**Brown University**

**Continuing Review Form**

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

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

**IRB Study ID#:** Click or tap here to enter text.

**Continuing Review Number**: Click or tap here to enter text.

1. **Study Progress [REQUIRED****]**
2. Provide a report sufficiently describing the progress of the research since the last approval (initial or continuing). Address any new risks identified since the last approval.

Click or tap here to enter text.

1. **Clinical Trial Information [REQUIRED****]**
2. Is the study a [clinical trial](https://www.brown.edu/research/clinical-trials#whatisact) that will be registered on ClinicalTrials.gov?

[ ]  YES

[ ] NO (Skip to Section III)

1. I certify that I have reviewed and will abide by the clinical trial registration, reporting, and consent form [posting requirements](https://www.brown.edu/research/clinical-trials#reporting).

[ ] YES

1. **More Information Requested on the Huron E-Form** **Question #6**

*This section only asks for information since the last progress report review. Only provide an explanation for the items that were left unchecked in question #6 on the E-form. Skip any items and/or questions that do not apply to your study. If you did not leave any boxes unchecked for question #6, SKIP TO IV Other Relevant Information.*

1. Subjects experienced unexpected harm.

Click or tap here to enter text.

1. Anticipated adverse events have taken place with greater frequency or severity than expected.

Click or tap here to enter text.

1. Subjects withdrew from the study.
	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 In the past year, have any participants withdrawn themselves from the study?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 In the past year, have any participants been withdrawn by the PI?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If YES, how many participants were withdrawn: Click or tap here to enter text.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.

1. There have been unanticipated problem(s) involving risks to subjects or others.

Click or tap here to enter text.

1. There have been complaints about the study.

Click or tap here to enter text.

1. New or previously unknown publications in the literature relevant to risks or potential benefits have been discovered.

Click or tap here to enter text.

1. If there are interim findings, provide them at this time.

Click or tap here to enter text.

1. Provide any multi-center trial reports for this review.

Click or tap here to enter text.

1. Provide any data safety monitoring reports for this review (e.g. DSMB).

Click or tap here to enter text.

1. There are regulatory actions that could affect safety and risk assessments for this study.

Click or tap here to enter text.

1. Provide any other relevant information regarding this study, especially information about risks, at this time.

Click or tap here to enter text.

1. What risks and benefits does the PI believe have changed?

Click or tap here to enter text.

1. Why are there still outstanding modifications NOT submitted to the IRB?

Click or tap here to enter text.

1. Why have problems that require prompt reporting to the IRB NOT been submitted?

Click or tap here to enter text.

1. **Other Relevant Information**
2. Attach any external reports not already requested in the E-form or this form (e.g. other IRB approvals).

Click or tap here to enter text.