FRANKLIN UNIVERSITY

UNANTICIPATED/ANTICIPATED PROBLEM/ADVERSE EVENT REPORTING

Regulatory guidance provided in 45 CFR 46.108(4)(i) requires the IRB to have in place written procedures for ensuring prompt reporting to the IRB, appropriate University officials, and applicable regulatory agencies of any unanticipated problems involving risks to human participants or others. In response to the regulatory obligation, the Franklin University IRB facilitates review of reports and determinations about whether the problem/event raises new concerns about 1) risks to participants or others; 2) the risk/benefit ratio; 3) the approved informed consent document; and 4) the need for re-consent.

There are two reporting categories for unanticipated problems:

1. Prompt reporting to the IRB of an unanticipated problem involving risks to participants or others or research-related deaths to the IRB.

2. Continuing review reporting to the IRB includes a written summary of both unanticipated problems and available information regarding adverse events since the last IRB review. The summary must include the PI's assessment of whether the problems/adverse events warrant changes to the protocol, consent process, or risk/benefit ratio.

The policy on prompt reporting and continuing review reporting of problems/events is the basis for the SOP. The policy details the IRB requirements for reporting, including adverse events and unanticipated problems involving risks to research subjects and others.

PROCEDURES

Franklin University Reporting Requirements for Prompt Reporting of Problems/Adverse Events

1. The PI reports unanticipated problems or other incidents (e.g., adverse events, complaints, data breaches, noncompliance, inappropriate behavior, and so on) involving risks to participants or others to the IRB Office. These incidents may or will result in physical injury, psychological distress, economic or social risk, or otherwise introduce the potential for harm to participants in the research process. Events should be reported if the injury, distress, or other event was directly related to participating in the research.

2. The PI reports unanticipated life-threatening events within seven (7) calendar days of his/her receipt of the information and all other unanticipated problems involving risks to participants or others within 14 calendar days of his/her receipt of the information.

Submissions/Screening and Review of Problems/Events: Prompt Report

1. The PI makes the preliminary determination if the event meets the criteria for an IRB reportable problem/event.

2. If the PI recognizes the problem/event involves risks to participants or others and the information is not already in the consent/assent document, he/she submits a revised consent/assent form with changes underlined. If the revised consent/assent form impacts the protocol/research description, the PI also submits a revised research description as well as a clean copy of the consent/assent form.

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3. IRB staff screen the report to determine whether it is complete and place the report on an IRB agenda.

4. Staff then forward the report(s) and related material(s) to the IRB Chair or designee who serves as the primary reviewer.

5. The individual serving as primary reviewer has access to the following: IRB protocol file; documents revised as a result of the problem/event; and/or documents which provide additional assessments or summary information.

6. After reviewing the materials, the primary reviewer makes comments. The PI's report and IRB reviewer comments are available to each IRB member for review prior to the meeting.

7. The IRB reviews events and problems at a convened IRB meeting using initial full review procedures.

8. If the study is federally funded (e.g., by the Department of Health and Human Services), additional IRB reporting requirements may be in effect. (See the Mandated Reporting to External Agencies SOP.)

REVIEW OUTCOME(S)

1. For all problems/events submitted under the IRB's prompt reporting policy, the IRB determines whether the problem/event meets the Franklin University definition of unanticipated problem involving risks to participants or others. If the unanticipated problem/event involves risks to participants or others, the IRB follows the established reporting policy. (See Mandated Reporting to External Agencies SOP.) The IRB actions may include, but are not limited to:

- Acknowledgement/acceptance without further recommendation;
- A request for further clarification from the investigator;
- Changes in the protocol (e.g., additional test or visits to detect similar events in a timely fashion);
- Changes in the consent/assent form(s);
- A requirement to inform participants already enrolled or to re-consent (e.g., when the information may relate to the participant's willingness to continue to take part in the research);
- A change in frequency of continuing review;
- Further inquiry into other protocols utilizing the particular procedure in question;
- Suspension or termination of the study; or
- Request for quality improvement review or other actions deemed appropriate by the IRB.

2. If the IRB acknowledges/accepts without recommendation the problem/event, IRB staff generate and send a letter to the PI indicating the review outcome.

3. If the IRB requests clarification(s) or additional information or revisions, IRB staff notify the PI in writing of the need for additional information and/or changes.

4. The PI responds to IRB requests for information or revisions in writing and sends the response to the IRB Office. IRB staff forward investigator responses to the IRB Chair for further review, who may forward the responses to the entire IRB for additional review, request additional information, or acknowledge/ accept the response without recommendation.

5. If the PI has concerns regarding the IRB decision/ recommendations for changes in the study, he/she may submit concerns to the IRB in writing including a justification for changing the IRB decision. The IRB reviews the request and makes a final determination. IRB staff send correspondence to the PI on the IRB's final determination.

Continuing Review Reporting of Problems and/or Adverse Events

1. At continuing review, the PI submits a written summary of both unanticipated problems and available information regarding adverse events since the last initial or continuing IRB review. The summary must include the PI's assessment whether the problems/adverse events warrant changes for the protocol, consent process, or risk/benefit ratio.