



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-030-2	04/03/2018	HSO	IRB	Page 1 of 2

1. PURPOSE

1.1. The University of Georgia Institutional Review Board has developed the following **policy** and **procedures** for conducting review of initial **research** eligible for Non-Committee Review.

2. DEFINITIONS

2.1. **Non-Committee Review:** is any of the following:

2.1.1. **Exempt Determination:** determination of whether **human research** is exempt from regulation

2.1.2. **Expedited Review:** review of non-exempt research using the expedited procedure

3. POLICY

3.1. See the table for possible IRB Actions for research eligible for Expedited Review.

Approval	Acceptable as is. No changes are required. Criteria for IRB approval 45 CFR 46.111 have been met.
*Modifications Required to Secure Approval	Criteria for IRB approval have been met, though specific, non-substantial revisions are required. Upon receipt of the required changes, the designated or regulatory reviewer will verify that the appropriate modifications required to secure approval were made and will approve the study.

**Exempt Studies: This option is only applicable if all necessary requirements for approval have been met as stated in the Policy: Exempt Review. Non-Exempt Studies: This option is only applicable if all requirements for CFR 46.111 have been met.*

3.2. The criteria for approval using the expedited procedure are the same as those for review by a convened IRB.

3.3. The Designated Reviewer or Regulatory Reviewer conducting non-committee review may not disapprove research.

3.4. If the Designated Reviewer or Regulatory Reviewer cannot approve or require modifications to approve the submission, the submission will be referred to committee review.

3.5. For Exempt research, "Approved" signifies that the criteria described in the institutional *Policy and Procedure: Exempt Review* have been sufficiently addressed and study is determined to be exempt.

3.6. Non-Committee review is not applicable for DOD supported research that involves **prisoners**.

4. PROCEDURES: Institutional Review Board

4.1. The IRB Staff will review all materials and consult any worksheets to guide the process as needed.



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-030-2	06/30/2017	HSO	IRB	Page 2 of 2

- 4.2. The IRB Staff will determine the required level of review (Exempt Determination or Expedited Review).
- 4.3. Use *WORKSHEET: Additional Federal Criteria* to determine if research supported by federal agencies meets applicable criteria for approval.
- 4.4. The Designated Reviewer will complete all checklists pertinent to the review (see MATERIALS).
- 4.5. If there are any edits or additional information needed in order to address sufficiently any items on the checklists, the Designated Reviewer must provide the study team with an opportunity to provide clarifications/additional information.
 - 4.5.1. The Designated Reviewer will incorporate any comments or suggestions from **Subject Matter Reviewer** or **Consultant** (if applicable).
- 4.6. When all items on the checklists and included in the clarification request are sufficiently addressed along with any criteria for approval required by regulation or institutional policy, the Designated Reviewer will submit the review outcome documenting any specific determinations or waivers granted, and set an approval period (of one or three years) as appropriate for the study unless the Subject Matter Expert or Consultant suggests more frequent review. See *WORKSHEET: Criteria for Approval and Additional Considerations* and *WORKSHEET: Calculation of Approval Intervals*.
 - 4.6.1. If an item has not been addressed as suggested but the submitted response is consistent with policy and/or regulatory requirements, the Designated Reviewer will add a comment to the submitted review.

5. MATERIALS

- 5.1. WORKSHEET: Additional Federal Criteria
- 5.2. WORKSHEET: Calculation of Approval Intervals
- 5.3. WORKSHEET: Criteria for Approval and Additional Considerations
- 5.4. Checklist: Research Involving Children
- 5.5. Checklist: Research Involving Cognitively Impaired Adults
- 5.6. Checklist: Exemption Determination
- 5.7. Checklist: Expedited Review
- 5.8. Checklist: HIPAA Waiver of Authorization
- 5.9. Checklist: Informed Consent Elements
- 5.10. Checklist: Informed Consent Waivers
- 5.11. Checklist: Neonates of Uncertain Viability
- 5.12. Checklist: Non-Viable Neonates
- 5.13. Checklist: Pregnant Women and Fetus

6. REFERENCES



**Human Research
Protection Program**
UNIVERSITY OF GEORGIA

Designated and Regulatory Review

6.1. 45 CFR 46.111

6.2. Policy and Procedure: Exempt Review

Revision History:

06/19/2015: REV0 New Document

06/30/2017: REV1

04/03/2018: REV2
