Office of Human Subjects Research
Institutional Review Boards

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Date: June 21, 2021

APPLICATION APPROVAL

Review Type:	Convened
Principal Investigator:	Matthew Hamill
Number:	IRB00274090
Title:	Ending the HIV Epidemic through Point-of-Care Technologies (EHPOC): Performance Evaluation of Novel POC HIV Tests in Baltimore
Committee Chair:	Richard Moore
IRB Committee:	IRB-3

Date of Approval: June 9, 2021

Date of review of Administrative Changes: June 9, 2021

Date of Expiration: May 10, 2023

The JHM IRB approved the above-referenced Application.

Please note that the IRB made additional changes to your consent form(s) prior to approval. You may view the revised consent form(s) uploaded in the Written Consent section of the eIRB application. Click on View to the left of the document name, then click History and open the document with the name starting with 'irb_.' If you do not agree with these changes, submit a change in research application with a revised consent form(s). If you submit a change in research application, use the IRB's clean copy of the consent form(s) to make additional revisions. To maintain an accurate history in eIRB, do not delete the consent form(s). If you are making additional changes, use the Update button to upload your revised copy(ies).

IRB review included the following:

Clinical trials must be registered with a clinical trials registry that is electronically searchable and accessible to the public at no charge (i.e.: http://www.clinicaltrials.gov) as required by the September, 2007 FDA Amendments Act (affecting new and ongoing trials as of January 25, 2008). If this is a commercially sponsored trial, the Hopkins PI should consult with the commercial sponsor to assure that posting of the trial is in accord with terms of the study contract.

Progress Report Required:

The Board determined that this research meets the criteria for submission of a Progress Report as an alternative to a Continuing Review Application. The Progress Report must be submitted using a Further Study Action and selecting progress report at least 6 weeks prior to the expiration date. Please note, the Progress Report **must** be submitted prior to the expiration date shown on this notice. If the Progress Report is not submitted prior to the expiration date all activity must stop. Before any research activity can resume, you must submit the progress report.

45CFR46.204 This study has been approved for the involvement of pregnant women and fetuses.

Changes in Research: All proposed changes to the research must be submitted using a Change in Research application. The changes must be approved by the JHM IRB prior to implementation, with the following exception: changes made to eliminate apparent immediate hazards to participants may be made immediately, and promptly reported to the JHM IRB.

Unanticipated Problems: All unanticipated problems must be submitted using a Protocol Event Report.

If this research has a commercial sponsor, the research may not start until the sponsor and JHU have signed a contract.

The JHMIRB is constituted to meet the requirements of the Privacy Rule at section 45 CFR 164.512(i)(1)(i)(B) and is authorized and qualified to serve as the Privacy Board for human subjects research applications conducted by Hopkins' faculty members. The JHM IRB reviewed your request to waive or alter authorization for the above-referenced project. The IRB determined that all specific criteria for a waiver or alteration of authorization were met, as follows:
(A) The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;
(1) An adequate plan to protect the identifiers from improper use and disclosure;
(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
(3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted;
(B) The research could not practicably be conducted without the waiver or alteration; and
(C) the research could not practicably be conducted without access to and use of the protected health information.

Study documents:

Written Consent:

Only consent forms with a valid approval stamp may be presented to participants. All consent forms signed by subjects enrolled in the study should be retained on file. The Office of Human Subjects Research conducts periodic compliance monitoring of protocol records, and consent documentation is part of such monitoring.
FINAL_Hamill_IRB00270490_Consent Form_EHPOC_6.9.21.docx

Recruitment Materials:
FINAL_Hamill_IRB00270490_Flyer 2_6.9.21
FINAL_Hamill_IRB00270490_Horizontal flyer_6.9.21
FINAL_Hamill_IRB00270490_Pocket Size Card_6.9.21
FINAL_Hamill_IRB00270490_EHPOC provider letter_6.9.21
FINAL_Hamill_IRB00270490_EHPOC_poster_6.9.21
FINAL_Hamill_IRB00270490_Facebook and Instagram_6.9.21
FINAL_Hamill_IRB00270490_Flyer 3_6.9.21
FINAL_Hamill_IRB00270490_Flyer 4_6.9.21
FINAL_Hamill_IRB00270490_Flyer 6_6.9.21
FINAL_Hamill_IRB00270490_Flyer 7_6.9.21

HIPAA Form 4:
FINAL_Hamill_IRB00270490_HIPAA Form 4_6.9.21

Additional Supplemental Study Documents:
5-21-2021_Dr. Clarke JHH POCT office.pdf
1PetitiontoResume_NewApplications.docx
HSRPRC Approval.pdf

Protocol:
EHPOC protocol_11APR2021 v1.5_clean.docx

Johns Hopkins Study Team Members:

Yu-Hsiang Hsieh, Agha Mirza, Yuka Manabe, Richard Rothman, Harris Bayan, Travis Smalls, Courtney Pasco