EMORY UNIVERSITY | Institutional Review Board

TO: Paula Frew, PhD/MPH
Principal Investigator
MedInfect

DATE: March 2, 2015

RE: **Expedited Approval**
IRB00077517
Understanding Barriers and Facilitators to HIV prevention for Men Who Have Sex With Men (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 **02/19/2015** and granted approval effective from **02/19/2015** through **02/18/2016**. 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:

- This study meets the criteria for permissible clinical research with children as set forth at 45 CFR 46.404/21 CFR 50.51.
- Parental permission is waived.
- Assent must be obtained of the child as per 45 CFR 46.408/21 CFR 50.55 and Emory's age-based assent guidelines.
- Waiver of signed documentation of consent for the telephone screener is granted.
- There is an IAA in place for RSS to rely on Emory as the IRB of record.

The following documents were included in this review:

- Study protocol, version date 12/16/2014
- Contact Form
- Interview Guide
- Screener
- 5a. Pulse Recruiting Ads English 4.0
- 5b. Pulse Recruiting Ads Spanish 4.0
- 5c. Pulse Flyers English v4.0
- 5d. Pulse Flyers Spanish v4.0
- 3a. Pulse Consent English 6.0, version date 02/09/2015
- 3b. Pulse Consent Spanish 6.0, version date 02/09/2015

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

Olga Dashevskaya, JD
Sr. Research Protocol Analyst
This letter has been digitally signed

Cc: Randall Laura Public Health

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