FRANKLIN UNIVERSITY

INITIAL FULL REVIEW

The IRB conducts initial review for non-exempt research at convened meetings unless the research is eligible for expedited initial review. Investigators must submit studies that do not meet the federally mandated criteria for exempt or expedited initial review for full review. (See Exempt and Expedited Initial Review SOPs.)

PROCEDURES

Submission and Screening

1. The Principal Investigator (PI) completes an application for IRB review of a research protocol for initial full review and submits it to the IRB Office.

2. IRB staff screen the protocol to determine whether it is complete (i.e., includes all pertinent documentation, answers questions sufficiently within the application). If it is not complete, IRB staff return the submission to the investigator and request the missing items or information.

3. IRB staff screen the IRB protocol to ensure compliance with pertinent federal and institutional requirements.

4. IRB staff schedule the IRB protocol on the agenda for the next available meeting. The IRB schedules meetings approximately once a month. IRB staff schedule protocols for review on a "first-come, first-served" basis, limiting the number of reviews as appropriate in order to permit adequate time for discussion and deliberation of agenda items. IRB staff send the PI a request for the PI or Co-Investigator to attend the meeting unless the IRB Chair or designee waives the requirement to attend.

5. IRB staff screen the protocol to determine whether additional expertise is necessary to conduct the review. If so, IRB staff may ask an ad hoc or cultural consultant who has appropriate expertise in the discipline, subject matter, or with non-English speaking populations or locations to participate in the review.

6. The PI may also recommend cultural consultants provided that they are not directly involved in the study. These consultants may review consent forms, provide verifications of translations, and provide guidance on the impact of the research on participants and the impact of the culture on the research to be conducted.

7. IRB staff ensure that ad hoc or cultural consultants do not have a conflict of interest in accordance with the IRB Member and Consultant Conflict of Interest SOP.

8. IRB staff send the ad hoc or cultural consultants the same information as voting IRB members and a detailed protocol/grant application, if applicable.

9. IRB staff assign a primary reviewer based on the IRB member’s educational background and expertise as necessary. For example, RN IRB members serve as primary reviewers for protocols in which the PI is an RN. If no IRB member has the appropriate expertise, IRB staff may ask an ad hoc or cultural consultant to serve as primary reviewer.

Effective Date: 02/13/2019
Older Versions: 02/13/2019, 03/11/2020, 03/28/2022
Last Reviewed and Modified: 10/02/2023

FRANKLIN UNIVERSITY

Submission of Applications to the IRB and Primary Reviewer Responsibilities

1. No fewer than seven (7) calendar days before each convened meeting, IRB staff will notify voting members to review protocols in Cayuse and send packets to selected ex officio IRB persons for review. IRB staff will send PIs requests to attend, unless the requirement is waived by the IRB Chair or designee. The initial full review applications that IRB members access include all applicable sections of the application:

- Core application with research proposal;
- Informed consent/assent process and forms including waiver requests, informed consent document, and translated consent document for non-English speaking participants;
- Additional materials, including advertisements, recruitment scripts, letters of introduction, proposed data instruments, and materials/letters of support for off-site research (e.g., organizations, agencies, universities);
- Sponsor's grant application;
- Other committee review or final approval materials when applicable;
- Conflict of Interest (COI) disclosures from all listed investigators (The IRB Office will receive the COI disclosures and investigators will confirm they have completed them in the application);
- All other application materials.

2. The member assigned as the primary reviewer is responsible for:

- Comparing the detailed grant application or industry/institutional approved protocol with the IRB application;
- Informing the full IRB of any discrepancies between the IRB application and other submitted materials; and
- Conducting an in-depth review.

3. All IRB members review all 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.

4. Ad hoc or cultural consultants may provide comments or recommendations in writing to the IRB prior to the meeting or attend the convened meeting to participate in the review. IRB staff maintain documentation of written comments or reports in the protocol file. In cases where the consultant participates in the meeting, the minutes of the meeting document the information provided by the consultant.

IRB Review

1. A majority of the voting IRB members (or an alternate), including at least one member whose primary concerns are in non-scientific areas, must be present in order to conduct a convened meeting. In order for the IRB to approve the proposed research, the protocol must receive the approval of a simple majority of those members present at the meeting.

