FRANKLIN UNIVERSITY

CONTINUING REVIEW (RENEWAL) AND ADMINISTRATIVE CHECK-IN

The IRB conducts continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, but not less than once per year [45 CFR 46.109(e)]. The research protocol must satisfy the criteria set forth in 45 CFR 46.111 for the IRB to approve the protocol for continuation.

In accord with federal requirements, the IRB approval period can extend no longer than one year after the start of the approval period. The PI may not continue research after expiration of IRB approval; continuing is a violation of federal requirements specified in 45 CFR 46.103(a). If the IRB approval expires, the PI must cease all research activities and may not enroll new participants in the study. Research activities include recruitment, participant enrollment, informed consent, data collection, data analysis and data storage of identifiable data, and sharing of identifiable data. If the IRB determines that there is an overriding safety concern and/or ethical issue or that it is in the best interest of the individual participants to continue participating in the research activities, the IRB may permit the participants to continue in the study for the time required to complete the continuing review process.

Unless the IRB determines otherwise, continuing review of research is not required in the following circumstances [45 CFR 46.109(f)]:

- Research eligible for expedited review in accordance with 45 CFR 46.110;
- Research reviewed by the IRB in accordance with the limited IRB review;
- Research that has progressed to the point that it involves only data analysis, including analysis of identifiable private information, as part of the IRB-approved study.

If the IRB determines that continuing review is necessary, PIs are required to submit a continuing review or administrative check-in form to the IRB for review and approval. Cayuse will send reminders with instructions to the PI prior to study expiration.

CONTINUING REVIEW PROCEDURES

Continuing Review Requests, Submissions, and Screening

1. IRB staff send continuing review requests and reminders to the PI before the IRB approval period expires, approximately 90 days prior to expiration. The PI must submit continuing review materials to the IRB at least 60 days prior to the study expiration date. The PI is responsible for responding to this request and meeting submission deadlines. The IRB will not grant an extension if revisions to the continuing review are required to secure approval but have not been completed by the study's expiration date. Failure to meet the study expiration deadline will result in a lapse of IRB approval and require a new initial full review submission to the IRB.

2. The PI completes the application for continuing review according to the instructions in Cayuse.

3. The PI must submit continuing review reports for studies as long as the research:

- Remains open to enroll new subjects; and/or
- Remains active for long-term follow-up.

See the Study Closure SOP for details on circumstances in which a PI may close a study.

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4. IRB staff screen the application to ensure compliance with selected federal requirements, such as need for prisoner representative review.

5. When the IRB Office receives the continuing review materials, IRB staff conduct a preliminary screening of the materials submitted and of the IRB's protocol records to ensure the materials are complete and consistent with IRB requirements.

6. During screening, IRB staff compare answers in the continuing review materials with the data in the existing IRB file.

7. IRB staff assign a meeting date and contact ad hoc and cultural consultants regarding issues for which the IRB does not have the appropriate expertise, using the procedures outlined in the Initial Full Review SOP.

8. The IRB Office may request additional information or materials from the PI if the application is not complete or requires clarity and detail. If the PI does not respond, IRB staff make up to three attempts to contact the PI and/or research staff for additional information/materials, provided there is sufficient time before the end of the approval period.

9. If the IRB Office does not receive a response from the PI, the IRB Office sends the continuing review to the IRB. If the approval period limits the amount of time available to resolve outstanding issues, IRB staff may schedule the protocol for IRB review "as is" to avoid a lapse of approval. IRB staff forward notes detailing the missing or incomplete materials to the IRB.

Continuing Review Procedures

1. The IRB conducts continuing review at regularly scheduled convened meetings.

2. A designated IRB member serves as the primary reviewer for continuing review IRB protocols. If the member has a conflict of interest, is unavailable, or does not have the appropriate expertise to review the continuing review, IRB staff send the continuing review to the IRB Chair, another voting member of the IRB, or a consultant with the appropriate expertise.

