



BROWN

Human Research Protection Program
Office of Research Integrity
Office of the Vice President for Research
Brown University

January 2, 2018

Stefan Gravenstein, M.D.
Department of Health Services, Policy and Practice
School of Public Health
Brown University
Box G-S121-6
Providence, RI 02912

**RE: CORE ELEMENTS OF ANTIMICROBIAL STEWARDSHIP IN NURSING HOMES
(protocol #1612001659)**

Dear Dr. Gravenstein,

Based on the information provided, Phase 2 of your study (program improvement with key informants) does not constitute human subjects research.

Therefore, Phase 2 as described to the Human Research Protection Program in December 2017, does not meet the definition of human subjects research as defined in Title 45 CFR 46.102(f).

The IRB will not need to review Phase 2 activities at this time, but an amendment should be submitted when you are ready to begin work with secondary data.

Please do not hesitate to contact our office should you have any questions regarding this matter.

Sincerely,

Ita Irizarry, MA, CIP
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Human Research Protection Program
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