge about and experience working with certain topics or populations. Consultants may be used for all aspects of IRB review, including, but not limited to initial review, modifications, reportable events, and continuing review.
- 3.2 Consultants with a Conflicting Interest may not provide information to the IRB.

## 4 RESPONSIBILITIES

- 4.1 For review by a convened IRB, IRB Office staff members carry out these procedures.
- 4.2 For Non-Committee Review, the Designated Reviewer carries out these procedures in conjunction with IRB Office staff, as applicable.

## 5 PROCEDURE

- 5.1 Identify a consultant with the required expertise who can provide a review. Identify individuals as follows:
  - 5.1.1 IRB members from other Northwestern University committees
  - 5.1.2 Other employees of the institution
  - 5.1.3 External consultants
- 5.2 Contact the consultant and determine availability for review. IRB consultants cannot participate in the review of any study in which they have a conflict of interest. Determine whether the consultant has a Conflicting Interest as defined in "SOP: Definitions (HRP-001)." If so, obtain another consultant.
- 5.3 Consultants may be given access to all documents relevant to the specific project under review. Use "WORKSHEET: Review Materials (HRP-301)" 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. If the additional expertise needed does not require a review of any specific materials, no materials need to be provided.
- 5.4 When the expertise of an external consultant is needed, the IRB requests, when appropriate, the investigator and sponsor for permission to release confidential/proprietary information to the external consultant.
- 5.5 For review by the convened IRB:
  - 5.5.1 A consultant to the IRB may participate, either in person or virtually, in the convened meeting at which the application is reviewed to present their review and answer the IRB's questions. The consultant may participate in the IRB's deliberations and make recommendations on the project. However, non-IRB member consultants may not vote with the IRB members, and a consultant's presence or absence will not be used in establishing a quorum.
  - 5.5.2 The consultant may provide a written review which is made available to the IRB Members participating in the specific meeting as follows:

N	<b>SOP: Consultation</b>		
	NUMBER	APPROVED BY	EFFECTIVE DATE
	HRP-051	Executive Director, IRB Office Northwestern University	11/01/2024
			PAGE
			Page 2 of 2

5.5.2.1 Make the consultant's written comments available to the IRB members attending the meeting by attaching them in the reviewer comments and saving them under supporting documents as a private comment.

5.5.2.2 Additionally, the consultant's written comments may also be attached in the Submit Committee Review activity, but must be documented in the meeting minutes.

5.6 For Non-Committee Review:

5.6.1 Directly obtain the information in writing from the consultant.

5.6.2 Document information received with the name of the consultant in the "Notes" section or "Supporting documents" section of the "Designated Review Submitted" activity.

## 6 MATERIALS

6.1 SOP: Definitions (HRP-001)

6.2 WORKSHEET: Review Materials (HRP-301)

## 7 REFERENCES

7.1 21 CFR §56.107(f)

7.2 45 CFR §46.107(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