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| **FORM-A2 - CONTINUING REVIEW** |
| **Howard University Institutional Review Board for Greater than Minimal Risk Research** |
| **IRB #** |  |
| **Principal Investigator** |  |
|  **Project Title** |  |
| **Funding Source** |  |

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| 1. **What is the status of your research project?**
 |
| **☐ No ☐ Yes** | Active (Still enrolling participants)? |
| **☐ No ☐ Yes** | Closed to participant enrollment, but participants are still undergoing protocol related procedures or activities? |
| **☐ No ☐ Yes** | All participants completed the protocol regimen, but research open for data analysis and follow- up of participants (***Expedited/Limited/Admin Review***)? |
| **☐ No ☐ Yes** | All research-related activities completed, including data analysis and manuscript writing? |
| **☐ No ☐ Yes** | Request termination of research with IRB |
| **☐ No ☐ Yes** | Others – ***Explain***: |

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| 1. **Participant Accrual Statistics:** Accrual Progress
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| **#:** | Total number of local participants ***currently approved*** by the IRB |
| **#:** | Total number of participants ***screened/consented including administrative censoring*** (this number may be higher than the number approved because some may have failed advanced screening procedures) |
| **#:** | Total number of participants ***enrolled*** at the ***Howard site*** (include from international) |
| **#:** | The number of participants currently ***enrolled*** and are ***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:*** |
| **#:**  | **Other sites:** The number ***enrolled nationally*** (if available and applicable). |
| **#:** | **Other sites:** The number ***enrolled internationally*** (if available and applicable). |
| ***If the total number of participants enrolled/followed*** *(excluding failed screen)* ***exceeds the number of participants currently approved, please explain:***  |

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| 1. **Project Period**
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| **#:** | What is the ***estimated duration*** of the study |
| **☐ No ☐ Yes** | Is the ***current estimated period greater than previously indicated*** in the initial application?  |
| ***If yes, provide justification:***  |

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| 1. **Withdrawals**
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| **#:** | How many **participants** **withdrew** consent? |
| ***Explain*** the reason for the withdrawals:  |
| **#:**  | How many participants were withdrawn by the PI? |
| ***Explain*** the reason for the withdrawals:  |
| **#:** | How many participants were lost to follow-up? |

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| 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)
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| **☐ No ☐ Yes** | If ***yes***, ***explain*** and attach ***documentation*** as needed:  |
| ***If you respond yes to the above question, were the modifications approved by the IRB?*** |
| **☐ No ☐ Yes** | If ***no***, please ***explain*** and attach the revised document(s):  |
| **☐ No ☐ Yes** | **Correct informed consent version:** Have you used an ***incorrect version*** of the consent form based on (date stamps, version #s, or initialing and dating)? |
| ***If yes, explain:*** |
| **☐ No ☐ Yes** | **Accuracy of information presented to subjects**: If the IRB waived the requirement for the investigator to obtain a signed consent form for some or all subjects (45 CFR 46.117(c)), is the content of the information being provided to subjects orally and in writing regarding the research accurate?  |
| ***If no, explain:*** |
| **☐ No ☐ Yes** | **Coercion or undue influence:** Do you continuously provide subjects with sufficient opportunity to consider whether or not to participate or minimize the possibility of coercion or undue influence (see 45 CFR 46.116)).  |
| ***If no, explain*** |
| **☐ No ☐ Yes** | **Findings**: Has there been ***new findings*** since approval? |
| ***If so, explain:*** |
| **☐ No ☐ Yes** | **New study findings/information:** If there were new findings, were these information shared with research subjects (45 CFR 46.116(b)(5))v(e.g., important new toxicity information or new UNANTICIPATED adverse events). |
| ***Explain:*** |
| **☐ No ☐ Yes** | **Changes to risk-benefit ratio:** Have you made discernable changes in risk benefit ratio since last review? |
| ***If yes, explain:*** |

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| 1. **Biologic sample(s)**
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| ☐ NA | Not applicable |
| ☐ **No** ☐ **Yes** | How many tissues/DNA or sets/blood samples (from this study) are stored? |
| ***Where are they located?:*** |
| Under what conditions they are the samples maintained?: |
| **☐ No ☐ Yes** | Are the samples shared with anyone else or other organizations? |
| ***If yes, explain:***  |
| **☐ No ☐ Yes** | Was any sample(s) lost or destroyed? |
| ***If yes, explain:***  |

