**Brown University**

**Progress Report for** **Continuing Review Determination**

**Project Title:** Enter text.

**Principal Investigator**: Enter text.

**Phone Number** Enter text.

**Email Address** Enter text.

**Protocol Number**: Enter text.

**Expiration Date**: Enter a date.

**Progress Report Number**: Choose an item.

*Please see the guidance document entitled: “*[*How to Complete a Progress Report*](https://www.brown.edu/research/sites/research/files/Progress%20Report%20Guidance%20Template%20v060419.pdf)*” for further instructions on completing the report.*

1. **Protocol Status:**
	1. Has this project been completed since the last IRB approval and is ready for closure?

[ ]  NO (*Continue to* [*II. Progress Report COI Questions*](#II_COI)*)*

[ ]  YES *(Select one of the choices below and continue to B.)*

[ ]  Please close this project now

[ ]  Please close this project on the expiration date

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

[ ]  NO *(Study must remain open while identifiers are still active. Continue to [II. Progress](#II_COI)*

 *[Report COI Questions](#II_COI))*

[ ]  YES (*This study is ready for closure. Please skip to section* [*VI. Investigator’s Electronic Signature*](#VI_SIGN)*, sign and date this form and send to* *IRB@brown.edu**)*

*\*If your study is a registered clinical trial, please visit our* [*Clinical Trials webpage*](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/clinical-trials) *for consent form reporting guidance.*

1. **Progress Report COI Questions:**
2. Current Investigator(s): Enter name.

Have you completed a conflict of interest disclosure (i.e., *Annual COI Assurance Form* **or** *COI Reporting Form*) within the past 12 months and is it accurate and up-to-date as of the time of this submission, as required by the [*Conflict of Interest in Research Policy*](https://policy.brown.edu/policy/conflict-interest-research-policy) (COI Research Policy)? (You may access the system [here](https://infoed.brown.edu/) to confirm.)

[ ]  YES [ ]  NO

Do you have a [significant financial interest](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#sfi) (SFI) that is related to this research protocol? “Related” could mean the research involves products, technology, intellectual property, or services made, owned, or provided by the entity/ies in which you have an SFI and that the SFI could be affected by the proposed research or its results.

[ ]  YES [ ]  NO

If YES, please describe:

Enter text.

1. Personnel Changes/New Investigator(s): Enter name.

The [COI Research Policy](https://policy.brown.edu/policy/conflict-interest-research-policy)defines the term “Investigator” as “the project director or principal investigator ***and any other person, regardless of title or position*** (e.g., full or part-time faculty member, staff member, student, trainee, collaborator, or consultant), who is **responsible** for the **design, conduct, or reporting** of sponsored research.”

**Using this definition of “Investigator,” have you added any new Brown Investigators to this project since your most recent IRB approval (Initial approval, or approval of your most recent progress report, or amendment)?**

[ ]  YES *(Please attach an* [*Additional Investigators’ COI Form*](https://www.brown.edu/research/sites/research/files/Additional%20Investigator%20COI%20v0607019.docx)*)*

[ ]  NO

1. **Continuing Review (CR) Determination**

Research protocols that are considered more than minimal risk must be reviewed by the convened IRB at least once per year. With justification, the IRB may require more frequent review or request continuing review of studies that may otherwise qualify for release from continuing review.

A. Does this research involve the use of an FDA-regulated product (i.e. [medical device](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#device), [drug](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#drug), [biologic](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#biological), etc.)?

[ ]  NO

[ ]  YES, the FDA-regulated product is approved and used [on-label](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#on) (Requires annual continuing review)

[ ]  YES, the FDA-regulated product is being used [in](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#ide) a [clinical investigation](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#clinical) under an [Investigational Device Exemption](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#ide) (IDE) or [Investigational New Drug](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#ind) (IND) authorization. (Requires annual continuing review)

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 (Expedited category 8a).

[ ]  YES

[ ]  NO

1. It **only involves** [data analysis](https://www.brown.edu/research/exemption-categories#exempt8), including analysis of identifiable private information or identifiable biospecimens (Expedited category 8c).

[ ]  YES

[ ]  NO

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

[ ]  YES *(This study is ready for closure. Please skip to section* [*VI. Investigator’s Electronic Signature*](#VI_SIGN)*, sign and date this form and send to* *IRB@brown.edu**)*

[ ]  NO *(Continue to next section)*

*\*If your study is a registered clinical trial, please visit our* [*Clinical Trials webpage*](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/clinical-trials) *for consent form reporting guidance.*

1. **Participants:**
	1. Has this study been approved for secondary analysis only?

[ ]  YES (*If Yes, skip to section* [*V. Study Progress*](#V_PROGRESS)*)*

[ ]  NO

* 1. 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.*

[ ]  YES

[ ]  NO (Expedited category 8b)

|  |  |
| --- | --- |
| How many participants have been entered/consented since the last approval *(initial or continuing)?* | Enter total. |
| How many participants have been entered/consented since initialapproval?\* | Enter total. |
| What is the total number of approved subjects for this study? | Enter total. |

*\*If the total number of enrolled subjects is approaching the total approved number of subjects, consider submitting an amendment to increase population.*

* 1. If the study activities continue, will additional participants be entered/consented?

[ ]  YES [ ]  NO

* 1. In the past year, have any participants withdrawn themselves from the study?

[ ]  YES [ ]  NO

If YES, how many participants withdrew: Enter total.

Briefly state the reason(s) if known: Enter text.

* 1. In the past year, have any participants been withdrawn by the PI?

[ ]  YES [ ]  NO

If YES, how many participants were withdrawn: Enter total.

Briefly state the reason(s): Enter text.

1. **Study Progress**

Please provide the following documents and/or information:

*\*\*All text fields will expand to accept an unlimited number of characters, so please type and/or copy/paste into the fields rather than attaching additional pages\*\**

1. A brief lay summary describing the study:

Enter text.

1. A report sufficiently describing the progress of the research since the last approval *(initial or continuing)* including any new risks identified since the initial approval as well as copies of any external interim reports (e.g., DSMB reports):

Enter text.

1. Please attach a copy of anot­­­­­­­her institution’s current IRB approval document if Brown issues a subaward to that institution for human research activities.

*(If Brown is the IRB of record through an IAA, no documentation is required.)*

1. A list of all [Reportable Events](https://www.brown.edu/research/sites/research/files/Reportable%20Events%20Policy%20%28Final_12Nov18%29.pdf) and [Protocol Deviations](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control-research-data-management-and-data-use-agreements/irb/hrpp-glossary#deviations) since the beginning of the project.

*(The list should include the date, location, and type of event; the date of IRB notification; and the relatedness to the study.)*

Enter text.

1. Please attach copies of all current consent/assent forms and/or verbal consent/assent scripts.

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1. **Investigator’s Electronic Signature:**



**PI Name**: Enter name.

**Date**: Enter date.

1. **Signature of Authorizing Official of the IRB:**



**Name**: Enter name.

**Date**: Enter date.