*IRB #* Click here to enter text.

*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 | Click here to enter text. |
| Title of Project | Click here to enter text. |

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 follow-

up of participants (EXPEDITED REVIEW)

All research related activities completed including all data analysis and paper writing; request

termination of research with IRB.

Other \_\_\_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Participant Accrual Statistics:

Accrual Progress

|  |  |
| --- | --- |
| Click here to enter text. | Total number of **local** participants **currently approved** by the IRB |
| Click here to enter text. | Total number of participants **enrolled** at the **local site**. |
| Click here to enter text. | 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.  Click here to enter text. | |

|  |  |
| --- | --- |
| Click here to enter text. | Number of participants **enrolled** **nationally**. *(if available and applicable).* |
| Click here to enter text. | 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. Click here to enter text.  Click here to enter text. | |

Time Frame

|  |  |
| --- | --- |
| Click here to enter text. | Estimated duration of total project |
| Please justify keeping trial open if the duration of the study exceeds the duration listed in the original that was approved by the IRB  Click here to enter text. | |

1. Withdrawals

|  |  |
| --- | --- |
| Click here to enter text. | Participant withdrawals |
| Click here to enter text. | Withdrawals by PI |

1. 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.

1. Has the research protocol, informed consent document, or recruiting material been modified in any way since the previous IRB review? (i.e., initial review or continuation review for the last approval period.)

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 the revised documents.

1. What is the source of the funds to support this project? \_\_\_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. State the number of banked tissues/DNA sets/blood samples being stored: \_\_\_\_\_\_\_\_\_\_\_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_

8a. Indicate where they are located and under what conditions they are maintained: \_\_\_\_\_\_\_\_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

8b. Indicate whether they are being shared and with whom they are being shared: \_\_\_\_\_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

8c. State the number of lost or destroyed banked tissues/DNA sets/blood samples: \_\_\_\_\_\_\_\_\_\_\_\_Click here to enter text.\_\_\_\_\_\_\_\_\_

Explain the circumstances: \_\_\_\_\_\_\_\_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**9. Adverse Events: Please attach a list of all study-related** [**adverse events**](http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm)**.**

**a. 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 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](http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm) since the previous IRB review. **Please**

**attach a summary of these adverse events; reports from Cooperative Group,**

**DSMB/DMC or 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.\***

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

There have been no [unanticipated problems](http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm) 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 of the event and the plan

of action to prevent further occurrence.

1. State the number of informed consent forms obtained during this reporting period and indicate where they are located and under what conditions they are maintained. \_\_\_\_\_\_\_\_\_\_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Attach copies of:**
   1. **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.**
   2. **Current IRB-approved executed informed consent document(s) which was obtained during the last approval cycle.**
   3. **Clean copy of the consent document(s) to be used for the next approval cycle.**
   4. **Copy of HIPAA Authorization (*if still consenting participants*)**
   5. **Copy of adverse events and summaries, local and global (*see question 4*)**
   6. **Copy of data and safety monitoring reports since the last IRB approval *(if applicable)***
   7. **Any communications from the FDA regarding IND, IDE, or humanitarian use applications related to this submission.**
   8. **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.**
   9. **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.**

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

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| **\_\_**Click here to enter text.**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature of Principal Investigator** |  | **\_\_\_\_\_\_\_\_**Click here to enter text.**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Date** |
|  |  |  |