

Human Research Progress Report

BROWN UNIVERSITY

INSTITUTIONAL REVIEW BOARD

Project Title:

Principal Investigator:

Expiration Date:

Funding Source:

Continuing Review Number:

Please see the guidance document entitled: "[How to Complete a Progress Report](#)" for further instructions on completing the report.

1. Protocol status:

- (a) This project has been completed since the last IRB approval.

YES _____ NO _____

- If 'YES', STOP here. Please sign this form and send it RPO. No additional information is needed and IRB approval will lapse/expire.
- If 'NO', please complete the form.

- (b) This project involves secondary data analysis only.

YES _____ NO _____

- If "yes", skip the following questions and proceed to Section 4.

- (c) Participants have *never* been entered/consented*.

YES _____ NO _____

- (d) Study activities continue but no further participants will be entered/consented*.

YES _____ NO _____

- (e) The remaining research activities are limited to data analysis.

YES _____ NO _____

2. Number of participants **entered/consented*** into the project:

since last approval (*initial or continuing*)

since initial approval

*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.

3. (a) In the past year, have any participants **withdrawn themselves** from the study?
YES _____ NO _____

If yes, number of participants who withdrew: _____
Briefly state the reason(s) if known:

- (b) In the past year, have any participants been **withdrawn by the PI**?
YES _____ NO _____

If yes, number of participants withdrawn: _____
Briefly state the reason(s):

4. **Please provide the following documents and/or information:**

- (a) A brief lay summary describing the study- please attach;
- (b) A report sufficiently describing the progress of the research since the last approval (*initial or continuing*) including any new risks identified since initial approval- please attach;
- (c) 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.*);
- (d) A list or table of all "unanticipated problems involving risks to participants or others" submitted for IRB review since the beginning of the project. (*The list/table should include the date of IRB notification, date of event, location of event, type of event, and relatedness to the study.*)
- (e) Blank copies of all current consent/assent forms and/or verbal consent/assent scripts.
(*No documentation is needed if you answered "yes" to either 1(d) or 1(e) in Section 1.*)

(PI Signature)

(Date)

Signature of Authorizing Official of the IRB

Date

(rev. March 2014)