FRANKLIN UNIVERSITY

MODIFICATIONS, DEVIATIONS, AND EXCEPTIONS - IRB REVIEW OF CHANGES

Investigators may not initiate any changes in research procedures or consent/assent form(s) without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participant. Examples of modifications that require IRB review include, but are not limited to, changes in:

- Study personnel removal/replacement;
- Advertising materials (flyers, radio spots, etc.);
- Research procedures;
- Subject populations (e.g., eligibility criteria, age range);
- Location where research will be conducted;
- Additional or change to letter(s) of support/site permissions;
- Consent/assent forms;
- Recruitment procedures (e.g., adding social media, outreach venues); or
- Date for completion of study.

If the investigator makes protocol changes (i.e., modifications, exceptions, or deviations) to eliminate apparent hazards to the participant(s) without prior IRB approval, the investigator must immediately report the changes to the IRB for review and a determination as to whether the changes are consistent with the participant's continued welfare.

Investigators must promptly notify the IRB in writing or via Cayuse of any change in a protocol's status, such as discontinuation or completion of a study.

DEFINITIONS

Modifications are defined as changes that impact the overall protocol.

Exceptions or ***deviations*** are changes that impact individual participants and do not change the overall protocol. Investigators may not initiate these changes without prior IRB review and approval, except where necessary to eliminate apparent hazards to the participant.

The IRB considers enrollment of a research participant in a protocol that fails to meet current IRB approved protocol inclusion criteria or falls under protocol exclusion criteria to be a protocol exception.

The IRB considers a departure from the current IRB approved procedures that impact an individual participant to be a protocol deviation.

PROCEDURES

Submission of Modifications, Deviations, and Exceptions

1. The PI is responsible for submitting a modification request or deviation/exception request prior to the implementation of any change.

2. The PI provides documents associated with the modification request.

Screening of Submissions and Approval of Administrative Changes

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Older Versions: 02/13/2019, 03/11/2020, 03/28/2022, 10/02/2023
Last Reviewed and Modified: 11/20/2024

1. IRB staff screen the modification request.

2. If the request is incomplete, IRB staff request additional information from the PI. IRB staff review the modification request once it is complete.

3. If the modification adds vulnerable populations or requires documentation of specific regulatory findings, IRB staff screen the application to ensure relevant materials are available for the IRB's review.

4. Depending on the requested change, IRB staff may also secure an additional reviewer (e.g., IRB member or prisoner representative). The reviewer is responsible for applying the applicable regulatory requirements.

5. If the modification request requires consent/assent form changes, IRB staff screen the documents for apparent issues (e.g., unapproved versions).

6. If the modification request includes additions to study personnel, IRB staff screen to ensure that all new investigators have completed required human subject protections training. If not, IRB staff inform the PI that he/she may not add the untrained investigator until they have completed required training. IRB staff ask the PI whether he/she wishes to remove the investigator in question and continue with the modification request. Alternately, the PI may choose to wait until the investigator in question completes the training.

Exempt Review Procedures

1. IRB staff conduct the review of changes to exempt protocols to determine whether the modified research continues to meet the criteria for exemption.
2. If a modification request requires limited review, an IRB member will review the proposed modification to determine whether changes to the research continue to meet the criteria for exemption.

Expedited Review Procedures

1. If the change is minor, the IRB Chair or one or more experienced IRB members (designated by the Chair) conduct(s) the review using expedited procedures. A minor change is one that makes no substantial alteration in:

- The level of risk to subjects;
- The research design or methodology;
- The subject population;
- Qualifications of the research team;
- The facilities available to support the safe conduct of the research; or
- Any other factor that would warrant review of the proposed changes by the convened IRB.

2. The IRB Chair or experienced IRB member(s) conduct(s) the modification request undergoing expedited review, using standard expedited review procedures. The expedited reviewer exercises all the authority of the IRB except the reviewer cannot disapprove the research. Listing the item on an agenda for the convened IRB serves to advise the IRB of the expedited review.

3. The IRB Chair or designated IRB member(s) is/are responsible for reviewing the proposed modification and determining whether the modified research continues to fulfill the criteria for IRB approval.

Full Review Procedures

1. If the IRB Chair or designated IRB member(s) recommend(s) full review, or if the sponsor or the PI specifically requests full review procedures, IRB staff place the modification request on an agenda for full review following procedures outlined in the Initial Full Review SOP.

2. For a modification request undergoing full review, IRB staff invite the PI to attend the convened meeting if the IRB so requires. The full IRB reviews the modification request following procedures outlined in the Initial Full Review SOP and applies the federal criteria for approval as applicable to the request.

3. No fewer than seven (7) calendar days before each convened meeting, IRB staff close the agenda. The modification request and the protocol materials affected by the proposed modification are available to the full board for review and determination as to whether the modified research continues to fulfill the criteria for approval.

4. For a modification request undergoing full review, the IRB Chair or designated IRB member serves as the primary reviewer.

5. The IRB Chair or designated IRB member reports recommendations to the IRB at a convened meeting. The IRB Chair or designated IRB member makes recommendations on issues he/she determines do not meet the federal criteria for approval, involve controverted issues, or need additional information.

6. The full IRB reviews and votes on the modification request consistent with procedures outlined in the Initial Full Review SOP.

REVIEW OUTCOME(S)

1. IRB staff notify the PI in writing of the IRB's decision.

2. If the IRB approves the modification, the end date of the approval period remains the same as that assigned at initial or continuing review.

3. If the IRB does not approve the modification, the PI may continue to conduct the research as initially approved, or, in consultation with the IRB Office, the PI may decide to close the currently approved study and submit a new initial submission to the IRB for review.

4. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit his/her concerns via a written appeal that includes justification for changing the IRB decision. The PI sends the request to the IRB Office. The expedited reviewer, IRB Chair, or convened IRB review the appeal. The appeal determination is final.