



## 1. PURPOSE

1.1. Scientific or scholarly review is required before the University of Georgia Institutional Review Board (UGA IRB) can approve non-Exempt human research to ensure that the risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and that potential risks are reasonable in relation to anticipated benefits. The UGA IRB has developed the following policy and procedures to determine that research procedures are consistent with sound research design and will yield the expected knowledge.

## 2. POLICY

- 2.1. Students conducting research must work under the oversight and supervision of a Principal Investigator, who will be a faculty member, and will provide review for scientific and scholarly validity. Student projects for thesis or dissertation will also be reviewed by the student's advisory faculty/committee.
- 2.2. The scientific or scholarly review requirement may be satisfied when a research project has been subjected to full peer review such as a review by a study section or grant committee of federal funding organizations (such as NIH or NSF), or non-federal funding organizations employing peer review mechanisms for awarding of funding (such as American Cancer Society, American Heart Association, or March of Dimes).
- 2.3. Research requiring committee review will be evaluated for scientific and scholarly validity by the primary and secondary reviewers assigned to the study. Additional expertise and review of anticipated benefits and risks may be provided during discussion by any attending committee member.
- 2.4. Research eligible for Expedited review may be reviewed for scientific and scholarly validity by the **Designated Reviewer** or, at the discretion of the **Designated Reviewer** by a **Subject Matter Expert** or **Consultant**. See *Policy and Procedure: Non-Committee Review Preparation and Conduct*.
- 2.5. The IRB has the discretion to utilize an expert **Consultant**, when needed, to assist in the evaluation of the scientific design, proposed anticipated benefits and risks, or the importance of the knowledge to be gained from a study. See *Policy and Procedure: Consultation to the IRB*.
- 2.6. The **Subject Matter Expert** or **Consultant** may not disapprove research.

### 3. PROCEDURES: Investigator

- 3.1. The Principal Investigator is required to provide sufficient information about the study background, objectives, potential participants, study procedures, anticipated risks and risk mitigation measures, potential benefits, and other aspects as necessary for the IRB to determine that the research has scientific or scholarly validity.

See *Policy and Procedure: Pre-Review of IRB Submissions*.

### 4. PROCEDURES: Institutional Review Board

- 4.1. The IRB Staff will review all materials.

- 4.2. IRB Staff will make an initial determination of the required level of review (Expedited Review, Committee Review).

- 4.3. For research eligible for **Expedited Review**, IRB staff will determine if assistance with scientific or scholarly review is required. This determination may be made through assessment of target population and procedures and with the guidance of *WORKSHEET: Scientific or Scholarly Review*. The following list describes types of studies that commonly require scientific or scholarly review by a **Subject Matter Expert** (Note - these are general examples and not an all-inclusive list):

- Studies where biological samples are collected (e.g., blood, tissue, urine, saliva)
- MRI/EEG/NIRS/Ultrasound procedures
- Studies that involve genetic analyses
- Studies with physical interventions (e.g., cold stressor or pressure tasks, electrical shock, exercise or nutritional intervention)
- Studies with psychological manipulation (interaction or deception) used to obtain sensitive information
- Studies with the potential for group harm
- Studies that involve vulnerable or special populations such as prisoners, individuals with cognitive impairment, children with disabilities, pregnant women, neonates or infants, and undocumented aliens

- 4.4. The **Subject Matter Expert** will assess anticipated risks and will determine if the submission meets criteria for **Expedited Review** or needs to be reviewed via Committee at a convened meeting. Recommendations for additional subject protections and measures to mitigate risk may be made as well as a recommendation for approval period. While not required, the consent process and materials may also be reviewed.

- 4.5. If the IRB does not have the necessary expertise, IRB Staff will assign a **Consultant**.

- 4.6. Using checklists and worksheets corresponding to the type of review conducted and/or inclusion of special or vulnerable populations, and incorporating any comments or suggestions from **Subject Matter Experts** or **Consultants** (if applicable), IRB staff will determine if there are any edits or additional information needed in order to address sufficiently any items.

- 4.6.1. For non-committee reviews, IRB staff will offer the investigator the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence that describes missing information or required modifications.

4.6.2. For committee reviews, IRB staff will offer the investigator the opportunity to provide additional information/materials and/or to revise the submission during a convened meeting or in appropriate review correspondence that describes missing information or required modifications.

4.7. IRB Staff will document determinations that the requirements of this policy have been met on the review checklist corresponding to the type of review being completed (if non-committee review) or in the meeting minutes by recording the motion to approve (if committee review).

## **5. MATERIALS**

- 5.1. WORKSHEET: Criteria for Approval
- 5.2. WORKSHEET: Scientific or Scholarly Review
- 5.3. WORKSHEET: Calculation of Approval Intervals
- 5.4. Checklist: Expedited Review
- 5.5. Checklist: Informed Consent Elements
- 5.6. Checklist: Children
- 5.7. Checklist: HIPAA Waiver of Authorization
- 5.8. Checklist: Prisoners
- 5.9. Checklist: Cognitively Impaired Adults
- 5.10. Checklist: Pregnant Women and Fetuses
- 5.11. Checklist: Non-Viable Neonates
- 5.12. Checklist: Neonates of Uncertain Viability
- 5.13. Checklist: Subject Matter Review

## **6. REFERENCES**

- 6.1. 45 CFR 46.111
- 6.2. Policy and Procedure: Consultation to the IRB
- 6.3. Policy and Procedure: Pre-Review of IRB Submissions
- 6.4. Policy and Procedure: Non-Committee Review Preparation and Conduct