FORM "C2"

HU IRB Application: Continuing Review

Title of Project:	
Submission Date:	
Principal Investigator:	**Department**:
	Email:
	Phone:
Co-Investigator:	**Department**:
	Email:
	Phone:
Co-Investigator:	**Department**:
	Email:
	Phone:
Co-Investigator:	**Department**:
	Email:
	Phone:
Student Investigator:	**Department**:
	Email:
	Phone:

IMPORTANT NOTE: Please Check to be sure that the following are attached

- ☐ New published findings, 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.
- ☐ **If Currently Enrolling:** Attach a copy of the currently IRB-approved executed informed consent document which from last approval cycle.
- ☐ **If Currently Enrolling:** Attach a copy of the clean copy of the consent document(s) to be used for the next approval cycle.
- ☐ **If Currently Enrolling or Continuing to Follow Subjects:** Attach a copy of adverse events and summaries, local and global (see question 4)
- ☐ **If Currently Enrolling or Continuing to Follow Subjects:** Copy of data and safety monitoring reports since the last IRB approval (if applicable)
- ☐ For all personnel: Proof of Human Research Protection Training
- ☐ For key personnel: (CITI) and Copy of Conflict of Interest or Financial Disclosure form(s) if changed since last IRB review

HU IRB Form C2: Continuing Review of Research

PLEASE ANSWER THE FOLLOWING QUESTIONS RELATED TO THE CONTINUING REVIEW of YOUR RESEARCH

HHS regulations set forth the criteria for IRB approval of research (45 CFR 46.111, 46.204-207, 46.305, and 46.404-409). These criteria apply to both initial review and continuing review of research and provide the framework for the IRB's evaluation of research. In order to re-approve research at the time of continuing review, the IRB must answer the following questions and provide comments as appropriate to the IRB in order to determine compliance with regulatory requirements.

1. Research progress

1a. 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***:

1b. Participant Accrual Statistics: Accrual Progress	
#:	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 <u>enrolled/followed</u> *(excluding failed screen)* ***exceeds the number of participants currently approved, please explain:***	

2. Criteria for IRB Approval of Research Undergoing Continuing Review

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Yes **No**	☐ ☐	**Risks Minimized:** Has there been changes to the protocol that affects: (i) procedures previously deemed consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes (45 CFR 46.111(a)(1)).
	Describe Click here to enter text.	
Yes **No**	☐ ☐	**Risks Reasonable:** Has there been changes to the protocol that alters the risk to benefit ratio of the research to the subjects and the importance of the knowledge that may reasonably be expected to result (45 CFR 111(a)(2))?.
	Describe Click here to enter text.	
Yes **No**	☐ ☐	**Subjects' Selection Equitable:** Has there been changes to the protocol that can potentially alter equitable selection of subjects (45 CFR 46.111(a)(3))?
	Comments if any: Click here to enter text.	
Yes **No**	☐ ☐	**Informed Consent:** Was informed consent sought or will be sought from each prospective subject or the subject's legally authorized representative, and appropriately documented in accordance with, and to the extent required by, HHS regulations at 45 CFR 46.116 and 46.117, respectively (45 CFR 111(a)(4) and (5))?.
	Comments if any: Click here to enter text.	
Yes **No**	☐ ☐	**Data Monitoring:** Has there been any changes in the adequacy of research plans and provision for monitoring the data collected?: to ensure the safety of subjects (45 CFR 46.111(a)(6))?
	Comments if any: Click here to enter text.	
Yes **No**	☐ ☐	**Privacy and Confidentiality:** When appropriate, are there adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (45 CFR 46.111(a)(7))?
	Comments if any: Click here to enter text.	
Yes **No**	☐ ☐	**Vulnerable Population Protection**: Have you altered approved safeguards to protect subjects likely to be vulnerable to coercion or undue influence (45 CFR 46.111(b))?
	Comments if any: Click here to enter text.	
Yes **No**	☐ ☐	**Vulnerable Population Others:** Have you altered of have additional ongoing requirements for IRB approval under HHS regulations at subpart B, C, or D, respectively, of 45 CFR part 46?
	Comments if any: Click here to enter text.	
3. Risk Assessment and Monitoring		
Yes **No**	☐ ☐	**New Information Received Since Approval:** Have you (the investigator) received any new information from sponsors, coordinating center, statistical center,

