KENNESAW STATE UNIVERSITY
OFFICE OF RESEARCH
Research Compliance

Policy Title	Continuing Review and Administrative Check-in
Last Updated	9/20/2022
Responsible Office	IRB Office
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1. Policy Purpose Statement

Federal Regulations require an IRB to conduct substantive and meaningful continuing review of human subjects research that is within the jurisdiction of the IRB. This policy outlines the criteria for continuing review and administrative check-in.

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

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
         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; other information pertaining to best practices; when required by sponsor; 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 review checklist 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.
   3.3. 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 KSU 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.

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. 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.

3.11. 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.

3.11.1. 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.

3.12. When continuing review is not required by regulation or this policy, the organization will maintain oversight over the research initially reviewed through Administrative Check In that includes the following information:
3.12.1. the enrollment totals;
3.12.2. the status of research milestone (e.g., enrollment, data collection, analysis of identifiable data, ready to close);
3.12.3. current conflict of interest status for all investigators;
3.12.4. description of any changes to the study that have not been reviewed by the IRB; and
3.12.5. a description of any adverse events, complaints, or other reportable events that have not been reviewed by the IRB.
3.13. Administrative Check In for non-Exempt research may be requested at intervals between one (1) year and three (3) years.
3.14. Progress Reports for Exempt research are requested at intervals of three (3) years.

4. Procedures

4.1. The PI must create a renewal submission in the Cayuse 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 renewal progress report includes:
4.2.1. 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);
4.2.2. Any adverse events, unanticipated problems involving risks to participants or others, noncompliance 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;
4.2.3. The number of participant withdrawals since the last IRB approval, and the reasons for withdrawal, if known;
4.2.4. A summary of any modifications to the approved protocol or materials that were not been submitted for prior IRB review;
4.2.5. A summary of any new and relevant information, published or unpublished, since the last IRB approval, especially information about risks associated with the research;
4.2.6. A summary of any relevant interim findings and/or any relevant multi-center trial reports;
4.2.7. 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 approval has lapsed before continuing review is approved, the PI must promptly submit an Incident Report in via the Cayuse IRB portal for review as non-compliance.