



BROWN

How to Complete a Progress Report for Continuing Review Determination

Items pre-filled by HRPP 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 a revision request, the new title will be reflected on this form. If the title is missing or inaccurate, please add/correct it and mention this in the submission email to the Human Research Protection Program @ 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.
- ✓ **Contact Information:** This is the Principal investigator's Brown phone number and email address. If this information is inaccurate, please correct it and mention this in the submission email to irb@brown.edu, so that the most recent contact information is in the IRB records.
- ✓ **Protocol Number:** This is the Brown protocol number given to the study by the Brown IRB. This information can be found on all approval memos.
- ✓ **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 HRPP staff to contact the PI to discuss any necessary clarifications or changes, and the IRB to review and approve the submission. If a progress report is not approved by this date, IRB approval will lapse and all human research work must stop immediately until such time as IRB approval has been reinstated.
- ✓ **Progress Report 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.

Tips to completing Each Section¹:

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 and the study may be closed. For example, when the only remaining activity of a research project involves the analysis of aggregate data sets without individual participant identifiers, no human subjects data remains in the study.
- 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 HRPP staff may close the protocol. Then continue to B.

B. Has the data been de-identified (i.e., ALL identifying information has been destroyed with no means to re-identify)?

- If all data is no longer identifiable with no means to re-identify then the study can be

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.



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closed. If the PI still has identifiable data, then it should remain open.

- If the study is now on the stage of only involving data analysis (with identifiable data) then it can receive an Expedited progress report review and potentially no longer require continuing review.

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 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. Even if this information was disclosed on previous progress reports, it should be included on every progress report going forward as long as it applies.

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.
- Please do not include individuals working or associated with the research that are not considered investigators (staff, fellows, etc.). Currently the Brown IRB does not require this information. The PI of the study is responsible for internally maintaining current training and information for all research personnel.
- 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?

- Research that involves the use of an FDA-regulated product (i.e. medical device, drug, biologic, etc.) requires continuing review (progress report submissions) to the IRB.
- Studies that use FDA-regulated products on label may qualify for Expedited continuing review (i.e. review by a designated member of the IRB rather than a Full Board review at a convened meeting) but FDA-regulations require that annual IRB review still take place.
- If this study uses an FDA-regulated product in a clinical investigation under an Investigational Device Exemption (IDE) or Investigational New Drug (IND) authorization then Full Board review is required annually.



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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.
 - The study can be reviewed by a designated member of the IRB within 30 days of the expiration date under Expedited category 8a.
 - The progress report still needs to be submitted by the date required in the reminder emails, in case it still needs to go to the Full Board.
2. Are the remaining research activities limited to data analysis?
 - 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.
 - If “YES” was checked then this study can receive a review by a designated member of the IRB within 30 days of expiration under Expedited category 8c. The progress report still needs to be submitted by the date required in the reminder emails, in case it still needs to go to the Full Board.
 - If “YES” was checked and the data is de-identified with no means of re-identifiability then the study can be closed.

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 biospecimens) 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 the 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.*
- The total number of approved subjects for the study should be how many individuals are approved to be consented for the study, not how many are expected to complete the study, since these numbers may differ.

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



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“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:

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.
- It is helpful to include a summary of any new Amendments approved since the last progress report or initial approval.
- 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.
- All protocol deviations should also be disclosed in this section. If the deviation occurred since the last approval, please include a more detailed description of the event and how



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the PI has addressed the issue.

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.
- If this is a multi-site study, please be sure the Brown PI signs the progress report.

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.
- ✓ Any questions or concerns should be directed to irb@brown.edu.