



EMORY
UNIVERSITY

Institutional Review Board

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

DATE: June 13, 2016

RE: **Expedited Approval**
IRB00087684
Mobile Messaging Intervention to Present New HIV Prevention Options for MSM -
Randomized Controlled Trial

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[(1)(b), (7)] as set forth in the Federal Register. The Emory IRB reviewed it by expedited process on **06/13/2016** and granted approval effective from **06/13/2016** through **06/12/2017**. 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:

- Phase 2 Protocol Final Draft 3-30-16.doc
- Phase II_Assessment 3.30.16
- MMI Eligibility Screener 05.13.16
- Appendix B_Study Description 05.13.16
- Example Online Banner Ads 05.12.16
- MMI Informed Consent Form - 3-30-16.docx
- MMI Screener Consent Form - 3-30-16
- AUCITY Scheduling System Walkthrough 05.13.16
- HealthMindr App Screenshots 05.12.16

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

[William Smith](#)

IRB Research Protocol Analyst

This letter has been digitally signed

CC: Zahn Ryan *SPH: Epidemiology
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