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1. PURPOSE

- 1.1. Federal regulations for the protection of human research participants require periodic substantive and meaningful Institutional Review Board (IRB) review of approved **human research** that is **federally supported** and not eligible for **Expedited Review**. FDA regulations require annual review of FDA-regulated **clinical investigations**. This policy and procedure describes the process for requesting, conducting, and documenting continuing review of human research as well as the process for maintaining oversight of research eligible for Expedited Review which, therefore, does not require continuing review per regulation.

2. DEFINITIONS

- 2.1. **Approval period:** is the interval between the day that the IRB grants approval of research and the day that the approval expires (see **Expiration date**.)
- 2.2. **Continuing Review:** the process of IRB review of approved research that will continue beyond the end of the **approval period**.
- 2.3. **Effective date:** the date on which the IRB chairperson or assigned designee determinations that any conditions for approval required at initial review have now been satisfied and research activities involving **human subjects** may be initiated.
- 2.4. **Expiration date:** is the first date that the research is no longer approved.
- 2.5. **Lapse of approval:** refers to the time including the **expiration date** to the day before the IRB grants a new **approval period**.
- 2.6. **Progress Report:** a report to the IRB providing the status of human research activities for approved, ongoing research including information that may impact the risk assessment or other approval criteria for the research.

3. POLICY

- 3.1. **Continuing review** of research subject to the **Common Rule** must occur at intervals appropriate to the degree of risk but not less than once per year except as described below:
 - 3.1.1. Research that is determined to be Exempt;
 - 3.1.2. Research eligible for **expedited review** in accordance with §46.110 categories 1-7 and 8a or 8c of the pre-2018 list or §56.110;
 - 3.1.3. Research reviewed by the IRB in accordance with the **limited IRB review** described in §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);
 - 3.1.4. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved **protocol**:
 - 3.1.4.1. Data analysis, including analysis of **identifiable private information** or identifiable biospecimens, or



