How to Complete a Progress Report Institutional Review Board

Items pre-filled by ORI Staff:

- ✓ **Project Title:** This is the title originally associated with the protocol. If over the course of the last year a change in title has been requested through an amendment, the new title will be reflected on this form. If for some reason it is not, please contact the Office of Research Integrity @ irb@brown.edu.
- ✓ **Principal Investigator:** This is the Brown faculty member, graduate student, or staff member who is responsible for the conduct and oversight of this project.
- ✓ **Expiration Date:** This is the date on which IRB approval will expire. It is important that the progress report is received well before this date to allow for appropriate time for review and to allow ORI to contact the PI to discuss any necessary clarifications or changes. If a report is not approved by this date, IRB approval should be considered as having lapsed and all human research work should stop until such time as approval has been reinstated.
- ✓ **Funding Source:** This is the entity or entities providing support for the project. If no external funding is in place, the funding source should be listed as "University". If new external funding was received since the last continuing review, or is expected to be received, an amendment request must be submitted for review and approval to have that funding added to the protocol.
- ✓ **Continuing Review Number:** This generally refers to how many years the project has been active except in cases where a protocol has been put on an approval cycle of less than 12 months.

Items that must be completed:

I. Protocol Status:

A. **Has this project been completed since the last IRB approval?**

- If all research-related interventions or interactions with human participants have been completed, all data collection and analysis of identifiable private information has been finished, and all activities described in the approved protocol are finished, then the research project no longer needs to undergo continuing review. For example, when the only remaining activity of a research project involves the analysis of aggregate data sets without individual participant identifiers, no further continuing review is necessary.
- Simply maintaining individually identifiable private information without using, studying, or analyzing such information is not human research and thus does not require continuing review.
- If the research no longer requires continuing review, please select whether you would prefer the project to be closed on the expiration date or if ORI staff may close the protocol early.

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II. Progress Report COI Questions:

A. Current Investigator(s):

- Select whether or not the primary investigator has completed a conflict of interest disclosure within the past 12 months. If any of the new investigators has a significant financial interest that is related to the research protocol, please select "YES" and provide a description in the space provided.
- If the primary investigator has a significant financial interest that is related to the research protocol, please select "YES" and provide a description in the space provided.
- Attach additional sheets for all investigators listed on the study.

B. Personnel Changes/New Investigator(s):

- Based on the definition of "investigator" provided, please select "YES" if any new Brown investigators have been added to the project since the most recent IRB approval.
- An "investigator" is defined as the project director or principal investigator and any other person, regardless of title or position who is responsible for the design, conduct, or reporting of sponsored research.
- If no new investigators have been added, then please skip II(C).

C. **Investigator(s) Conflict of Interest:**

- If any new investigators have been added per II(B), please provide the name(s) and title(s).
- Select whether or not each new investigator has completed a conflict of interest disclosure within the past 12 months.
- If any of the new investigators has a significant financial interest that is related to the research protocol, please select "YES" and provide a description in the space provided.

III. Continuing Review Determination:

A. Is this research FDA regulated?

- Under the revised Common Rule, research protocols that are not FDA regulated and also meet conditions in B below may be released from the annual continuing review (progress report submission) requirement.[1]

B. Has the research progressed to the point that:

1. It only involves accessing follow-up clinical data from procedures that participants would undergo as part of clinical care.
    - The research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions and the research remains active only for long-term follow-up of subjects.
2. Are the remaining research activities limited to data analysis?

[1] It is the responsibility of the Principal Investigator to be aware of any specific funding/contractual terms and conditions that require continuing review. With justification, the Brown IRB may also require continuing review for studies that may otherwise have qualified for release from continuing review.

- If all interactions with participants have been completed and the only research activity remaining is analyzing data, then check "YES".
- At this point, blank copies of consent/assent forms and/or verbal consent/assent scripts are no longer needed for the progress report.

IV. Participants:

A. **Has this project been approved for secondary data analysis only?**
   - If the research project has been approved for the analysis of materials (data, documents, records or specimens) that have been collected, or will be collected for non-research purposes, this would be a secondary analysis study.

B. **Have participants been entered/consented?**
   - Anyone who has been consented, whether verbal or written, is considered to have been "entered" into the project whether or not they complete all parts of the study.
   - If the study has not entered/consented any participants as of the writing of the progress report, then check "NO".
   - If participants have been entered/consented, then check "YES".
   - Complete table identifying the number of participants entered since last approval (initial or continuing, since initial approval and total number of approved subjects. **If the total number of enrolled participants is approaching the total approved number of subjects, consider submitting an amendment to increase participant population.*

C. **If the study activities continue, will additional participants be entered/consented?**
   - Anyone who has been consented, whether verbal or written, is considered to have been "entered" into the project whether or not they complete all parts of the study.
   - If the study is closed to recruitment, then check "NO". At this point, blank copies of consent/assent forms and/or verbal consent/assent scripts are no longer needed for the progress report.

D. **In the past year, have any participants withdrawn themselves from the study?**
   - This number should include participants who were entered/consented and who decided to withdraw as a participant.
   - If information is available on why participants withdrew themselves, please provide that information in the space provided in III(D).
   - Do not include participants who did not meet eligibility requirements or who were lost to follow up or contact.

E. **In the past year, have any participants been withdrawn by the PI?**
   - This number should include participants who were enrolled/consented and who the PI decided to withdraw from the study for any reason.
   - Please include information on why the PI withdrew the participants in the space provided in III(E).

V. Please provide the following documents and/or information:

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A. **Brief lay summary describing the study:**
   - This should be the lay summary that was included with the initial protocol and with all subsequent submissions to the IRB.

B. **A report sufficiently describing the progress of the research since the last approval (*initial or continuing*) including new risks identified since the initial approval:**
   - Please provide information regarding the progress since the last review (*initial or continuing*). It is expected that this information will change from year to year as the project moves forward to meet its aims and goals. There needs to be sufficient current information so the IRB can evaluate the progress of the research.
   - Please include any new risks identified since initial approval.

C. **Copy of another institution's current IRB approval document if Brown issues a subaward to that institution for human research activities:**
   - A copy of another institution's current IRB approval document is required ONLY if Brown issues a subaward to that institution.

D. **List of all "unanticipated problems involving risks to participants or others" submitted for IRB review since the beginning of the project:**
   - Please provide a list of all "unanticipated problems" that have occurred since the start of the project. This should include only items which meet the definition of a reportable event as outlined in the Brown University Policies and Procedures Manual and which have been previously submitted to the IRB for review.

E. **Copies of all current consent/assent forms and/or verbal consent/assent scripts:**
   - Please provide a blank copy of all currently-approved consent/assent forms and/or verbal consent/assent scripts that are being used when consenting participants into the project unless "NO" was selected for III(C) or "YES" was selected for III(A) or III(D).
   - Please attach all documents at the end of the progress report.
   - Not submitting these documents in the progress report submission and gaining renewal of IRB approval will render those materials invalid and, as such, those documents cannot be used going forward unless approval to reinstate is obtained through an amendment request.

VI. Investigator's Electronic Signature:

- In addition to typing the PI's name and date in the space provided on the form, please also include the Investigator's electronic signature.

Directions for Submitting a Progress Report:

- ✓ Save the signed report, together with any attachments into ONE PDF file. Saving all attachments into one PDF file will contribute to a more efficient and timely review.
- ✓ Please email the PDF file to irb@brown.edu by the deadline date mentioned in the reminder email sent from ORI.

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