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: 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.

<table>
<thead>
<tr>
<th>Approval</th>
<th>Acceptable as is. No changes are required. Criteria for IRB approval 45 CFR 46.111 have been met.</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Modifications Required to Secure Approval</td>
<td>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.</td>
</tr>
</tbody>
</table>

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

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

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

3.4. For Exempt research, “Approved” signifies that the criteria described in the institutional Policy and Procedure: Exempt Determination have been sufficiently addressed.

3.5. 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.

4.2. The IRB Staff will determine the required level of review (Exempt Determination, 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 Experts** or **Consultants** (if applicable).

4.6. When all items on the checklists are sufficiently addressed along with any criteria for approval required by regulation or institutional **policy**, the **Designated Reviewer** will submit the review outcome (determination) documenting any specific determinations or waivers granted and setting an approval period for no more than one year unless the **Subject Matter Expert** or **Consultant** suggests more frequent review, if applicable (see WORKSHEET: Criteria for Approval and WORKSHEET: Calculation of Approval Intervals).

5. **MATERIALS**

5.1. WORKSHEET: Additional Federal Criteria

5.2. WORKSHEET: Criteria for Approval

5.3. WORKSHEET: Calculation of Approval Intervals

5.4. Checklist: Exempt Determination

5.5. Checklist: Expedited Review

5.6. Checklist: Informed Consent Elements

5.7. Checklist: Informed Consent Waivers

5.8. Checklist: Children

5.9. Checklist: HIPAA Waiver

5.10. Checklist: Cognitively Impaired Adults

5.11. Checklist: Pregnant Women and Fetus

5.12. Checklist: Non-Viable Neonates

5.13. Checklist: Neonates of Uncertain Viability

6. **REFERENCES**

6.1. 45 CFR 46.111

6.2. Policy and Procedure: Exempt Determination

Revision History:
06/19/2015: REV0 New Document