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## 1. PURPOSE

- 1.1. The IRB should have or acquire the scientific or scholarly expertise, competence, and knowledge to review **research** in order to protect the rights and welfare of the **research participants**. From time to time, the University of Georgia IRB may use a consultant to supplement the review process. The consultant may provide information directly related to experience and knowledge: of the country in which transnational research may be conducted, of specific procedures or designs, or of a special or **vulnerable population**. UGA has developed the following **policy** and **procedure** to describe the process for obtaining consultation to the IRB.

## 2. DEFINITIONS

- 2.1 **Consultant:** A **scientist** or **non-scientist** from within or external to University of Georgia who has special expertise to assist in the review of a research project at the request of the IRB.
- 2.2 **Confidentiality Agreement:** A written agreement that pertains to the treatment of information that was obtained during a review or consultation that is considered privileged or protected and will not be divulged to others without permission.

## 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 **conflicting interest** may not provide information to the IRB. See *Policy and Procedure: Conflicting Interest of IRB Members*.
- 3.3. Consultants may be granted access to any materials relevant to the specific project under review (see *Policy and Procedure: Pre-Review*), may participate in the deliberations and make recommendations on the project, but may not vote and are not counted towards quorum.

## 4. PROCEDURES: IRB Staff

- 4.1. Identify a consultant with the required expertise who can provide a review.
  - 4.2. Contact the consultant and determine availability for review.
  - 4.3. Determine whether the consultant has a Conflicting Interest. See *Policy and Procedure: Conflicting Interest of IRB Members*.
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- 4.4. Determine if any materials must be made available to the consultant and provide the proper access to view materials accordingly. If the additional expertise needed does not require review of any materials, no materials need to be provided.
- 4.5. All information and materials received by the IRB is considered confidential and will be distributed to IRB members and consultants accordingly for the purpose of review. Consultants will be expected to sign the IRB Confidentiality Agreement prior to attending a convened meeting and/or reviewing any documents or submissions.
- 4.6. For review by the convened IRB:
  - 4.6.1. The consultant's written comments, if any, will be added to the submission record and made available to the IRB members attending the meeting.
  - 4.6.2. The consultant will be invited to the IRB meeting if he/she did not provide a written comment/report or if requested by an IRB member.
- 4.7. For Non-Committee review:
  - 4.7.1. The consultant's written comments, if any, will be added to the submission record.
  - 4.7.2. If the consultant provided oral information, document the information in the determination comments/notes.

## **5. MATERIALS**

None

## **6. REFERENCES**

- 6.1. 45 CFR 46.107(f)
- 6.2. 21 CFR 56.107(f)
- 6.3. Policy and Procedure: Conflicting Interest of IRB Members
- 6.4. Policy and Procedure: Pre-Review

### Revision History:

05/15/2015: REV0 New Document

02/15/2017: REV1

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