

TO: Patrick Sullivan, Ph.D., DVM
Principal Investigator
*SPH: Epidemiology

DATE: February 25, 2016

RE: **Expedited Approval**
IRB00085716
Mobile Messaging Intervention to Present New HIV Prevention Options for MSM

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 the regulatory categories F[(6) (7)] as set forth in the Federal Register. The Emory IRB reviewed it by expedited process on **02/25/2016** and granted approval effective from **02/25/2016** through **02/24/2017**. 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. Please note carefully the following items with respect to this approval:

- PS-15-002-Notice of Award and Research Project Cooperative Agreement (CDC-Centers for Disease Control and Prevention)
- MMI4MSM IRB Proposal (Nov 24)
- Appendix A - Focus Group Discussion Guide
- Appendix B - In-Depth Interview Guide
- Appendix E - Eligibility Screener and information Collection Form
- Appendix F - Core Messages.pdf
- A Parital HIPAA waiver for identifying potential subjects and determining eligibility was approved.
- Appendix G - Promotional Images and Guidelines.pdf
- Appendix C - Focus Group Discussion Information Sheet
- Appendix D - In-Depth Interview Information Sheet
- Appendix H - Consent to Screen Form
- Waiver of Documentation of Consent was approved
- Public Health Solutions_IAA_FullyExecuted_02222016.pdf
- UMichigan_IAA_FullyExecuted_02232016.pdf
- UMinnesota_IAA_FullyExecuted_02232016.pdf

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

Will Smith, MPH
IRB Research Protocol Analyst

This letter has been digitally signed

CC: Olansky Evelyn *SPH: Epidemiology
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