 TEXAS A&M UNIVERSITY KINGSVILLE ®	SOP: Consultation	
	Section III: IRB Protocols	
	Number	Date
	IRB III-007	9/13/2025

1. PURPOSE

- 1.1. This SOP outlines the process for the IRB to obtain consultants in support of a specific IRB review.
- 1.2. The process begins when the research compliance staff assigned to the IRB, IRB Chair, or IRB member has identified the need for consultation.
- 1.3. The process concludes when the consultant has provided additional expertise to the IRB.

2. REVISION FROM PREVIOUS VERSIONS

- 2.1. None

3. SOP STATEMENT

- 3.1. The IRB invites consultants with competence in specialized areas to assist in the IRB review of issues that require expertise beyond or in addition to that available within the IRB.
- 3.2. Consultants will follow the same Conflict of Interest (COI) procedures as IRB members. Consultants who are determined to have a COI with the protocol they are being consulted about may not perform a review for the IRB on that protocol.

4. RESPONSIBILITIES

- 4.1. For review by a convened IRB: IRB members carry out these procedures.
- 4.2. For Non-Committee Review: the designated reviewer, in consultation with the IRB Chair or research compliance staff assigned to the IRB, carries out these procedures.

5. PROCEDURE

5.1. Non-Committee Review

- 5.1.1. When a committee member determines that additional expertise is needed to review a protocol, they are to contact the IRB Chair and research compliance staff.
 - 5.1.1.1. The IRB Chair may reassign the review to a member with sufficient expertise.
 - 5.1.1.2. The IRB Chair may determine that an outside consultant is necessary following procedures in 5.3

5.2. Convened Review


- 5.2.1. When the primary reviewer, in consultation with the IRB Chair or a Convened IRB, determines that there is not sufficient expertise to review a protocol, an outside consultant will be contacted.

- 5.3. Outside consultants are defined as Non-IRB members. This includes TAMUK faculty, employees of other TAMU system institutions, or individuals outside of the TAMU system who may serve as an external consultant, either informally or by contract.

- 5.3.1. Contact the consultant, determine availability for consultation, and identify any concerns precluding their participation such as a Financial Conflict of Interest with the research.
TAMUK SOP: Participant Selection Recruitment and Payments (IRB SOP III-009).
- 5.3.2. Send the consultant a list of questions as determined by the convened board/primary reviewer regarding procedures, populations, etc. via the TAMUK IRB email (the protocol in its entirety will not be shared with the consultant).
- 5.3.3. The consultant's response will be returned to the TAMUK IRB email and shared with the appropriate members.
- 5.3.4. In cases requiring verbal communication, a written summary shall be documented and submitted to the TAMUK IRB email to be shared with appropriate members.
- 5.4. The accuracy of all documented information, including the consultant's name, will be verified directly with the consultant to ensure data integrity.

6. REFERENCES

- 6.1. [21 CFR §56.107](#)(f)
6.2. [45 CFR §46.107](#)(e)

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