



# CITY OF PHILADELPHIA

DEPARTMENT OF PUBLIC HEALTH  
INSTITUTIONAL REVIEW BOARD  
HEALTH CENTER #5  
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<http://www.phila.gov/health/Commissioner/IRB.html>

Donald F. Schwarz, MD, MPH  
Deputy Mayor, Health & Opportunity  
Health Commissioner

S. Gulino, MD  
Chairperson

Judith Samans-Dunn, MSIA, CIP  
Administrator

May 16, 2014

Helena Kwakwa, MD, Director  
HIV Clinical Services  
Ambulatory Health Services  
500 S. Broad Street  
Philadelphia, PA 19146

RE: 2014-21 Context Matters: Measuring Provider and Community Factors in the Sustainable Health Center Implementation PrEP Pilot (SHIPP) Study

Dear Dr. Kwakwa:

The above noted proposed protocol has been determined to be exempt from Institutional Review Board review based upon the following Federal Regulation:

#### 45 CFR 46 PROTECTION OF HUMAN SUBJECTS


Section 101 (b): Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy.

Subsections (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

NOTE: This study will require approval of the Health Commissioner's Office Review Committee, if there is any intent to present or publish.

Should any changes in the procedure be desired, they must be submitted to the IRB in advance in writing. I can be reached at 215-685-7630 or through e-mail at [Judith.SamansDunn@Phila.Gov](mailto:Judith.SamansDunn@Phila.Gov) if you have any questions.

Sincerely,

  
Judith Samans-Dunn, MSIA, CIP  
Administrator

CC: Correspondence file  
2014-21  
S. Gulino, MD  
T. Storey, MD, MPH