1. PURPOSE

1.1. Federal regulations require periodic IRB review of approved research at intervals appropriate to the degree of risk, but not less than once per year. The University of Georgia Institutional Review Board (UGA IRB) has developed this policy and procedure to provide guidance for researchers to request continuation of non-exempt research and for IRB members and staff who will review requests for continuation.

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.

2.3. **Long term follow-up**: includes

   2.3.1. Data collection after research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); and

   2.3.2. Collection of follow-up data from procedures or interventions that would have been done as part of routine intervention or clinical practice (for example, to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol.

3. POLICY

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

3.2. The **Principal Investigator (PI)** is responsible for submitting a study closure request. A study closure must be requested upon study completion and/or if the study was not initiated.

3.3. The study team members are responsible for fulfilling requirements associated with continuing review in time for the IRB to carry out continuing review prior to the expiration date of the current IRB approval; therefore, the continuing review 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.

3.4. Upon expiration, all study-related activities involving human subjects must stop until a new approval has been granted. This includes recruitment, advertising, screening, enrollment of new participants, obtaining research informed consent, interventions, interactions, and the collection and/or analysis of private identifiable information.
3.5. The failure to request continuing review or enrollment of subjects after expiration is considered a minor protocol deviation. The Human Subjects Office courtesy notifications do not replace the responsibility of the PI to be aware of the approval period for research studies. The failure to receive courtesy notifications is not an acceptable reason for failure to submit a continuing review request.

3.6. The IRB may allow continuation of research intervention or interactions in already enrolled participants only when discontinuing the related research activities would jeopardize the rights or safety of the current subjects. The researcher must submit Reportable New Information (RNI) for review by the convened IRB Board, IRB Chairperson, or an IRB member or groups of IRB members designated by the IRB Chairperson who will determine if there is an over-riding safety concern or ethical issue involved such that it is in the best interests of individual subjects to continue.

3.7. If the IRB subsequently re-approves a study that had a lapse of approval the IRB may approve the study for one year and establish a new anniversary date for the expiration of subsequent approval periods or may re-approve the study for less than one year, either to retain the original anniversary, or to address any study risks.

3.8. The proposed modifications to the study protocol or materials may be submitted in conjunction with the request for continuing review or separately. Depending on the breadth of the modification and the imminence of the study expiration, the IRB may choose to review these requests at the same time or separately.

3.9. A continuing review is no longer required when all human subjects activities have been completed as indicated by reaching all of the following four milestones. If all four milestones have been reached, the study will be closed.

3.9.1. Study is permanently closed to enrollment.

3.9.2. All subjects have completed all study-related interventions.

3.9.3. Collection of private identifiable information is complete.

3.9.4. Analysis of private identifiable information is complete.

3.10. If enrollment of subjects and/or data collection will continue after five years, the PI must submit a new project.

3.11. A Continuing review of research previously approved by committee must take place at a convened meeting at which a majority of the IRB members are present, including at least one member whose primary concerns are in nonscientific areas, unless the research is eligible for Expedited review:

3.11.1. Expedited category 8(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii)
the research remains active only for long-term follow-up of subjects; (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

3.11.2. The continuing review must receive approval of a majority of those members present at the meeting.

3.11.3. The committee may approve, approve with conditions, defer taking action, or disapprove the request for continuation.

3.12. A continuing review of research reviewed via Expedited procedure must be conducted by one or more experienced reviewers designated by the IRB chairperson from among the IRB members.

3.12.1. The designated IRB member can approve or require modification in the continuing review, but may not disapprove the research.

3.13. The continuing review of research involving prisoners will be reviewed by the Prisoner representative member of the IRB.

3.14. The criteria for approval for continuing review are defined by federal regulations and are the same as for approval of new research.

4. PROCEDURES: Researchers

4.1. It is the PI’s responsibility to seek continuing review by creating a request in the IRB electronic submission system. All information requested in the online forms should be provided in as much detail as possible. This progress report includes but is not limited to:

4.1.1. The number of subjects accrued (for multicenter research studies, the number of subjects accrued at the local institution and the number accrued study-wide, if available, should be provided);

4.1.2. Any new and relevant information, published or unpublished, since the last IRB review, especially information about risks associated with the research;

4.1.3. A summary of both any unanticipated problems and available information regarding adverse events;

4.1.4. A summary of any withdrawal of subjects from the research since the last IRB review, and the reasons for withdrawal, if known;

4.1.5. A summary of any complaints about the research from subjects or others since the last IRB review;

4.1.6. For FDA-regulated research, the current Investigator’s Brochure, if available, including any modifications; and
4.1.7. Any other significant information related to subject risk, such as the most recent report from any entity monitoring the research, if available.

