EMORY UNIVERSITY | Institutional Review Board

TO: Patrick Sullivan, PhD, DVM
Principal Investigator
Epidemiology

DATE: January 26, 2012

RE: **Continuing Review Expedited Approval**
CR1_IRB00047676
IRB00047676
Web-based HIV behavioral trend analysis among men who have sex with men (MSM)

Thank you for submitting a renewal application for this protocol. The Emory IRB reviewed it by the expedited process on 01/22/2012, per 45 CFR 46.110, the Federal Register expeditable category(ies) F(6), F(7), and/or 21 CFR 56.110. This reapproval is effective from **02/08/2012** through **02/07/2013**. 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:

- A request to waive documentation of written/signed informed consent has been reviewed and renewed under 45 CFR 46.117(c)(1): 1) the research is not FDA-regulated AND; 2) the only record linking the subject and the research would be the signed consent document AND; 3) the principal risk of the research would be potential harm resulting from a breach of confidentiality.

Document(s) reviewed with this application:

- EmoryIRBprotocol_HIV_Behavioral_Analysis_10_13_11Editsv09
- 221995_Consent1_4800_MSM Web Surveillance Survey PILOT Consent_Spanish_Version_Version Date: 06/09/2011
- 221995_Consent1_85000_MSM Web Surveillance Survey Consent_Spanish Version_Version Date: 06/09/2011
- MSM Web Surveillance Survey Consent CLEAN 2.11.11.v05
- MSM Web Surveillance Survey Consent_10_13_clean
- MSM Web Surveillance Survey PILOT Consent CLEAN 2.11.11.v01
- WS.InPerson_FGD_Consent.2.10.11 CLEANv04
- WS.Online_FGD_Consent.CLEAN.2.10.11v04

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, and 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,

Carol Corkran, MPH, CIP
Senior Research Protocol Analyst
This letter has been digitally signed

CC:	Khosropour	Christine	Public Health
	Sineath	Robert	Public Health
	Salazar	Laura	Behavioral Science

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