IRB #

Howard University Institutional Review Board
Continuing Review Form (A-2)
For Funded and/or Drugs and/or Devises and/or Greater than Minimal Risk Research

(Please type form)

Principal Investigator	
Title of Project	

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

2. Participant Accrual Statistics:

Accrual Progress

	Total number of **local** participants **currently approved** by the IRB
	Total number of participants **enrolled** at the **local site**.
	The 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, and request that the number approved be increased to a new limit.	

	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 justify keeping the study open if the duration of the study exceeds the duration listed in the original protocol approved by the IRB	

3. 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 explain the changes [in an attachment/].
   - ❑ No

     If yes, have all modifications been approved by the IRB?
     - ❑ Yes
     - ❑ *No. If no, briefly explain [in an attachment].

* Submissions will not be approved without these explanations.

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

7. State the number of banked tissues/DNA, or sets/blood samples being stored:
   _____

8a. Indicate where they are located and under what conditions they are maintained and secured:
_____
_____

8b. Indicate whether they are being shared, and with whom[they are being shared]:
_____
_____

8c. State the number of lost or destroyed banked tissues/DNA or sets/blood samples:
_____

Explain the circumstances:
_____

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

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

   - ❑ No adverse events have occurred since the previous IRB review.
   - ❑ Adverse events have occurred at or below the expected frequency and/or level of severity as documented in the research protocol, the informed consent document, and/or any investigator brochure. * EXPLAIN THE BASIS AND EVIDENCE THAT SUPPORTS THE CONCLUSION THAT THE FREQUENCY AND SEVERITY ARE AT OR BELOW THE LEVELS EXPECTED.
   - ❑ Yes there have been **unexpected** adverse events since the previous IRB review, OR ADVERSE EVENTS WERE ABOVE THE EXPECTED LEVELS OF FREQUENCY OR SEVERITY. **Please attach a summary of these adverse events; reports from Cooperative Group, DSMB/DMC or other central monitoring entity will suffice.**

     ***PLEASE AMEND THE PROTOCOL OR INFORMED CONSENT DOCUMENTS TO ACKNOWLEDGE AND INFORM PARTICIPANTS OF THE UNEXPECTED OR UNEXPECTEDLY FREQUENT AND/OR SEVERE NATURE OF THESE ADVERSE EVENTS, OR EXPLAIN WHY NO CHANGES ARE DEEMED NECESSARY.**

   *** Submissions will not be approved without these explanations.**

   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.

10. 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?

    Were these deviations reviewed and approved by the IRB?

    Yes _____ No _____

*Please attach an explanation for any item marked "No" above. Submissions without explanations will not be approved.

11. State the number of executed informed consent forms obtained during this reporting period, and indicate where they are located and under what conditions they are maintained. If executed consent forms are not on file for all participants, explain why not

    _____

    _____

12. 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(s) which was obtained during the last approval cycle.

c. Clean copy of the consent document(s) to be used for the next approval cycle.

d. Copy of HIPAA Authorization (*if still consenting participants*)

e. Copy of adverse events and summaries, local and global (*see question 4*)

f. Copy of data and safety monitoring reports since the last IRB approval *(if applicable)*

g. Any communications from the FDA regarding IND, IDE, or humanitarian use applications related to this submission.

h. For PI and any Co-Investigators: Proof of Human Research Protection Training and Copy of Conflict of Interest or Financial Disclosure form(s) if changed since last IRB review.

i. Copy of current grant non-competing or competing continuation grant application submitted to the agency. If this is a no cost extension, provide a copy of that request.

SUBMISSIONS THAT DO NOT INCLUDE ALL THE APPLICABLE DOCUMENTS LISTED ABOVE ARE INCOMPLETE AND CANNOT BE REVIEWED UNTIL THE DOCUMENTS ARE PROVIDED.

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

_____ _____

Signature of Principal Investigator **Date**

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.