4.2. The researcher should not submit materials for continuing review so far in advance of the expiration date that the materials may not reflect the study’s status by the time the continuing review actually occurs.

4.3. The researcher should consider submission timelines for continuing review when planning leave or travelling in order to meet requirements of continuing review by the expiration date.

4.4. It is the PI’s responsibility to seek study closure by creating a continuing review request and selecting study closure and providing the required information.

4.4.1. If study closure is not selected, the researcher must indicate that study has reached all four milestones by selecting all four milestones and providing the required information.

5. PROCEDURES: Institutional Review Board

5.1. The IRB electronic system will send a courtesy reminder notification to the researcher via email 90, 60, and 30 days prior to the study’s expiration date. The courtesy notifications contain information regarding the study’s expiration date and actions to take to submit a continuing review.

5.2. Continuing review may be conducted up to thirty days prior to expiration and retain the fixed anniversary date for expiration.

5.3. If the IRB approves a continuing review request earlier than the 30 days prior to the expiration date, the IRB Staff member must assign the study a new approval period.

5.4. Continuing review requests are pre-reviewed and assigned to reviewers as described in Policy and Procedure: Pre-Review and Policy and Procedure: Review Preparation and Assignment.

5.5. Continuing review by Expedited Procedure is conducted as described in Policy and Procedure: Designated Review.

5.6. Continuing review by committee is conducted according to this policy and by using a primary reviewer system where the IRB member has previously reviewed the research or has appropriate expertise in the research topic or procedures or with similar populations.

5.7. The IRB will consider any new information or interim findings provided by the researcher that may affect prior determinations, assessment and/or monitoring of potential benefits or risks to the subjects, or the adequacy of the process for obtaining informed consent.

5.8. The IRB will consider researcher and/or institutional issues such as new financial conflict of interest, satisfaction of training requirements, new/revised institutional policies, and reports from any third party observations of the research carried out under regulations.
5.9. The IRB may determine that the protocol needs verification from sources other than the study team that no material changes had occurred since previous IRB review. This determination is made on a case-by-case basis and according to the following criteria:

5.9.1. Protocol conducted by PI who has previously been found to be non-compliant with federal, state or institutional regulations and policies or the requirements/determinations of the IRB.

5.9.2. Protocol where concern about possible material changes occurring without IRB approval have been raised based on information provided in the continuing review submission or from other sources.

5.10. The IRB will consider the research progress including any realized subject benefits, previously reported or unreported problems or complaints, consistency of continuing review information with the IRB-approved protocol and materials (e.g., approved consent document is still accurate and complete), total subject enrollment and withdrawals.

5.10.1. If the research represents collaboration or is sponsored research that requires data/subject safety monitoring board (DSMB), request verification from the collaborating institution/researcher or the DSMB that no material changes have occurred since the previous/initial review, if these have not been submitted with the continuing review request.

5.11. For non-committee reviews, IRB staff will offer the PI the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence.

5.12. For committee reviews, IRB staff will offer the PI the opportunity to provide additional information/materials and/or to revise the submission in appropriate review correspondence that describes missing information or required modifications.

5.13. IRB Staff will document information pertaining to determinations that the requirements of this policy have been met in the review history for non-committee reviews and in the meeting minutes by recording the motion to approve for research reviewed by committee.

5.14. When the study expires, the IRB will notify the PI via email which will prompt him/her to stop all research activities as well as list actions to take if the researcher wishes to close or continue the research study.

5.15. For study closures, the IRB staff will review the submission and provide the PI the opportunity to provide additional information or revise the submission in appropriate review correspondence.

6. MATERIALS

6.1. WORKSHEET: Criteria for Approval

6.2. WORKSHEET: Calculation of Approval Intervals
7. REFERENCES

7.1. 45 CFR §46.108(b)
7.2. 45 CFR §46.109(e)
7.3. 45 CFR §46.110
7.4. 21 CFR §56.110
7.7. Policy and Procedure: Pre-Review
7.8. Policy and Procedure: Review Preparation and Assignment
7.9. Policy and Procedure: Review of Modifications to Previously Approved Research