3. Prior to the convened meeting, the primary reviewer and IRB members scheduled to attend the meeting review the completed continuing review report (renewal submission) for each study and any updated forms, letters, applications, and so on requiring IRB review.

4. All IRB members review information in the agenda packet in advance of the meeting (including those protocols for which the IRB member is not the primary reviewer) in enough depth to be familiar with the protocol, to be prepared to discuss the protocol at the meeting, and to be prepared to determine whether the research meets the regulatory criteria for approval.

5. IRB staff ensure that the complete IRB protocol record is available to all IRB members prior to and, if requested, during the convened meeting. All IRB members have the opportunity to discuss each research protocol during the convened meeting.

6. The convened IRB assesses the continuing review materials using the federal criteria for approval (45 CFR 46.111).

7. When the IRB reviews research that involves categories vulnerable to coercion or undue influence, IRB staff ensure that adequate representation or consultation is present for discussions of research involving vulnerable human participants.

8. The IRB and IRB staff conduct the convened meeting in accordance with the Conduct of IRB Meetings SOP. Members who have a conflict of interest follow procedures outlined in both the Conduct of IRB Meetings and IRB Member and Consultant Conflict of Interest SOP.

9. IRB staff serve as intermediaries between the PI and the IRB primary reviewer. However, the primary reviewer may contact the PI or members of a student's dissertation committee directly for clarification. The reviewer documents in the continuing review materials the issues discussed with the PI.

10. Primary reviewers provide recommendations to the IRB at the convened meeting on issues which they determine do not meet the federal criteria for approval, are controverted, and/or need additional information.

11. If the primary reviewer is unable to attend the meeting, IRB staff provide his/her comments or recommendations in writing for presentation to the IRB at the convened meeting.

12. At the meeting, the IRB reviews the continuing review report and any controverted issues and their resolution prior to voting. During discussion, IRB members raise only those controverted issues that the IRB determines do not meet the federal criteria for approval as specified in 45 CFR 46.111. IRB approval of the continuing review materials documents that the IRB agrees with the PI assessment of any specific findings included in the continuing review report that the IRB has not previously addressed.

13. The convened IRB makes the final determination on the outcome of the review.

Lapse of Approval

1. If a PI fails to submit the continuing review materials, or if the IRB has not completed its continuing review by the end of the approval period, IRB staff notify the PI in writing that the approval will lapse or has lapsed. IRB staff inform the PI that he/she must cease all research activities and may not enroll new participants in the study. Research activities include recruitment, participant enrollment, informed consent, data collection, data analysis and data storage of identifiable data, and sharing of identifiable data. IRB staff also inform the PI that he/she should, if appropriate, notify participants that the study approval has lapsed and that, if applicable, it is his/her responsibility to notify the funding agency of the expiration of the IRB approval.

2. The PI may ask the IRB for permission to allow subjects currently participating to continue due to an overriding safety concern, ethical issues, or because it is in the best interest of the individual participants. The IRB makes the determination, if appropriate. The IRB Office or IRB notifies the PI in writing of that determination.

3. If a protocol approval has expired and the PI wants to reactivate or resubmit the study, the IRB Office requests from the PI either a written statement that verifies no research activities have occurred since the lapse (i.e., recruitment or enrollment of new subjects; interaction, intervention, or data collection from currently enrolled subjects; or data analysis), or a written summary of events that occurred from the PI during the lapse.

4. If the PI submits the continuing review materials/revisions after the end of the approval period, the IRB requires a new initial review application along with the continuing review documents.

5. When continuing review and approval of a research study does not occur prior to the end of the approval period, the IRB does not report the expiration as a suspension of approval under the US Department of Health and Human Services regulations.

