



## Non-Committee Review Preparation and Conduct

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### 1. PURPOSE

- 1.1. The University of Georgia Institutional Review Board should have the competence and knowledge to review proposed **research** in order to protect the rights and welfare of the **research participants**. This **policy** and **procedure** describes the process for review assignment and conduct of a submission that is eligible for a **Non-Committee Review (exemption determination or expedited review procedure)**.

### 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. **Designated Reviewer:** is the person assigned to complete the non-committee review of a submission.
- 2.3. **Experienced IRB Member:** an IRB member is considered experienced if the IRB Chairperson or designated IRB Staff considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.
- 2.4. **Regulatory Reviewer:** *is the person assigned to complete the non-committee review for a submission where there is also a Subject Matter Reviewer assigned.*
- 2.5. **Subject Matter Reviewer:** is the person who may provide scientific or scholarly review and expert assessment of risk when the submission requires expertise outside of the IRB staff.

### 3. POLICY

- 3.1. Only experienced IRB members may conduct the review of a submission eligible for non-committee review.
  - 3.2. The IRB Chairperson has designated the IRB Staff to carry on the assignment of Designated Reviewers, Subject Matter Reviewers, and Regulatory Reviewers.
  - 3.3. The Subject Matter Reviewer should be an IRB Member qualified to assess risk based on IRB staff knowledge of the IRB Member's expertise or experience with the research methods or procedures, target study population, or theoretical framework for the proposed study design.
  - 3.4. The Designated Reviewer/Regulatory Reviewer of research that meets the criteria for Expedited Review will be an IRB Staff member with the appropriate knowledge of applicable federal regulations, federal, state and local laws, and local research context. The IRB Staff members are appointed to the IRB as alternate members by the HSO Director when sufficient training has been completed and the individual has demonstrated adequate capability to make all the determinations required by 45 CFR 46.111.
  - 3.5. The Designated Reviewer for research that fits within one or more of the federally or institutionally defined categories of Exemption will be an IRB Staff member with the
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appropriate knowledge of applicable federal regulations, federal, state and local laws, and local research context. The IRB staff members will be assigned submissions when sufficient training has been completed and the individual has demonstrated adequate capability to make all the determinations required by the *Policy and Procedure: Exempt Research*.

- 3.6. The Designated Reviewer and Subject Matter Reviewer will have access to the initial submission which includes all responses to submission form questions and all supporting materials attached to the submission and any associated submissions (e.g., follow-ons such as **Modifications** and **Continuing Reviews**).
- 3.7. **IRB Rosters** are maintained and updated in the electronic system by IRB Staff upon direction by the IRB Director.
- 3.8. The IRB Staff will maintain and update the list of members eligible to perform Designated Review in the electronic system. Any member on this list can potentially be a Subject Matter Reviewer.

#### 4. PROCEDURES: IRB Staff

- 4.1. Upon completion of **Pre-Review**, the IRB Staff will assign an experienced reviewer based on the appropriate review route and in consideration of any automatic **conflicting interest**. See *Policy and Procedure: Conflicting Interest of IRB Members*.
  - 4.1.1. For studies eligible for exempt determination, the IRB Staff member who completed the pre-review will assign the appropriate IRB Staff member as Designated Reviewer.
  - 4.1.2. For studies eligible for Expedited Review and where the scientific or scholarly review requires expertise outside of the IRB staff, the IRB Staff member who completed the pre-review will assign a Subject Matter Expert.
  - 4.1.3. For studies eligible for Expedited Review and where IRB staff members are capable of conducting scientific or scholarly review, the IRB Staff member who completed the pre-review will assign the appropriate IRB staff member as Designated Reviewer.
  - 4.1.4. For studies that may require **Committee Review**, the IRB Staff may consult a Subject Matter Reviewer for this determination.
- 4.2. The IRB Staff will confer with the HSO Director if a consultant may be required. See *Policy and Procedure: Consultation to the IRB*.
- 4.3. The assignment of a review role will provide access to all of the submission materials to the reviewer.

#### 5. MATERIALS

- 5.1. None
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### 6. REFERENCES

- 6.1. Policy and Procedure: Conflicting Interest of IRB Members
- 6.2. Policy and Procedure: Consultation to the IRB
- 6.3. Policy and Procedure: Exempt Research
- 6.4. 45 CFR 46 Department of Health and Human Services Protection of Human Subjects
- 6.5. 21 CFR 50 Food and Drug Administration Protection of Human Subjects