Effective Date: 02/13/2019
Older Versions: 02/13/2019, 03/11/2020, 03/28/2022
Last Reviewed and Modified: 10/02/2023

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

3. All IRB members attending the meeting receive materials listed in the Submission of Applications section above prior to the convened meeting; have the opportunity to discuss each research protocol during the convened meeting; and participate in the determination of whether the research meets the regulatory criteria for approval.

4. The IRB reviews each initial full review application with the PI or Co-Investigator present during the convened IRB meeting, or with the study team available for questions and waiting in a meeting room during the IRB's review, unless the IRB Chair or designee waives the requirement. The IRB reviews the application and discusses any controverted issues and their resolution prior to voting. The PI and/or Co-Investigators may not be present when the IRB discusses controverted issues and votes.

5. During discussion, IRB members raise only those issues that the committee determines do not meet the federal criteria for approval as specified in 45 CFR 46.111. In addition, the IRB determines whether the risk level assigned by the PI is appropriate. Also, the IRB considers whether the PI's preliminary assessment of federally mandated specific findings requirements (e.g., request for waiver of informed consent) is acceptable with respect to meeting federal requirements.

6. In conducting the initial review of the proposed research, the IRB uses a reviewer checklist to determine whether criteria have been met for IRB approval.

7. A member or consultant with a conflict of interest must leave the room during the vote and only participate in the review by providing information in accordance with the IRB Member and Consultant Conflict of Interest SOP.

REVIEW OUTCOME(S)

1. An IRB member makes a motion, another member seconds the motion, and then the convened IRB votes for or against or abstains from one of the following actions:

> APPROVED: A vote for approval indicates that the IRB has concluded that the research and consent/assent forms meet the federal criteria for approval. IRB approval verifies that the IRB agrees with the assessment of the protocol and/or specific findings as described by the PI in the application. IRB staff issue approval to the investigator, which includes 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 and that the IRB has given the individual chairing the meeting (and/or other IRB member with appropriate expertise or qualifications) the authority to approve the minor revisions. IRB staff send the investigator a letter describing the revisions requested by the IRB.
>
> The PI responds to the IRB's suggested revisions in writing and sends the response to the IRB Office, which gives the response to the IRB Chair (and/or other IRB member with appropriate

expertise or qualifications). The Chair or designee may forward the responses to the entire IRB for additional review, request additional information, or approve.

TABLED: A vote of tabled indicates that the IRB withholds approval pending submission of major revisions and/or additional information. IRB staff send the investigator a letter listing the reasons for tabling and include a description of the revisions or clarifications 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 tabled: 1) IRB staff may schedule the PI's response to the requested revisions for review by the full committee; the IRB does not require the PI to attend, or 2) the PI needs 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: If the vote is for disapproved, IRB staff send the investigator a letter describing the reasons for disapproving the protocol. Disapproval of a protocol usually occurs when the IRB determines that the risk of the procedures outweighs any benefit to be gained or if the proposed research does not meet the federal criteria for IRB 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 high-risk protocols or protocols with high-risk/low potential benefit ratios.

3. When a protocol receives final approval, the IRB Office assigns the start of the approval period as the date of the convened IRB meeting. If a protocol has received a vote for minor revisions and the PI completes the revisions, the approval period starts from the meeting date of the convened IRB on which the IRB initially reviewed the protocol. Should there be serious concerns or a lack of significant information (a tabled vote) requiring the convened IRB to complete its review and issue approval of the study at a subsequent meeting, the approval period starts with the date of the subsequent convened IRB meeting.

4. Before issuing approval, IRB staff also ensure that all study personnel have completed the required human subjects training. If any study personnel have not completed training, IRB staff notify the PI in writing. The investigator must send the appropriate certifications of training before the IRB can issue approval.

5. Once the IRB approves a protocol, IRB staff send an approval letter to the PI, which includes the approval period, a reminder to use only the approved consent/assent form, and a reminder that the IRB must approve any changes to the protocol prior to initiation of the changes.

6. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit a written appeal that includes a justification for changing the IRB decision. The convened IRB reviews the appeal. The appeal determination is final.