



EMORY  
UNIVERSITY

Institutional Review Board

TO: Paula Frew, PhD/MPH  
Principal Investigator  
MedInfect

DATE: January 22, 2014

RE: **Expedited Approval**  
IRB00070771  
Understanding barriers to HIV prevention, care, and treatment for persons living with HIV (PLWH)

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 category F[7] as set forth in the Federal Register. The Emory IRB reviewed it by expedited process on 01/22/2014 and granted approval effective from **01/22/2014** through **01/21/2015**. 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.

- Partial HIPAA waiver for identifying potential subjects and determining eligibility was granted.

The following documents were included in this review:

- Study Protocol HIV Barriers and Facilitators, version date 01/15/2014
- Consent form, version date 01/21/2014
- Spanish consent form, version date 01/21/2014

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](http://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  
Research Protocol Analyst

*This letter has been digitally signed*

Cc: Saint-Victor Diane Public Health

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