		independent medical monitoring, data and safety monitoring board or any other sources since last approval?
	Comments if any: Click here to enter text.	
Yes No	☐ ☐	**New Unanticipated Problems:** Have subject in the protocol reported unanticipated problems?
	Comments if any: Click here to enter text.	
Yes No	☐ ☐	**Changes in Risk Benefit Ratio**: Have you made discernable changes in risk benefit ratio since last review?
	Comments if any: Click here to enter text.	
Yes No	☐ ☐	**Ongoing Monitoring**: Is this protocol currently being monitored by a DSMB or have plans for monitoring?
	Comments if any: Click here to enter text.	
	4. Adequacy of the process for obtaining informed consent	
Yes No	☐ ☐	**Informed Consent Version:** Have you used an incorrect version of the consent form based on (date stamps, version #s, or initialing and dating)?
	Comments if any: Click here to enter text.	
Yes No	☐ ☐	**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?
	Comments if any: Click here to enter text.	
Yes No	☐ ☐	**Appropriate Elements of Informed Consent:** Have you made changes to the currently approved or proposed consent document previously deemed to adequately address the elements of informed consent required under 45 CFR 46.116(a) and (b).
	Comments if any: Click here to enter text.	
Yes No	☐ ☐	**New Information:** Do you continuously provide subjects with sufficient opportunity to consider whether or not to participate or that minimize the possibility of coercion or undue influence (see 45 CFR 46.116)).
	Comments if any: Click here to enter text.	
Yes No	☐ ☐	**Findings**: Has there been new findings since approval, and 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).
	Comments if any: Click here to enter text.	

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5. 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.	
Yes **No**	☐ ☐	**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)?
	Comments if any: Click here to enter text.	
Yes **No**	☐ ☐	**Complaints Evaluation**: Have the research team had any complaints lodged against them about the conduct of the research. If so, what was the resolution?
	Comments if any: Click here to enter text.	
Yes **No**	☐ ☐	**Institutional Resources:** Please describe change in the resources available to the study if any.
	Comments if any: Click here to enter text.	
6. Continuing Expedited Review Only		
	Indicate Below the Category Permitting Expedited Review: Confirming that minimal risk criteria remains unchanged: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c8	
Yes **No**	☐ ☐	**Previous approval:** Has the research been previously reviewed and approved by the IRB using expedited procedures?
	Comments if any: Click here to enter text.	
Yes **No**	☐ ☐	**Confirmed no more than Minimal Risk:** Why do you believe that the research continue to meet minimal risk requirements
	Comments if any: Click here to enter text.	
Yes **No**	☐ ☐	**Category 8:** (a) Are you still recruiting new subjects at this site or permanently closed to enrollment of new subjects? **and** Have all subjects completed all research-related interventions? **and** Does the research at this site remain active only for long-term follow-up of subjects?
	Comments if any: Click here to enter text.	
Yes **No**	☐ ☐	**Category 8 (b):** Have you not enrolled subjects at this site **and** Have not identified additional risks anywhere else?
	Comments if any: Click here to enter text.	
Yes **No**	☐ ☐	**Category 8 (c) - Ongoing Activity:** Is your remaining research activities at this site limited to data analysis only?

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	Comments if any: Click here to enter text.	
Yes ☐ **No** ☐	**Category 9:** Is the research conducted under and IND or IDE? (If **YES**, review by a convened IRB is required)?	
	Comments if any: Click here to enter text.	
Yes ☐ **No** ☐	**Previous IRB Determination**: Was you research previously reviewed and designated as no more than minimal risk?	
	Comments if any: Click here to enter text.	
Yes ☐ **No** ☐	**Additional Risk Since Reviewed:** Are you aware of any additional risks been identified since IRB review at a convened meeting? (If **YES**, review by a convened IRB is required)?	
	Comments if any: Click here to enter text.	

7. 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		
☐**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)]?

General Comments:

8. 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.

SIGNATURE		
Principal Investigator	**Signature**	**Date**

Applications/Protocols should be submitted via email to:
IRB-Medical.ORRC@howard.edu (Medical IRB-related submissions)
IRB-NonMedical.ORRC@howard.edu (Non-Medical IRB-related submissions)

For general inquiries or communications, you may use theorrc@howard.edu
Should you have any questions, you may visit our website: www.howard.edu/orrc
Or call the HUIRB office at (202) 865-8597.