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- 3.1.4.2. Accessing follow-up clinical data from procedures that participants would undergo as part of clinical care.
- 3.2. The IRB may require **continuing review** for any research that falls within the above exception criteria.
- 3.2.1. Factors that the IRB may consider to determine that **continuing review** is required include: the research involves topics, procedures, or data that may be considered sensitive or controversial; the research involves particularly vulnerable participants or circumstances that increase participants' vulnerability; an investigator has minimal experience in research or the research type, topic, or procedures; federal guidance on the regulation and/or information pertaining to best practices; and/or an investigator has a history of noncompliance.
- 3.2.2. When the IRB determines that **continuing review** is required for such research, the rationale is documented in the IRB Portal record and communicated to the investigator in the approval letter 45 CFR §46.115(a)(8)).
- 3.2.3. **Continuing review** of such research may be conducted by **Expedited procedure**.
- 3.2.4. While not required by regulation, federal guidance (see OHRP Draft Guidance, 2018 Requirements FAQs, IRB Review) recommends that IRBs conduct **Continuing review** of research subject to the **Common Rule** and that is eligible for **Expedited Review** under pre-2018 categories 8(b) or 9 at intervals appropriate to the degree of risk but not less than once per year. UGA IRB has elected to follow this guidance.
- 3.2.5. The IRB may conduct **continuing review** of such research by **Expedited procedure**.
- 3.3. **Continuing review** of research that is **not** FDA-regulated, supported by the Department of Justice (DOJ), **or** subject to the Common Rule **and** is determined to be **more than minimal risk** by the convened board is required and must occur at intervals appropriate to the degree of risk but not less than once per year.
- 3.4. **Continuing review** of research that is **not** FDA-regulated, supported by the Department of Justice (DOJ), **or** subject to the Common Rule **and** is determined to be **minimal risk** by the convened board is required and may be conducted at intervals greater than one year and up to three (3) years if **all of the following criteria are satisfied**:
- 3.4.1. The research is not covered by a Certificate of Confidentiality.
- 3.4.2. The research does not involve prisoners or parolees.
- 3.4.3. The research has no contractual obligations or sponsor restrictions requiring an annual review.
- 3.4.4. The UGA IRB is not serving as the **Reviewing IRB** for an institution that applies the federal regulatory standards to all human research and/or requires annual review.
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- 3.4.5. The IRB will base the decision to extend the approval interval on the following:
population (e.g., vulnerability of participants), investigator experience, and expectation of interim results that may affect the risk analysis.
- 3.5. The IRB may require **continuing review** more frequently than once a year and will base this determination on certain specific criteria that could include some or all of the following:
- 3.5.1. Complex projects involving unusual levels or types of risk to participants;
 - 3.5.2. Type or vulnerability of population involved in the study;
 - 3.5.3. 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.
 - 3.5.4. 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.
- 3.6. **Continuing Review** of research not eligible for **Expedited review** must take place at a convened meeting at which a **quorum** is present (45 CFR §46.108(b)).
- 3.6.1. The **continuing review** must receive approval of a majority of those members present at the meeting.
 - 3.6.2. The committee may approve, approve with conditions, defer, table, or disapprove the request for continuation.
- 3.7. **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.
- 3.7.1. The **designated reviewer** can approve or require modification in the continuing review, but may not disapprove the research.
- 3.8. **Continuing Review** of research involving **prisoners** must be conducted by the Prisoner representative member of the IRB.
- 3.9. The criteria for approval of **Continuing Review** are defined by federal regulations and institutional policy and are the same as for approval of new research.
- 3.10. UGA IRB has elected to follow federal guidance on conduct of **continuing review** and may conduct up to 30 days prior to expiration and retain the original effective and expiration month and day.
- 3.11. If the IRB approves **continuing review** more than 30 days prior to the **expiration date**, a new **approval period** will be assigned.
- 3.12. The Principal Investigator (PI) is responsible for fulfilling requirements associated with **continuing review** in time for the IRB to complete review and provide approval prior to the **expiration date**; therefore, the **continuing review** request must be submitted no later than 30 days before the **expiration date**. Submission nearer to the **expiration date** may result in a **lapse of approval**.
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- 3.12.1. The IRB Portal courtesy reminders do not replace the responsibility of the PI to be aware of the **approval period** for research. The failure to receive courtesy notifications is not an acceptable reason for failure to submit a **continuing review** request.
- 3.13. Upon **lapse of approval**, all research activities involving **human subjects** must stop until a new **approval period** has been granted. These activities include: recruitment, advertising, eligibility screening and enrollment of new participants, obtaining **informed consent**, all **interventions** and **interactions** with research participants, and the collection and/or analysis of **private identifiable information** or specimens.
- 3.13.1. If there is an over-riding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating, 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.
- 3.14. The failure to request **continuing review** or the enrollment of participants after expiration is considered **non-compliance** with UGA (Human Research Protection Program) HRPP policy (see Investigator Manual).
- 3.15. If the IRB subsequently approves research that had a **lapse of approval**, the IRB may approve the **continuing review** request and establish a new **approval period** for the same interval as the initial approval or may assign a shorter **approval period**, either to retain the original expiration month and day or to address any concerns.
- 3.16. Proposed **modifications** to the research **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.
- 3.17. When **continuing review** is not required by regulation or this policy, the organization will maintain oversight over the research initially reviewed through review of a **Progress Report** that includes the following information:
- 3.17.1. the enrollment totals;
 - 3.17.2. the status of research milestone (e.g., enrollment, data collection, analysis of identifiable data, ready to close);
 - 3.17.3. current conflict of interest status for all investigators;
 - 3.17.4. description of any changes to the study that have not been reviewed by the IRB; and
 - 3.17.5. a description of any adverse events, complaints, or other reportable events that have not been reviewed by the IRB.
- 3.18. **Progress Reports** for non-Exempt research may be requested at intervals between one (1) year and three (3) years.
- 3.19. **Progress Reports** for Exempt research are requested at intervals of five (5) years.
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3.20. The **Progress Report** due date is documented in the IRB Portal record and communicated to the study team in the approval letter.

3.21. Failure to submit a **Progress Report** when requested is considered **non-compliance**.

4. PROCEDURES: Investigators

4.1. The PI must create a **continuing review** submission in the IRB Portal no later than 30 days prior to expiration but not so far in advance (i.e., more than 90 days before the **expiration date**) that the information may not reflect the study's status by the time the **continuing review** actually occurs.

4.2. All information requested in the online forms must be provided. This research continuing review progress report includes:

(a) The number of participants accrued (for multicenter research studies, the number of participants accrued at the local **institution** and the number accrued study-wide, if available);

(b) Any **adverse events**, unanticipated problems involving risks to participants or others, non-compliance or protocol deviations, or complaints about the research from participants or others reported or occurred since the last IRB approval, initial approval or continuing review, whichever was most recently conducted;

(c) The number of participant withdrawals since the last IRB approval, and the reasons for withdrawal, if known;

(d) A summary of any modifications to the approved protocol or materials that were not been submitted for prior IRB review;

(e) A summary of any new and relevant information, published or unpublished, since the last IRB approval, especially information about risks associated with the research;

(f) A summary of any relevant interim findings and/or any relevant multi-center trial reports;

(g) A summary of the Investigator's current risk-potential benefit assessment based on study results, if applicable.

(h) For FDA-regulated research, the current Investigator's Brochure, if available, including any modifications; and

(i) Any other significant information related to subject risk, such as the most recent report from any entity monitoring the research, if available.

