



May 30, 2017

Paula Frew, Ph.D., MPH
Asst. Professor/Director Community Research
Emory University School of Medicine/Infectious Diseases
Atlanta, GA 30322

RE: Re-Determination: No IRB Review Required
eIRB#: 96631
Title: Understanding Decisions about Pre-Exposure Prophylaxis (PrEP) Refusal and Unsuccessful Uptake of PrEP among High-Risk Men Who Have Sex with Men (MSM)
PI: Paula Frew, Ph.D., MPH

Dear Dr. Frew:

Thank you for requesting a re-determination from our office about the above-referenced project. Based on our review of the additional information you provided, we have determined that it does not require IRB review because it does not meet the definition of "research" as set forth in Emory policies and procedures and federal rules, if applicable. Specifically, in this project, you will assess factors associated with PrEP refusal and unsuccessful uptake, in line with other public health practice efforts to appropriately and successfully implement PrEP as an HIV prevention tool. In addition, this study will explore the acceptability of emerging biomedical HIV prevention options among MSM. Findings will be shared with the CDC to enhance its efforts to promote PrEP use among eligible MSM. The shared findings with the CDC will direct future dissemination including informing the study partners of the results. No PII will be shared with the CDC. There are no plans to directly share findings with study participants. Findings will be shared with stakeholders and via scientific peer-reviewed publications and at scientific conferences and meetings. All disseminated data will be de-identified and stripped of PII or presented in aggregate form.

Please note that this determination does not mean that you cannot publish the results. This determination could be affected by substantive changes in the study design, subject populations, or identifiability of data. If the project changes in any substantive way, please contact our office for clarification.

Thank you for consulting the IRB.

Sincerely,

Will Smith, MPH
Research Protocol Analyst
Emory University Institutional Review Board