



TO: AD McNaghten, Ph.D
Principal Investigator
Epidemiology

DATE: April 18, 2013

RE: **Notification of Amendment Approval**
AM3_IRB00057255
IRB00057255
Evaluation of Rapid HIV Self-Testing among MSM in High Prevalence Cities

Thank you for submitting an amendment request. The Emory IRB reviewed and approved this amendment under the expedited review process on 4/19/2013. This amendment includes the following:

- Changes to Consent Forms:
 - Added: Part 4 In-Depth Interview Consent Form 03.28.2013
 - Added: Part 4 Participant Self-Test Referral Sheet 03.28.2013
 - Added: Part 4 Study Consent Form 03.28.2013
 - Added: Part 4 Messages for Different Self-Reported Test Results_03.28.2013
 - Added: Part 4 Focus Group Consent Form 03.28.2013
 - Added: Part 4 Basic Study Information 03.28.2013
- Changes to Protocol Documents:
 - Added: eSTAMP Part 4 Lay Summary 3.28.2013
 - Added: eSTAMP Part 4 Protocol 3.27.2013
 - Added: Part 4 Eligibility Screener 03.28.2013
 - Added: Part 4 Follow Up Survey 03.28.2013
 - Added: Part 4 In-Depth Interview Guides 03.28.2013
 - Added: Part 4 Reporting of Self-Test Results 03.28.2013
 - Added: Part 4 Registration 03.28.2013
 - Added: Part 4 Focus Group Discussion Guides 03.28.2013
 - Added: Part 4 Baseline Survey 03.28.2013
- Changes to Study Team:
 - Added: Laura Graves and Colleen Kelley
- Changes to study enrollment
 - Added Part 4 which increases subjects total to 4495

Important note: If this study is NIH-supported, you may need to obtain NIH prior approval for the change(s) contained in this amendment before implementation. Please review the NIH policy directives found at the following links and contact your NIH Program Officer, NIH Grants Management Officer, or the Emory Office of Sponsored Programs if you have questions.

Policy on changes in active awards: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-129.html>

Policy on delayed onset awards: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-130.html>

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

Sincerely,

Aric Edwards
Research Protocol Analyst

This letter has been digitally signed

CC:	Gravens	Laura	Public Health
	Ricca	Alexandra	Public Health
	Sharma	Akshay	Public Health
	Stephenson	Robert	Global Health
	Sullivan	Patrick	Epidemiology

Emory University IRB
1599 Clifton Road, 5th Floor - Atlanta, Georgia 30322
Tel: 404.712.0720 - Fax: 404.727.1358 - Email: irb@emory.edu - Web: <http://www.irb.emory.edu/>
An equal opportunity, affirmative action university