IRB #:

Howard University Institutional Review Board
Continuing Review Form (C-2)
For Student and/or Minimal Risk Research

(Please type form)

PI/Faculty Advisor and Student Investigator	
Title of Project	

1. What is the status of your research project?
   - ❑ Active (still enrolling participants).
   - ❑ Closed to participant enrollment, but participants still on protocol regimen
   - ❑ All participants completed protocol regimen, but research open for data analysis and follow-up of participants
   - ❑ All research related activities completed including all data analysis and paper writing; request termination of research with HUIRB.
   - ❑ Other _____

1. Participant Accrual Statistics:

Accrual Progress

	Total number of **local** participants **currently approved** by the IRB
	Total number of participants **enrolled** at the **local site**.
	Number of participants **currently enrolled** that are being followed.
If the total number of participants enrolled at the local site including those who are still being followed exceeds the number of participants currently approved, please explain.	

	Number of participants **enrolled nationally**. *(if available and applicable).*
	Number of participants **enrolled internationally**. *(if available and applicable).*
If the total number of participants enrolled exceeds the number of participants currently approved, please explain.	

Time Frame

	Estimated duration of total project (Please see "Duration of project" on original D-1 form)
Please justify keeping trial open if the duration of the study exceeds the duration listed in the original that was approved by the IRB	

2. Withdrawals

	Participant withdrawals
	Withdrawals by PI

4. Have there been any complaints about the research since the last review? Reportable complaints are those that cannot be resolved by research staff

- ❑ Yes. If yes, please explain briefly.
- ❑ No.

5. Has the research protocol, informed consent document, or recruiting material been modified in any way since the previous IRB review?

- ❑ Yes. If yes, please attach additional information to explain the changes.
- ❑ No.

If yes, have all modifications been approved by the IRB?

- ❑ Yes.
- ❑ No. If no, briefly explain, and attach additional information.

6. What is the source of the funds for this project? _____

7. Adverse Events: Please attach a list of all study-related adverse events.

Please check one of the following three choices and submit additional information when designated:

- ❑ No adverse events have occurred since the previous IRB review.
- ❑ Adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and/or any investigator brochure.
- ❑ Yes there have been **unexpected** adverse events since the previous IRB review. **Please attach a summary of these adverse events; reports from other central monitoring entity will suffice. Please include any changes to the protocol or informed consent documents due to unexpected adverse events, including the date of IRB review or approval of the changes.***

Please check one of the following two choices and submit additional information when designated:

- ❑ There have been no unanticipated problems involving risks to participants or others since the previous annual review.
- ❑ Yes there have been unanticipated problems since the previous annual review. Please attach a description of any local unanticipated problems involving risks to participants or others.

1. Review research files for participants on the study for the following:

   Yes _____ No _____ Are there signed consent forms on all participants?

   Yes _____ No _____ Have terms of the protocol been followed?

   Yes _____ No _____ Have there been any protocol deviations?

   If there were deviations, were they reviewed and approved by the IRB?

   Yes _____ No _____ If no, please attach an explanation.

2. Do any study investigators have a conflict of interest as defined in the Howard University Faculty handbook:

   Yes _____ No _____ If yes, please attach an explanation.

3. Is there a current (within the past 12 months) Conflict of Interest or Financial Disclosure form for each investigator on file at the Office of Regulatory Affairs?

   Yes _____ No _____

4. **Attach copies of:**
   - **a. Recent literature; published findings obtained thus far, including study-wide reports if applicable; or other relevant information (especially information about risks associated with the research) available since the last IRB annual review.**
   - **b. Current IRB-approved executed informed consent document which was acquired during the last approval cycle.**
   - **c. Clean copy of the consent document(s) to be used for the next approval cycle.**
   - **d. Copy of adverse events and summaries, local and global (*see question 4*)**
   - **e. Copy of data and safety monitoring reports since the last IRB approval *(if applicable)***
   - **f. For PI and any Co-Investigators: Proof of Human Research Protection Training (CITI) and Copy of Conflict of Interest or Financial Disclosure form(s) if changed since last IRB review.**
   - **g. Copy of current grant application (*if this research is sponsored by a federal agency*)**

I certify that the above information accurately represents the status of the research and the participants enrolled.

_____
Date

_____
Signature of Student Investigator

_____
Date

_____
Signature of PI/Faculty Advisor

_____ _____
Signature of Person Completing Form **Date**
If the PI/FA and/or SI has changed since the last review

Applications/Protocols are to be delivered to the Office of Regulatory Research Compliance, located in the HU Research Building-1, 1840 Seventh Street, N.W., Suite #309, Howard University, Washington, DC 20001.

The Office of Regulatory Research Compliance does not accept electronic submissions at this time, should you have any questions, you may e-mail: theorrc@howard.edu or call the ORRC at (202) 865-8597.