



Institutional Review Board
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DATE: June 9, 2016

TO: Jonathan Finkelstein

FROM: Harvard Pilgrim Health Care Institutional Review Board

STUDY TITLE: [190254-16] SPARC: Study of Pneumococcal Antibiotic Resistance in Communities

IRB REFERENCE #: 0809000038

SUBMISSION TYPE: Amendment/Modification

ACTION: APPROVED

APPROVAL DATE: June 8, 2016

EXPIRATION DATE: October 1, 2016

REVIEW TYPE: Expedited Review

Thank you for your submission of Amendment/Modification materials for this research study. The Harvard Pilgrim Health Care IRB has APPROVED your submission.

This submission has received Expedited Review based on the applicable federal regulation.

Please note that any revision to previously approved materials, including adding/removing any data fields for analysis, must be approved by this office prior to initiation using the appropriate revision forms for this procedure. Only IRB approved consent forms, questionnaires, letters, advertisements, etc. may be used in your research.

Unanticipated events/problems involving risks to subjects or others and SERIOUS and UNEXPECTED adverse event(s) that occur during the course of this project must be reported in accordance with the IRB policy. Please use the appropriate event reporting forms for these procedures. All FDA and sponsor reporting requirements should also be followed. All NON-COMPLIANCE issues or COMPLAINTS regarding to this study must also be reported to the IRB.

Please retain this letter with your research records. Research records include all Institutional Review Board submissions and responses and must be kept in the principal investigator's file for a minimum of three (3) years after completion of the study. If you have questions, please contact Paula Tebeau at 617 867-4587 or Paula_Tebeau@hphc.org.