



Date: April 19, 2016

Paula Frew, Ph.D., MA, MPH
Principal Investigator
SOM: Medicine: Infectious Dis

RE: **Exemption of Human Subjects Research**

IRB00086980

Local Effectiveness Assessment Project, Part II: Case Studies of Local Jurisdictions Providing HIV Services to Men Who Have Sex with Men (MSM)

Dear Dr. Frewr:

Thank you for submitting an application to the Emory IRB for the above-referenced project. Based on the information you have provided, we have determined on **04/19/2016** that although it is human subjects research, it is exempt from further IRB review and approval.

This determination is good indefinitely unless substantive revisions to the study design (e.g., population or type of data to be obtained) occur which alter our analysis. Please consult the Emory IRB for clarification in case of such a change. Exempt projects do not require continuing renewal applications.

This project meets the criteria for exemption under 45 CFR 46.101(b)(2). Specifically, you will .In this project, you will conduct four cross-sectional case studies in Houston, Miami, New Orleans, and Washington, DC. You seek to identify and describe the set of local conditions that currently promote or impede successful delivery of HIV prevention, care, and treatment services to MSM residing in the city. You will take a comprehensive approach and assess jurisdiction-wide factors affecting the effectiveness of MSM services being delivered by local health departments, Ryan White clinical programs, community based organizations, and other private non-governmental organizations in each city. You will also utilize an integrated approach to gather and analyze information, including qualitative and structured data collection methods.

The following documents were reviewed as part of the approval process:

- Appendix B LEAP 2 consent 4.0.DOCX
- LEAP 2 Study Protocol 6.0. DOCX
- Appendix A Scripts and materials v3.0.DOCX
- Appendix C LEAP - 2 Revised KPI Guide - CM Version 4.0.DOCX
- Appendix C LEAP - 2 Revised KPI Guide - HD CBO Version 6.0. DOCX
- Appendix D LEAP - 2 Structured Observation tools v4.0.DOCX
- Appendix E LEAP - 2 Document review tools.docx

Please note that the Belmont Report principles apply to this research: respect for persons, beneficence, and justice. You should use the informed consent materials reviewed by the IRB unless a waiver of consent was granted. Similarly, if HIPAA applies to this project, you should use the HIPAA patient authorization and revocation materials reviewed by the IRB unless a waiver was granted. CITI certification is required of all personnel conducting this research.

Unanticipated problems involving risk to subjects or others or violations of the HIPAA Privacy Rule must be reported promptly to the Emory IRB and the sponsoring agency (if any).

In future correspondence about this matter, please refer to the study ID shown above. Thank you.

Sincerely,

Will Smith, MPH
Research Protocol Analyst

This letter has been digitally signed

CC: Randall Laura SOM: Medicine: Infectious Dis