

Progress Report

Instructions: PDF Version

This format is designed for those who wish to print the form and complete it with a typewriter. If you would prefer to complete the form on a computer, please choose a different format.

If you need additional room to answer any questions, attach a separate page.

If you have any questions, contact the IRB Office at 718-270-2680.

Submission Checklist:

Before you submit this form, ensure that all study staff have completed the IRB training requirements.

In your submission to the IRB, please include the following:

- _____ Progress Report Form
- _____ Current Abstract
- _____ Clean Copies of any Consent and Assent Forms (Required only if you plan to enroll new participants.)
- _____ Recent Reports From Sponsor, Data and Safety Monitoring Board (DSMB) etc.
- _____ List of additional study staff, FDA Form 1572, or NIH “Key Personnel” section (if applicable)

Protocol #

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SUNY Health Science Center at Brooklyn
Kings County Hospital Center
Institutional Review Board

Progress Report

GENERAL INFORMATION

Principal Investigator:

Dept:

Box:

Co-Investigator:

Co-Investigator:

Additional Study Staff Authorized to Conduct Consent Interview:

Append list of additional staff if necessary. Please provide a copy of FDA Form 1572 or NIH application section "Key Personnel" (NIH Form 398 p2), if applicable.

How should we contact you?

Name (if not PI):

Email:

Ph:

Fax:

Cell:

Page:

Protocol Title:

1) What activities would you like to continue? (Choose the highest applicable option.)

- Enrollment of new participants. (Please submit a clean consent form.)
- Follow-up of existing participants, including additional research interventions.
- Long-term follow-up and data analysis only. No new enrollment. No administration of study drugs, no research interventions, etc. with any participant.

CONDUCT OF STUDY AT LOCAL SITES

(Local sites are those for which this IRB is responsible)

2) Number of participants enrolled at this site:

Since last IRB review

Since project inception

3) What percentage (since inception, at this site) have been:

Under age 18

Women

Racial/ethnic minorities

4) Have there been any unanticipated problems (e.g. obtaining consent, following the protocol)? Have there been any complaints about the research? Have any participants withdrawn?

No Yes If yes, please explain.

5) Serious or unexpected adverse events at local sites must be reported to the Board immediately. Here, please summarize the internal serious or unexpected adverse events that have occurred at local sites since the last Progress Report.

CONDUCT OF THE STUDY IN GENERAL

6) How many participants have been enrolled in total, at all sites?

7) Have there been any adverse events at any sites since the last progress report?

No Yes

If yes, how many?

Please describe any trends or patterns of serious or unexpected adverse events related to the study.

8) Please provide preliminary results from the study.

9) Has there been any substantive recent literature relevant to the risks or design of the study?

No Yes If yes, please summarize.

10) Are any changes required to the study or consent form?

No Yes If yes, please submit an amendment.

Please attach any publications and recent sponsor or DSMB reports.

Principal Investigator

Date