1. PURPOSE

1.1. The UGA IRB has developed this **policy** and **procedure** for the protection of **human research subjects** related to continuing review of non-exempt research. Federal regulations require periodic Institutional Review Board (IRB) review of approved **human research** that are **federally supported** at intervals appropriate to the degree of risk, but not less than once per year. The University of Georgia’s **Federal Wide Assurance** allows flexibility in applying human subjects federal regulations to non-federally supported research. The UGA IRB may, therefore, grant study approval of up to three (3) years for non-exempt studies that meet certain criteria.

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. 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 conducted 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. Continuing review and re-approval of a federally supported research project must occur at least annually if the project will continue to involve human subjects. The Office for Human Research Protections (OHRP) considers a research project to continue to involve human subjects as long as the investigators conducting the research continue to obtain:

   3.1.1. Data about the subjects of the research through intervention or interaction with them; or

   3.1.2. **Identifiable private information** about the subjects of the research.

3.2. Continuing review and extended approval of up to three (3) years may be granted by the IRB for non-exempt studies that will continue to involve human subjects if **all** of the following criteria are satisfied:

   3.2.1. The research does not involve greater than minimal risks to participants.

   3.2.2. The research does not have any direct or indirect federal funding, including federal training and program project grants.
3.2.3. The research is not directed or overseen by a federal agency that has signed on to the Common Rule.

3.2.4. The research is not subject to FDA oversight.

3.2.5. The research is not covered by a Certificate of Confidentiality.

3.2.6. The research does not involve prisoners or parolees.

3.2.7. The research has no contractual obligations or restrictions that would allow an extended approval (e.g., the non-federal sponsor requires an annual review).

3.2.8. The UGA IRB is not serving as the Reviewing IRB for an institution that applies the federal regulatory standards to all human research regardless of the funding and/or requires annual review.

3.3. 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:

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

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

3.3.3. 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.

3.3.4. 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.

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

3.5. 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 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.

3.6. 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.

3.7. 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 participants. The researcher must submit a Reportable New Information (RNI) for review by the convened IRB Board, IRB Chairperson, or an IRB member or
an IRB sub-committee 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 participating.

3.8. If the IRB subsequently approves a study that had a lapse of approval, the IRB may approve the
study for one year or three years, and establish a new anniversary date for the expiration of
subsequent approval periods or may assign a shorter approval period, either to retain the
original anniversary, or to address any study-related risks.

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

3.10. 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.

3.10.1. Study is permanently closed to enrollment.
3.10.2. All subjects have completed all study-related interventions.
3.10.3. Collection of private identifiable information is complete.
3.10.4. Analysis of private identifiable information is complete. (Note: Analysis of private
information that is not individually identifiable is not human subjects research and,
therefore, does not require continuing review.)

3.11. Simply maintaining individually identifiable private information without using, studying, or
analyzing such information is not human subjects research and, therefore, does not require
continuing review.

3.12. A continuing review of research previously approved by the Full Board 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.

3.12.1. The continuing review of research previously approved at a convened meeting is eligible
for expedited review under 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 analysis of private
individually identifiable information.
3.12.2. The continuing review must receive approval of a majority of those members present at the meeting.
3.12.3. The committee may approve, approve with conditions, defer taking action, table, or disapprove the request for continuation.
3.13. 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.
3.13.1. The designated IRB member can approve or require modification in the continuing review, but may not disapprove the research.
3.14. The continuing review of research involving prisoners will be reviewed by the Prisoner representative member of the IRB.
3.15. 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 research progress or status report includes:
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);
4.1.2. A summary since the last IRB review of:
   4.1.2.1. adverse events, untoward events, and adverse outcomes experienced by the participants;
   4.1.2.2. unanticipated problems involving risks to participants or others;
   4.1.2.3. participant withdrawals since the last IRB review, and the reasons for withdrawal, if known;
   4.1.2.4. complaints about the research from subjects or others;
   4.1.2.5. amendments or modifications;
   4.1.2.6. any new and relevant information, published or unpublished, since the last IRB review, especially information about risks associated with the research;
4.1.3. Any interim findings.
4.1.4. Any relevant multi-center trial reports.
4.1.5. The Researcher’s current risk-potential benefit assessment based on study results.
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. If a study becomes ineligible for an extended three-year continuing review approval, such as if a new federal funding is secured or other changes (see eligibility criteria described above), the Principal Investigator (PI) is responsible for promptly submitting an Amendment that describes the change(s) via the IRB electronic submission system.

4.2.1. The study will then receive a new expiration date following the policy for federally-supported studies, as appropriate.

4.3. The researcher is cautioned, however, to not submit a continuing review request so far in advance (i.e., more than 90 days before the expiration date) since the information may not reflect the study’s status by the time the continuing review actually occurs.

4.4. The failure to request continuing review or the enrollment of subjects after expiration is considered a violation of UGA policy (see Investigator Manual). 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.

4.5. The PI is responsible for submitting a study closure by creating a continuing review request, selecting study closure and providing the required information. A study closure must be requested upon study completion and/or if the study was not initiated.

4.5.1. 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 30 days prior to expiration and retain the anniversary date for expiration.

5.3. If the IRB approves a continuing review more than 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: Non-Committee Review Preparation and Conduct.
5.5. Continuing review by Expedited Procedure is conducted as described in Policy and Procedure: Designated and Regulatory Review.

5.6. Continuing review by a Convened Board is conducted according to this policy and by using a primary reviewer system where the assigned IRB member has previously reviewed the research or has appropriate expertise with the research topic, procedures or 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 may determine that any significant new findings that arise from the review process and that may relate to participants’ willingness to continue participation will be provided to participants.

5.9. The IRB will consider researcher and/or institutional issues such as new financial conflict of interest, satisfaction of training requirements, new/revised institutional polices, and reports from any third party observations of the research carried out under regulations.

5.10. The IRB may determine that the protocol needs verification from sources other than the study team members that no material changes have occurred since previous IRB review. This determination is made on a case-by-case basis and according to the following criteria:

5.10.1. Protocol conducted by investigators who have previously been found to be non-compliant with federal, state or institutional regulations and policies, or the requirements and determinations of the IRB.

5.10.2. 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.

5.11. 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), and total subject enrollment and withdrawals.

5.11.1. If the research represents collaboration or is sponsored research that requires data/subject safety monitoring board (DSMB), the IRB will 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.

5.12. 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.
5.13. 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.

5.14. 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 convened Board.

5.15. 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.

5.16. For study closures, the IRB staff will review the submission and, if needed, 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. Investigator Manual
7.8. Policy and Procedure: Designated and Regulatory Review
7.9. Policy and Procedure: Pre-Review
7.10. Policy and Procedure: Non-Committee Review Preparation and Conduct
7.11. Policy and Procedure: Review of Modifications to Previously Approved Research

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