1. PURPOSE

1.1. This policy is an addendum to the University of Georgia Human Research Protections Program (UGA HRPP) HRP – 057 Policy and Procedure: Continuing Reviews and describes the variations in requirements and procedures that the UGA HRPP/IRB and investigators will adhere to in order to ensure business continuity for research requiring Continuing Review when exigent circumstances impede access to information and processes normally utilized.

2. DEFINITIONS

2.1. Continuing Review: the process of IRB review of approved research that will continue beyond the end of the approval period.

2.2. Lapse of approval: refers to the time after expiration of research approval and before a new approval period is granted.

3. POLICY

3.1. Continuing Review (from HRP-057) - For non-exempt research subject to the pre-2018 Common Rule and some non-exempt federally supported research subject to the 2018 Common Rule, Continuing review and re-approval of a project must occur at least annually if the project will continue to involve human subjects.

3.1.1. The requests for continuing review of research must be approved by the IRB prior to the expiration date of the study.

3.1.2. The study team members are responsible for fulfilling requirements associated with continuing review in time for the IRB to carry out review and approval prior to the expiration date; therefore, the continuing review request should be submitted no later than 30 days before the study expires. Submission nearer to the expiration date may result in a lapse of approval.

3.1.3. All information requested in the online forms should be provided in as much detail as possible. This research progress or status report includes:

3.1.3.1. The number of enrolled participants;

3.1.3.2. The number of participant withdrawals and the reasons for withdrawal, if known;

3.1.3.3. A summary of any modifications to the approved protocol or materials that were not submitted for prior IRB review;

3.1.3.4. A summary of any new and relevant information about risks associated with the research, published or unpublished, since the last IRB approval;
3.1.3.5. A summary of any relevant interim findings and/or any relevant multi-center trial reports;

3.1.3.6. A summary of the PI’s current risk assessment based on study results, if applicable;

3.1.3.7. For FDA-regulated research, the current Investigator’s Brochure; and

3.1.3.8. Any other significant information related to subject risk, such as the most recent report from any entity monitoring the research.

3.1.4. Upon expiration, all study-related activities involving human subjects must stop until a new approval has been granted. These activities include recruitment, advertising, eligibility screening, enrollment of new participants, obtaining informed consent, all interventions and interactions with research participants, and the collection and/or analysis of private identifiable information.

3.1.5. The IRB may require more frequent continuing review and will base this determination on certain specific criteria that could include some or all of the following:

3.1.5.1. Complex projects involving unusual levels or types of risk to subjects;

3.1.5.2. Type or vulnerability of population involved in the study;

3.1.5.3. Projects conducted by investigators who previously have failed to comply with the federal, state or institutional regulations and policies, or the requirements and determinations of the IRB.

3.1.5.4. Projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.

3.2. When exigent circumstances (for example: pandemic-related travel restrictions) impact the study team’s access to research records so that information required to submit a continuing review request cannot be obtained, the Investigator may request review based on estimates. The IRB may conduct continuing review based on estimates or best-recall of the required information.

3.2.1. If enrollment information is necessary to make determinations of risk or noncompliance the IRB can provide approval for a limited time period to avoid a lapse in approval with the contingency that no research activities can be conducted until a complete progress report is submitted and reviewed by the IRB.

3.2.2. If enrollment information is not necessary to make determinations of risk or noncompliance, the IRB can provide approval for a limited time period to avoid a lapse in approval and will specify activities that can continue such as remote data collection and
data analysis. The IRB will require a complete progress report before allowing other research activities to start up again.

3.3. **Modifications to Previously approved Research** – The above policies apply only to **Continuing Review** requests. When modifications are included in a **Continuing Review** request, all information requested in the online Progress Report must be provided.

3.4. **Informed Consent** – The study consent document will only be processed for the new approval period (e.g., date-stamped) for studies that provided a complete progress report.