

FORM-A2 - CONTINUING REVIEW

Howard University Institutional Review Board for Greater than Minimal Risk Research

IRB #	
Principal Investigator	
Project Title	
Funding Source	

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

2. Participant Accrual Statistics: Accrual Progress	
#:	Total number of local participants <i>currently approved</i> by the IRB
#:	Total number of participants <i>screened/consented including administrative censoring</i> (this number may be higher than the number approved because some may have failed advanced screening procedures)
#:	Total number of participants <i>enrolled at Howard</i> (For HU investigator-initiated study that includes an international site, please include all enrolled in this number)
#:	Of the above (total enrolled), please indicate the number of participants that are currently <i>followed</i>
<i>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:</i>	
For Multi-Center Studies	
#:	Other sites: The number <i>enrolled nationally</i> (if available and applicable).
#:	Other sites: The number <i>enrolled internationally</i> (if available and applicable).

If the total number of participants enrolled/followed (excluding failed screen) exceeds the number of participants currently approved, please explain:

3. Project Period

	What is the estimated duration of the study
<input type="checkbox"/> No <input type="checkbox"/> Yes	Is the current estimated period greater than previously indicated in the initial application?
	If yes, provide justification:

4. Withdrawals

#:	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?

5. 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)

<input type="checkbox"/> No <input type="checkbox"/> Yes	If <u>yes</u> , explain and attach <i>documentation</i> as needed:
<input type="checkbox"/> No <input type="checkbox"/> Yes	If you respond yes to the above question, were the modifications approved by the IRB?
	If <u>no</u> , please explain and attach the revised document(s):
<input type="checkbox"/> No <input type="checkbox"/> Yes	Correct informed consent version: Have you used an <i>incorrect version</i> of the consent form based on (date stamps, version #s, or initialing and dating)?
	If yes, explain:
<input type="checkbox"/> No <input type="checkbox"/> 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 yes, explain:
<input type="checkbox"/> No <input type="checkbox"/> 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 yes, explain:
<input type="checkbox"/> No <input type="checkbox"/> Yes	Findings: Has there been <u>new findings</u> since approval?
	If yes, explain:

<input type="checkbox"/> No <input type="checkbox"/> Yes	New study findings/information: If there were new findings, were these information shared with research subjects (45 CFR 46.116(b)(5))(e.g., important new toxicity information or new UNANTICIPATED adverse events). <i>Explain:</i>
<input type="checkbox"/> No <input type="checkbox"/> Yes	Changes to risk-benefit ratio: Have you made discernable changes in risk benefit ratio since last review? <i>If yes, explain:</i>

6. Biologic sample(s)	
<input type="checkbox"/> NA	Not applicable
<input type="checkbox"/> No <input type="checkbox"/> Yes	How many tissues/DNA or sets/blood samples (from this study) are stored? <i>Where are they located?</i> Under what conditions they are the samples maintained?
<input type="checkbox"/> No <input type="checkbox"/> Yes	Are the samples shared with anyone else or other organizations? <i>If yes, explain:</i>
<input type="checkbox"/> No <input type="checkbox"/> Yes	Was any sample(s) lost or destroyed? <i>If yes, explain:</i>

7. Adverse Events Reporting – Were there any adverse event during the reporting period? (Please attach a list of all study-related adverse events)	
<input type="checkbox"/> No	No adverse events occurred since the previous IRB review
<input type="checkbox"/> Yes	Adverse events occurred at the expected frequency and level of severity as documented in the research protocol, informed consent, or investigational brochure
<input type="checkbox"/> Yes	Yes, unexpected adverse event(s) occurred since the previous IRB review. <i>Please attach:</i> 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)*

8. Unanticipated Problems – Were there any unanticipated problems during the reporting period? (Please attach relevant documents)	
<input type="checkbox"/> No <input type="checkbox"/> Yes	If yes, <i>explain</i> and <i>attach</i> a description of any unanticipated local problems involving risks to participants or others.

9. Review research files for participants on the study for the following:		
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Are there signed consent forms on all participants?
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Have you followed the terms of the protocol?
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Were there any protocol deviations?
<input type="checkbox"/> No	<input type="checkbox"/> Yes	If yes to protocol deviation, was the IRB informed?
<input type="checkbox"/> No	<input type="checkbox"/> 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:

10. 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.

<input type="checkbox"/> No <input type="checkbox"/> 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:
<input type="checkbox"/> No <input type="checkbox"/> Yes	Complaints: Have you/research team received any complaints about the conduct of the research. If yes, explain:
<input type="checkbox"/> No <input type="checkbox"/> Yes	Institutional Resources: Please describe change in the resources available to the study if any. If yes, explain:

11. 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.

Biospecimens		
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Are you collecting biospecimens?
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Do you plan to de-identify the biospecimen?
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Do you plan to use the biospecimen (<i>whether de-identified or not</i>) for future research or shared with other investigators [46.116 (b)(9)] ?
Commercial use of biospecimen		
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Do you plan to use the subject's biospecimen for commercial purposes/profit?
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Will subjects share in the commercial profit [46.116 (c)(7)]?
Disclosure of Research Results		
<input type="checkbox"/> No	<input type="checkbox"/> 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		
<input type="checkbox"/> No	<input type="checkbox"/> Yes	Will the research include (if known) or might include whole genome sequencing [46.116 (c)(9)]?

12. Please attach copies of the documents listed below

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.

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

Signature of Principal Investigator	Date

