

TO: AD McNaghten
Principal Investigator
Epidemiology

DATE: September 25, 2012

RE: **Full Board Approval**
IRB00057255
Evaluation of Rapid HIV Self-Testing among MSM in High Prevalence Cities

Thank you for submitting a new application for this protocol. The Emory IRB reviewed it at its convened meeting on 8/1/2012, met all of its contingencies on **9/19/2012** and granted effective approval from **8/1/2012** through **7/31/2013**. Thereafter, continuation of human subjects research activities requires the submission of another renewal application, which must be reviewed and approved by the IRB prior to the expiration date noted above. Please note carefully the following items with respect to this reapproval:

- Partial HIPAA waiver was granted

The following devices were determined to be non-significant risk:

- SureCheck'
- OraQuick

Also, these documents have been approved during the initial review:

- eSTAMP Parts 1-2 Protocol 06132012
- Eligibility Screener 05.18.2012
- Focus Group Discussion Guide 05.18.2012
- In Depth Interview Guide 05.18.2012
- Proficiency Assessment Observation Forms 06132012
- Proficiency Assessment Survey 05.18.2012
- Proficiency Assessment Testing Panel Images 05.18.2012
- Eligibility Screener Consent 06132012
- Focus Group Consent 06132012
- In Depth Interview Consent 06132012
- Proficiency Assess Consent 06132012

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,

Aric Edwards
Research Protocol Analyst

This letter has been digitally signed

CC: Ricca Alexandra Public Health
Sullivan Patrick Epidemiology

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