

For Internal Use Only

Protocol Type:

[ ] Full Board [ ] Expedited

 [ ] Exempt

**Brown University**

**Revision Request Form:**

**Full Board/Expedited Amendments and Exempt Modifications**

Protocol Title: Click or tap here to enter text.

Principal Investigator: Click or tap here to enter text.

Faculty Advisor (if applicable): Click or tap here to enter text.

Protocol Number: Click or tap here to enter text.

Date of Request: Click or tap here to enter text.

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| **PART I. PROPOSED CHANGES** |
| **1. Provide a brief lay summary of the overall project. Include enough detail to allow the IRB/HRPP to evaluate the requested change(s) within the context of the overall project.** |
| Click or tap here to enter text. |
| **2. Please provide a detailed list of the change(s) being requested.** |
| Click or tap here to enter text. |
| **3. State the reason (justification) for the requested change(s).** |
| 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. Do you have a** [**significant financial interest**](https://www.brown.edu/research/coi#Faq6) **(SFI) that is related to this research study? “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 (Continue to 5a.) [ ]  NO (Skip to 6.) |
| 5a.  |  If YES, has this conflict been previously disclosed to the IRB/HRPP? [ ]  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 and Commitment Policy*](https://www.brown.edu/about/administration/policies/sites/brown.edu.about.administration.policies/files/uploads/Univ-COIC-Policy-10-26-19.pdf) (“*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/HRPP review (initial review or review of your most recent amendment/modification)?** [ ]  YES (Continue to 7.) [ ]  NO (Skip to Part II. Attachments) |
| **7. New Investigator(s) Conflict of Interest:**  |
| Any **new Brown Investigators** 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? (You may access the system here to confirm.)

[ ]  YES [ ]  NO1. Do you have a [significant financial interest](https://www.brown.edu/research/coi#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 HRPP may require modifications to any informed consent document(s).***If **YES**, please describe: Click or tap here to enter text. |

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| **PART II. ATTACHMENTS** |
| **Do the proposed changes require changes to the following documents?****Yes No** |
|[ ] [ ]  Updated Data Security Assessment |
|[ ] [ ]  Informed consent, assent, parent permission documents / scripts |
|[ ] [ ]  Data collection materials (questionnaires, surveys, interview scripts, etc.) |
|[ ] [ ]  Recruitment materials (emails, flyers, letters, posters, brochures, etc.) |
|[ ] [ ]  Other: Click or tap here to enter text. |
| **If \*Yes\* to any of the above, please attach the appropriate revised document with all changes highlighted.**  |

Principal Investigator’s signature: Date: Click or tap to enter a date.



*For IRB/HRPP Use Only*

Signature of IRB/HRPP: Date Approved/Accepted by IRB/HRPP: Click or tap to enter a date.

