



TO: Paula Frew, Ph.D., MPH
Principal Investigator

DATE: May 23, 2016

RE: **Clarification of Exempt Status**

IRB00086980

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

Thank you for requesting clarification of whether the above-referenced study still qualifies as exempt in view of a change in plans. We have reviewed the information you submitted to the IRB on 05/23/2016 and find that the project, as changed, is still exempt from further IRB review.

As you know, a determination of exempt status is good indefinitely unless something changes substantively in the project that affects our analysis. The PI is responsible for contacting the IRB for clarification about any *substantive* changes in the project. Therefore, please *do* notify us if you plan to:

Add a cohort of *children* to a survey or interview project, or to a study involving the observation of public behavior in which the investigators are participating.

- Change the study design so that the project no longer meets the exempt categories (e.g., adding a medical intervention or accessing identifiable and potentially damaging data)
- Make any other kind of change that does not appear in the list below.

Please *do not* notify us of the following kinds of changes:

- Change in personnel, except for the PI
- Change in location
- Change in number of subjects to be enrolled or age range for *adults*
- Changes in wording or formatting of data collection instruments that have no *substantive* impact on the study design

For more information about the exemption categories, please see our Policies & Procedures at www.irb.emory.edu. In future correspondence about this study, please refer to the IRB file number, the name of the Principal Investigator, and the study title. Thank you.

Sincerely,

Will Smith, MPH
Research Protocol Analyst
This letter has been digitally signed

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