4.3. If the research was initially granted an extended approval interval (e.g., more than one year) but becomes ineligible for the extended **approval period**, such as if a new federal funding is secured or other changes (see eligibility criteria described above), the PI must promptly submit a modification request that describes the change(s) via the IRB portal.

4.4. If the research approval has lapsed before **continuing review** is approved, the PI must promptly submit an **RNI** in via the IRB portal for review as **non-compliance**.



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- 4.5. Study closure must be requested in the IRB Portal upon study completion and/or if the study was not initiated.
- 4.6. If the research does not require continuing review per regulation or this policy, submit a **Progress Report** in the IRB Portal when prompted by email notification.

5. PROCEDURES: Institutional Review Board

- 5.1. The IRB Portal will send a courtesy reminder notification to the investigator via email 90, 60, and 30 days prior to the study's expiration date or the Progress Report due date. The courtesy notifications contain information regarding the actions to take to submit a request for **continuing review** or a **Progress Report**.
- 5.2. **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*.
- 5.3. **Continuing review by Expedited Procedure** is conducted as described in *Policy and Procedure: Designated and Regulatory Review*.
- 5.4. **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.
- 5.5. IRB members conducting continuing review must be provided access to the following materials for review: the full protocol, the current consent document, any newly proposed consent document, and the research progress report.
 - 5.5.1. All information pertaining to the research including modifications approved after initial approval and continuing review information is available to all IRB members in the IRB Portal when the submission is assigned to a meeting.
- 5.6. The IRB will consider investigator 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.
- 5.7. 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:
 - 5.7.1. 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.
 - 5.7.2. 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.



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- 5.8. The IRB must consider the research progress including any realized participant 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 participant enrollment and withdrawals.
- 5.8.1. If the research represents collaboration or is **sponsored research** that requires data/participant safety monitoring board (DSMB), the IRB will request verification from the collaborating institution/investigator 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.
- 5.9. During **continuing review**, the IRB will consider any new information or interim findings provided by the investigator that may affect prior determinations, assessment and/or monitoring of potential benefits or risks to the participants in order to determine whether the proposed research continues to fulfill the criteria for approval.
- 5.10. During **continuing review**, the IRB will consider the adequacy of the process for obtaining informed consent and may determine that any significant new findings that may relate to participants' willingness to continue participation will be provided to participants.
- 5.11. 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. IRB Staff use WORKSHEET: Calculation of Approval Intervals as a guide to calculate the new approval interval and must document the new approval interval in the IRB Portal.
- 5.13. For research subject to the Common Rule, when the IRB conducts continuing review that is not required by regulation:
- 5.13.1. IRB Staff will document the rationale for requiring continuing review in the minutes and in the IRB Portal review form for reviews completed in convened meetings.
- 5.13.2. IRB Staff will document the rationale for requiring continuing review in the IRB Portal review form for reviews completed via Expedited procedure.
- 5.14. When the study expires, the IRB Portal sends a notification via email that instructs the PI to stop all research activities and describes actions to take if the investigator wishes to close or continue the research.
- 5.15. 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.
- 5.16. Progress Reports for research not requiring continuing review are reviewed via Expedited procedure by designated IRB members on the IRB Staff.
- 5.16.1. IRB Staff select the next Progress Report due date using WORKSHEET – 302 - Calculation of Approval Intervals as a guide.
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5.16.2. The IRB Staff may request corrective actions (e.g., submission of a Report of New Information).

5.16.3. The Progress Report will be acknowledged with a portal notification by email.

6. MATERIALS

- 6.1. WORKSHEET: Criteria for Approval
- 6.2. WORKSHEET: Calculation of Approval Intervals
- 6.3. WORKSHEET: Eligibility for Review Using the Expedited Procedure

7. REFERENCES

- 7.1. 45 CFR §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8)
- 7.2. 45 CFR §46.108(b)
- 7.3. 45 CFR §46.109(e)(f)
- 7.4. 45 CFR §46.110
- 7.5. 21 CFR §56.110
- 7.6. 45 CFR §46.115(a)(8)
- 7.7. OHRP Draft Guidance, 2018 Requirements FAQs, IRB Review <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/2018-requirements-faqs/index.html>
- 7.8. OHRP Categories of Research That May be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure, <http://www.hhs.gov/ohrp/policy/expedited98.html>
- 7.9. OHRP Guidance on IRB Continuing Review of Research, <http://www.hhs.gov/ohrp/policy/continuingreview2010.html>
- 7.10. Investigator Manual
- 7.11. Policy and Procedure: Designated and Regulatory Review
- 7.12. Policy and Procedure: Pre-Review
- 7.13. Policy and Procedure: Non-Committee Review Preparation and Conduct
- 7.14. Policy and Procedure: Review of Modifications to Previously Approved Research

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