



Review of Modifications

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1. PURPOSE

- 1.1. The University of Georgia IRB must review and approve proposed changes to non-Exempt **research** design, activities, or materials during the period for which IRB approval has already been given. Changes to **Exempt research** that may affect the risk assessment or that may disqualify **research** from exemption must be reviewed and approved by the IRB. The purpose of this **policy** and **procedure** is to provide guidance for researchers who wish to modify ongoing **research** and for IRB members and staff who will review requests for **modification**.

2. DEFINITIONS

- 2.1. **Modification**: any change to a previously approved protocol.
- 2.2. **Minor changes** are changes that do not affect the overall conduct and design of a study or the potential risk assessment. These may include: editorial or administrative revisions to consent documents, data collection materials, or other study documents; adding or revising questions to a survey, interview or focus group, if the questions are similar in nature or follow the same theme/topic; adding or revising recruitment procedures and/or materials, if consistent with UGA's **policy** for recruitment and advertisements; adding a new group of participants that have the identical inclusion/exclusion criteria as the previously approved group; onboarding of relying sites when UGA IRB serves as the IRB of record; adding or revising **research incentive** that does not influence a participant's voluntary participation; change in study title; changes to study team, excluding change in **Principal Investigator**.

3. POLICY

- 3.1. Changes in **research** procedures, the informed consent process, and/or the consent/assent document cannot be initiated by the investigator without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject.
 - 3.2. **Modifications** that represent a **minor change** to non-Exempt **research** will be reviewed via Expedited procedure.
 - 3.3. **Minor changes** to **Exempt research** are not required to be reviewed by the IRB (see Policy and Procedure: Exempt Research).
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- 3.4. **Modifications** to **research** previously approved by committee may be assigned to Expedited review or committee review based on risk assessment.
- 3.5. The IRB may determine that the proposed changes so significantly impact the design and/or risk assessment that a **modification** is not appropriate and that a new initial submission will be required.
- 3.6. The criteria for approval of **modifications** are the same as those for approval of the initial non-Exempt **research** or the initial Exempt **research** (Policy and Procedure: Exempt Research).
- 3.7. Approval of a **modification** does not change the approval period expiration of a study.
- 3.8. Proposed **modifications** to the study protocol or materials may be submitted with a request for continuing review.

4. PROCEDURES: Institutional Review Board

- 4.1. The IRB Staff will confirm that the person/s assigned to review the submission do not have a **conflicting interest**.
 - 4.2. The IRB Staff will make an initial determination whether the proposed **modifications** affect the risk assessment and/or the previous review category.
 - 4.2.1. If necessary, the IRB Staff will assign a **Subject Matter Expert** or **Consultant** to assist with this determination.
 - 4.2.2. If the proposed **modifications** do affect the previous review category, the submission will be assigned the appropriate review route (see Policy and Procedure: Non-Committee Review Preparation) or the investigator will be instructed to submit a new initial study for review.
 - 4.3. If the proposed modification requires committee review, the IRB staff will stop this procedure and follow the Policy and Procedure: IRB Meeting Preparation.
 - 4.4. If the **modification** is eligible for Expedited review or represents a change that does not affect the initial Exempt determination, the **Designated/Regulatory Reviewer** and/or **Subject Matter Expert** will complete any required checklists. Only **modifications** such as the introduction of new populations or materials would require completion of a checklist (e.g., Checklist: Informed Consent Elements if there is a new consent process and document).
 - 4.5. If there are any edits or additional information needed in order to address sufficiently any items on the checklists, the IRB staff will provide the study team with an opportunity to provide clarifications/additional information.
 - 4.5.1. Any comments or suggestions from **Subject Matter Experts** or **Consultants** (if applicable) will be incorporated.
 - 4.6. The **Designated/Regulatory Reviewer** will submit the review documenting any new specific determinations or waivers granted and setting an approval period beginning the date that the review is complete/submitted and ending with the current **expiration date** as set during initial review or the last **continuing review**. When continuing review is not required, the date for a requested Progress Report is entered.
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4.7. All proposed changes will be incorporated (published) to the main study record when the approval (post-review) process is complete.

5. MATERIALS

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

6. REFERENCES

- 6.1. 45 CFR §46.110
- 6.2. 21 CFR §56.110
- 6.3. OHRP Guidance on the Use of Expedited Review Procedures
- 6.4. Policy and Procedure: Conflicting Interest of IRB Members.
- 6.5. Policy and Procedure: IRB Meeting Preparation
- 6.6. Policy and Procedure: Non-Committee Review Preparation and Conduct