**Project Title**: Click or tap here to enter text.

**Principal Investigator**: Click or tap here to enter text.

**Protocol Number**: Click or tap here to enter text.

**Expiration Date**: Click or tap to enter a date.

**Funding Source**: Click or tap here to enter text.

**Continuing Review Number**: Choose an item.

*Please see the guidance document entitled: “*[*How to Complete a Progress Report*](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-policies#amendments)*” for further instructions on completing the report.*

1. **Protocol Status:**
   1. Has this project been completed since the last IRB approval?

YES

Please close this project now

I would like for this project to close on the expiration date

*If YES, please skip to section VII, sign and date this form and send to* [*IRB@brown.edu*](mailto:IRB@brown.edu)*.*

NO

*If NO, please complete the remaining sections and send to* [*IRB@brown.edu*](mailto:IRB@brown.edu)*.*

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1. **Progress Report COI Questions:**
   1. Personnel Changes/New Investigator(s):

The[*Brown University Conflict of Interest Policy for Officers of Instruction and Research*](https://www.brown.edu/research/about-brown-research/policies/conflict-interest-policy-officers-instruction-and-research) *(“COI 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  NO  *(If NO, skip to section III.)*

New Investigator(s) Conflict of Interest:

Any new Investigators (if applicable) must answer the below questions. Please include additional sheets if needed to identify all new Investigators by name and title.

*Please note that if any new Investigators have an SFI related to this research protocol, the IRB may require modifications to the informed consent document(s).*

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

**Name of Investigator:** Click or tap here to enter text.

**Title:** Click or tap here to enter text.

* 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 [COI Policy](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/ori-staff-directory/coi-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/compliance-education-training/research-compliance/conflict-interest/conflict-interest/coi-frequently#Faq6) (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  ***(*If YES, skip to section V*.)*** NO

If YES, please describe:

Click or tap here to enter text.

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

The IRB must review research protocols no less than once per year unless the research is no more than minimal risk and meets certain conditions. As of 1/21/19, 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]](#footnote-1)

A. Is this research FDA regulated?

YES  **(If YES, CR is required, skip to section V.)**

NO

B. Has the research progressed to the point that:

1) It **only involves** data analysis, including analysis of identifiable private information or identifiable biospecimens; or

2) It **only involves** accessing follow-up clinical data from procedures that participants would undergo as part of clinical care.

YES  (If YES to either of the above, CR **is not** required. Go to section IV. and sign Investigator Acknowledgement)

NO  (if NO, **CR is required**, **skip to section V.**)

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

1. **Investigator Acknowledgment (when CR is not required)**

IMPORTANT REMINDER:

[Reportable Events](https://www.brown.edu/research/sites/research/files/Reportable%20Events%20Policy%20%28Final_12Nov18%29.pdf) and modifications to the study must still be submitted to the IRB for review, even if this study is released from Continuing Review.

I understand that I am responsible for protecting the rights, safety, and welfare of each research participant. I will conduct this research in compliance with the IRB-approved protocol, Brown University institutional policies and procedures, and applicable federal (45 CFR 46) and state laws, and the principles of research ethics set forth in [The Belmont Report](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html).

Please complete and sign this section and return to [IRB@brown.edu](mailto:IRB@brown.edu).

|  |  |
| --- | --- |
| Principal Investigator (type name): | |
| Principal Investigator’s signature: | Date: |

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1. **Participants:**
   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

How many participants have been entered/consented since the last approval *(initial or continuing)?*

Click or tap here to enter text.

How many participants have been entered/consented since initialapproval?

Click or tap here to enter text.

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

YES  NO

* 1. Are the remaining research activities limited to data analysis?

YES  NO

*If YES, has the data been de-identified (i.e., ALL identifying information has been destroyed)?*

YES  NO

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

YES  NO

If YES, how many participants withdrew: Click or tap here to enter text.

Briefly state the reason(s) if known: Click or tap here to enter text.

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

YES  NO

If YES, how many participants were withdrawn: Click or tap here to enter text.

Briefly state the reason(s): Click or tap here to enter text.

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1. **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:

Click or tap here to 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):

Click or tap here to 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) 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.)*

Click or tap here to 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**: Click or tap here to enter text.

**Date**: Click or tap here to enter text.

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

**Name**: Click or tap here to enter text.

**Date**: Click or tap here to enter text.

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. [↑](#footnote-ref-1)