



UNIVERSIDAD CENTRAL DEL CARIBE
INSTITUTIONAL REVIEW BOARD
Continuing Review Form

Principal Investigator _____ Date _____

1. IRB Study Number: _____
2. Study Title : _____

3. Study Status:

- Pending funding
 Enrolling subjects
 Enrollment closed – Subjects continue to receive study treatment/intervention
 Follow-up – Enrollment closed, collecting data only
 Data analysis only

4. How many subjects have you recruited to date? _____

5. Have there been any unreported changes or amendments to the protocol since the last review?

- No
 Yes: Describe and justify all changes here (You will need to re-consent participants already enrolled and if affected by the change) _____

6. Have there been any unexpected or negative effects to the subjects?

- No
 Yes: Describe all unexpected or negative effects to the subjects here: _____

7. How many subjects did you expect to recruit in the original proposal? _____

8. Have any subjects withdrawn or been removed from the study?

- No
 Yes: State the number of subjects withdrawn/removed and the reasons for their withdrawal/removal here: _____
 Screen failures

9. What is your proposed date for completing the study? _____

PI is requested to submit the following documents:

- a. Expand on the above answers on a separate sheet.
- b. Informed consent/assent forms. Please submit a copy of the informed consent/assent forms that are/were currently being used in the study. If the informed consent form requires revision, a copy of the revised form with the changes highlighted must be attached along with the previously used consent form. Please submit a clean copy on the letterhead, which will be stamped with updated information and returned to you.
- c. Publications. Attach a reprint of any publication derived from the study.