

Attachment 3

Emory University

IRB Approval Letter



EMORY
UNIVERSITY

Institutional Review Board

TO: AD McNaghten
Principal Investigator
Epidemiology

DATE: January 8, 2013

RE: **Notification of Amendment Approval**
AM1_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 12/10/2012. This amendment includes the following:

- Changes to Consent Forms:
 - Added: Part 3 Study Consent 9.25.2012
 - Added: Part 3 Registration 9.25.2012.
 - Added: Part 3 Reporting of Results 9.25.2012
 - Added: Communication Messages 08072012
- Changes to Protocol Document:
 - Added: eSTAMP Part 3 Protocol 9.26.2012
 - Added: Lab Algorithm and Data Plan 08072012
- Changes to Advertisements:
 - Added: Banner advertisements 06272012
 - Added: AIDSvu 06272012
- Changes to Study Team:
 - Added: Robert Stephenson, Catherine Finneran, Mary Ann Chiasson, and Sabina Hirshfield
- Changes to Study Enrollment:
 - Increased to 995 subjects
- Changes to Questionnaire/Survey Materials:
 - Added: Part 3 Baseline Survey 9.25.2012
 - Added: Part 3 Follow Up Survey 9.25.2012
 - Added: Part 3 Registration 9.25.2012
 - Added: Part 3 Eligibility Screener 9.25.2012
 - Added: Part 3 Reporting of Results 9.25.2012
- Other Changes:
 - Altered date for when PHI will no longer be used to August 31, 2015.

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: Ricca Alexandra Public Health
Stephenson Robert Global Health
Sullivan Patrick Epidemiology

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