CONTINUING REVIEW OUTCOME(S)

1. An IRB member makes a motion, the motion is seconded, and then the IRB members vote for, against, or abstain from one of the following actions:

- APPROVED: IRB approval – An approved vote indicates that the IRB concluded that the research and, if applicable, consent forms meet the federal criteria for approval. The IRB's approval vote verifies that the IRB members agree with the information/materials submitted for continuation of the protocol and/or specific findings described in the continuing review report by the PI. IRB staff send the investigator an approval letter with valid dates of IRB approval.

- REVISIONS and/or ADDITIONAL INFORMATION REQUIRED: A vote for revisions indicates that the IRB has approved the protocol pending submission of minor revisions (e.g., correcting language in the informed consent document, updating recruitment text, etc.) and that the IRB has given the primary reviewer (and/or IRB Chair, or his/her designee, and/or other IRB member(s) or consultants, as needed, who have the appropriate expertise or qualifications) the authority to approve the minor revisions which do not involve substantive issues. IRB staff send a letter to the PI describing the revisions requested by the IRB.

  The PI responds to the IRB's required and suggested revisions in writing and sends the response to the IRB Office. IRB staff give the responses to the IRB member(s) designated at the IRB meeting to review the requested revisions. The IRB member(s) may forward the responses to the entire IRB for additional review, to request additional information, or to approve.

- DEFERRED: A vote of deferred indicates the IRB withholds approval pending submission of major revisions and/or additional information. IRB staff send the PI a letter listing the reasons for the deferral and include a description of the revisions or clarifications required and/or requested. For some studies, the IRB may appoint one or more members of the IRB to discuss the reasons with the investigator. If the vote is for deferred, IRB staff schedule the PI's response to the requested revisions for review by the full committee. The IRB does not require the PI to attend. In some cases, the committee may ask the PI to attend the future IRB meeting at which the IRB reviews his/her response to discuss or answer IRB concerns or questions. IRB staff notify the PI of the request for him/her to attend that future IRB meeting.

- DISAPPROVED: A disapproved vote indicates that the IRB disapproves continuation of the study. IRB staff send the investigator a letter describing the reasons for disapproving the protocol. This outcome usually occurs when the IRB determines that the risk of the procedures outweighs any

benefit, the IRB-required changes have not been implemented, or the research does not meet the federal criteria for approval.

2. During the convened meeting, the IRB determines the approval period as appropriate to the degree of risk but not less frequently than once per year. The IRB may set a shorter approval period (for continuing review to occur more often than annually) for high-risk protocols or protocols with a high risk/low potential benefit ratio. No approval period extends beyond one year. When a protocol receives final approval, IRB staff document the approval period in the approval letter to the investigator. IRB staff include the approval period in the meeting minutes.

3. The date of the start of the approval period is the date of the convened meeting. When the outcome of the IRB vote is approval pending submission of minor revisions, IRB staff issue approval after the designated reviewer approves the PI's response. The approval period begins on the date on which the convened IRB reviewed the protocol.

4. If the PI has concerns regarding the IRB decision/ recommendations for changes in the study, the PI may submit his/her concerns to the IRB in writing with a justification for altering the IRB decision. The appropriate reviewer or, if need be, convened IRB review the appeal. The appeal determination is final.

ADMINISTRATIVE CHECK-IN PROCEDURES

1. Most research projects at Franklin University do not require an administrative check-in (or continuing review), though Cayuse will send an automated reminder for all studies when it is the anniversary of the study's approval. These reminders are sent to the PI before the one-year period after initial IRB approval (e.g., approximately 90 days, 60 days, and 30 days prior to one year).

2. The administrative check-in is an opportunity to submit any updates to the protocol, such as new study end dates or personnel changes. If a PI needs to update the protocol, he or she completes the check-in according to the instructions in Cayuse. If no changes to the protocol are necessary, there is nothing for the PI to submit to the IRB.

3. If a PI submits any updates to the approved study, IRB staff review the form and contact the PI for missing information or clarification.

4. IRB staff issue an approval letter to the PI.