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1. PURPOSE

- 1.1. This document establishes the **policy** and process for the University of Georgia Institutional Review Board (UGA IRB) to determine whether current participants may continue participation in **human subjects research** activities when IRB approval has expired.

2. DEFINITIONS

- 2.1. **Expiration Date:** is the last date that the protocol is approved.

3. POLICY

- 3.1. IRB approval expires at 12:00 midnight on the expiration date.
- 3.2. If a follow-on submission to previously approved research is granted *Modifications Required to Secure Approval* and the IRB approval expires before responsive materials are reviewed and approved, this policy and procedures must be followed.
- 3.3. New **human participants** must never be enrolled if IRB approval has expired.

4. PROCEDURES: IRB Staff

- 4.1. The Designated IRB Staff must determine from the Investigator which participants need to continue in the expired research, what procedures are being requested to continue, and why.
- 4.2. The IRB Chair or Designee must determine which subjects can continue in the research based on the following principles:
- 4.2.1. In general, research procedures should be safely discontinued.
- 4.2.2. In general, the only research procedures that should continue are those that are not available outside of the research context. If the required procedures can be provided as standard of care or non-research intervention or interaction, these should be provided as such.
- 4.2.3. In general, research procedures conducted to collect data with no direct benefit to the participant should not continue.
- 4.2.4. In some cases, an ethical issue may be raised where the above general principles may not be followed.
- 4.3. The Designated IRB Staff must communicate the determination with the Investigator using *TEMPLATE LETTER: Continuation of Subjects in Expired Research*.
- 4.4. The Designated IRB Staff must include in the study's electronic record any relevant protocol materials and/or correspondence to and from the IRB.
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5. MATERIALS

5.1. TEMPLATE LETTER: Continuation of Subjects in Expired Research

6. REFERENCES

6.1. None