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| 1. **Adverse Events Reporting – Were there any adverse event during the reporting period? (Please attach a list of all study-related adverse events)**
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| ☐ **No**  | No adverse events occurred since the previous IRB review |
| **☐ Yes** | Adverse events occurred at the expected frequency and level of severity as documented in the research protocol, informed consent, or investigational brochure |
| **☐ Yes** | Yes, unexpected adverse event(s) occurred since the previous IRB review. ***Please attach:*****i)** A summary of these adverse events or **ii)** Reports from Cooperative Group, DSMB/DMC or other central monitoring entity **iii)** Revised protocol or informed consent documents due to unexpected adverse events, including the date of IRB review or approval of the changes (if applicable)\* |

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| 1. **Unanticipated Problems – Were there any unanticipated problems during the reporting period? (Please attach relevant documents)**
 |
| ☐ **No** **☐ Yes** | If yes, ***explain*** and ***attach*** a description of any unanticipated local problems involving risks to participants or others. |

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| 1. **Review research files for participants on the study for the following:**
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| **☐ No**  | **☐ Yes** | Are there signed consent forms on all participants? |
| **☐ No**  | **☐ Yes** | Have you followed the terms of the protocol? |
| **☐ No**  | **☐ Yes** | Were there any protocol deviations? |
| **☐ No**  | **☐ Yes** | If yes to protocol deviation, was the IRB informed? |
| **☐ No**  | **☐ Yes** | If the IRB was informed, was the plan of correction approved by the IRB? |
| ***If the IRB is yet to be informed, please describe the protocol deviation:*** |
| ***Please describe the plan of correction:***  |

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| 1. **Investigator and institutional issues - When appropriate, the reviewing IRB should consider issues regarding the investigator and the institution(s) where the research is being conducted during its continuing review, such as the following.**
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| **☐No ☐Yes** | **Investigator’s situation or qualifications:** Has the PI experienced changes in qualifications (e.g., suspension of hospital privileges, change in medical license status, or increase in number of research studies conducted by the investigator)? |
| **If yes, explain:**  |
| **☐No ☐Yes** | **Complaints**: Have you/research team received any complaints about the conduct of the research.  |
| **If yes, explain:**  |
| **☐No ☐Yes** | **Institutional Resources:** Please describe change in the resources available to the study if any.  |
| **If yes, explain:**  |

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| 1. **Has there been any changes to these NEW ELEMENTS of INFORMED CONSENT (Medical Sciences) since the last approval? If so, please describe the details in your consent document.**
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| **Biospecimens**  |
| **☐No**  | **☐Yes** | Are you collecting biospecimens? |
| **☐No**  | **☐Yes** | Do you plan to de-identify the biospecimen? |
| **☐No**  | **☐Yes** | Do you plan to use the biospecimen (***whether de-identified or not***) for future research or shared with other investigators [46.116 (b)(9)] ? |
| **Commercial use of biospecimen** |
| **☐No**  | **☐Yes** | Do you plan to use the subject’s biospecimen for commercial purposes/profit?  |
| **☐No**  | **☐Yes** | Will subjects share in the commercial profit [46.116 (c)(7)]? |
| **Disclosure of Research Results** |
| **☐No**  | **☐Yes** | Do you plan to disclose clinically relevant research results, including individual research results, to subjects, and if so under which conditions [46.116 (c)(8)]? |
| **Genome Sequencing** |
| **☐No**  | **☐Yes** | Will the research include (if known) or might include whole genome sequencing [46.116 (c)(9)]? |

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| 1. **Please attach copies of the documents listed below**
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| i. | 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. |
| ii. | Current IRB-approved executed informed consent document(s) which was obtained during the last approval cycle |
| iii. | Clean copy of the consent document(s) to be used for the next approval cycle |
| iv. | Copy of HIPAA Authorization (if still consenting participants) |
| v. | Copy of adverse events and summaries, local and global (see question 4) |
| vi. | Copy of data and safety monitoring reports since the last IRB approval (if applicable) |
| vii. | Any communications from the FDA regarding IND, IDE, or humanitarian use applications related to this submission |
| viii. | 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 |
| ix. | If this is a “no-cost extension”, provide a copy of that request. |

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| 1. **I certify that the above information accurately represents the status of the research and the participants enrolled.**
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| **Signature of Principal Investigator** | **Date** |