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

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

**Date of Request**: Click or tap to enter a date.

**Original Type of Review**:  Exempt  Expedited  Full Board

**1.) Provide a brief lay summary of the overall project. Include enough detail to allow the IRB to**

**evaluate the requested change(s) within the context of the overall project:**

Click or tap here to enter text.

**2.) Provide a detailed description of the changes being requested:**

Click or tap here to enter text.

**3.) State the reason (justification) for the requested amendment:**

Click or tap here to enter text.

**4.) What is your assessment of how the changes will affect the overall risk/benefit ratio of the study and the willingness of individuals to participate?**

Click or tap here to enter text.

**5.) New documents / changes to existing documents:**

(a)Does the requested amendment require new documents or changes to the approved consent form or other documents?

Consent/assent documents (attach revised version with changes highlighted)

New/revised instruments (attach -if revised, highlight changes)

New/revised advertising materials (attach -if revised, highlight changes)

(b) 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/or that the SFI could be affected by the proposed research or its results. YES NO

If **YES**, has this conflict been previously disclosed to the IRB?

YES

NO

If **NO**, please describe: Click or tap here to enter text.

**6.) 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, stop here. No need to proceed to the next question.)

**7.) 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.

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

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

1. 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

*(b)* 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/or that the SFI could be affected by the proposed research or its results. YES NO

***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).***

If **YES**, please describe: Click or tap here to enter text.

**PI Electronic Signature**: ­­­­­­­­­­­­­­­

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

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