EMORY UNIVERSITY | Institutional Review Board

TO: Patrick Sullivan, DVM PhD
Principal Investigator
*SPH: Epidemiology

DATE: June 18, 2018

RE: **Expedited Approval**
IRB00099710
iSTAMP (Implementation of Rapid HIV Self-Testing among MSM Project)

Thank you for submitting a new application for this protocol. This research is eligible for expedited review under 45 CFR.46.110 and/or 21 CFR 56.110 because it poses minimal risk and fits expedited review categories F(1b, 2a, and 7) as set forth in the Federal Register. The Emory IRB reviewed it by expedited process on 6/15/2018 and granted approval effective from **6/15/2018** through **6/14/2019**. Thereafter, continuation of human subjects research activities requires the submission of a renewal application, which must be reviewed and approved by the IRB prior to the expiration date noted above.

A request to waive documentation of informed consent (i.e. signature) for screening purposes only has been approved. Signed consent must be obtained before doing any human subjects research beyond the screening procedures described in the approved protocol. Please note that you are required to consent subjects for screening with the verbal consent script approved with this submission, and document this consent process. Informed consent has not been waived; only the requirement for subject signature has been waived.

A complete waiver of HIPAA authorization and informed consent has been granted by the IRB. Protected Health Information of which use or access has been determined to be necessary by the IRB:

- HIV Surveillance Data held by state and federal entities

The following documents are approved for use or otherwise acknowledged:

- CDC Grant Application 1U01PS005181-01
- Study Protocol, version date May 3, 2018
- Research Instruments, undated:
  - Eligibility Screener
  - Registration
  - Baseline Survey
  - Follow-up Survey
  - HIV Test Result Reporting Survey
- Recruitment Materials, undated:
  - Facebook ad
  - Grindr-inbox ad
  - Instagram ad

  - General gay interest ad
- Consent Documents, both version date 05/22/2018:
  - Screening Assessment Consent form
  - Main Consent form

Any reportable events (e.g., unanticipated problems involving risk to subjects or others, noncompliance, breaches of confidentiality, HIPAA violations, protocol deviations) must be reported to the IRB according to our Policies & Procedures at www.irb.emory.edu, immediately, promptly, or periodically. Be sure to check the reporting guidance and contact us if you have questions. Terms and conditions of sponsors, if any, also apply to reporting.

Before implementing any change to this protocol (including but not limited to sample size, informed consent, study design, you must submit an amendment request and secure IRB approval.

In future correspondence about this matter, please refer to the IRB file ID, name of the Principal Investigator, and study title. Thank you.

Sincerely,

Samuel Roberts
Senior Research Protocol Analyst
This letter has been digitally signed

CC:	Gravens	Laura	*SPH: Epidemiology
	Weiss	Kevin	*SPH: Epidemiology
	Benkeser	David	*SPH: Biostatistics
	Curran	James	EVP Health Affairs
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