NCEZID Tracking Number: RD-012411SM

Determination of Non-applicability of Human Subjects Regulations

National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

Project title Phase 3 Emerging Infections Program Healthcare-Associated Infections and Antimicrobial Use Prevalence Survey

Primary contact Shelley Magill **Division/Branch** DHQP/SB

The purpose of this form is to document NCEZID's determination that the above-listed protocol does not require submission to CDC's Human Research Protection Office. Under existing institutional policy, authority to determine whether a project is research involving human subjects or whether CDC is engaged in human subjects research is delegated to the National Centers.

Determination

☒ Project does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required.

☐ Project does not involve human subjects under 45 CFR 46.102(f). IRB review is not required.

☐ CDC is not engaged in the conduct of human subjects research per 2008 OHRP engagement guidance. CDC IRB review is not required. *Investigator has provided documentation of appropriate local review.*

Rationale This is phase 3 of a project that was previously determined to be non-research. This phase of the project describes the large scale implementation of an HAI and antimicrobial use point prevalence survey. The objectives of this activity are to describe the burden of HAI, characterized by pathogen and site of infection, and to describe current antimicrobial use practices. This activity will not explore previoiusly uncharacterized risk factors. This activity is not designed to further the scientific understanding of HAI or of antimicrobial use practices; rather it is designed to monitor the burden of illness and describe current medical practice.

Additional considerations We acknowledge that several of the participating EIP sites will obtain IRB review as a matter of institutional practice. We further acknowledge that CT considers this project to be research; as such, language has been added to the version submitted to CT that refers to this project as research. This form serves to document that NCEZID does not consider this project to meet the regulatory definition of research [45 CFR 46.102(d)] for the reasons described above.

Additional requirements Changes to the data collection instrument for the purpose of remaining consistent with NHSN definitions, should they change, do not need to be submitted for review. However, any other changes should be provided, per usual practice. NCEZID would also like to see any protocol changes/insertions made by participating EIP sites.

Changes in the nature or scope of this activity may impact the regulatory determination. Please discuss any changes with your NC Human Subjects Advisor before they are implemented.

Reviewed by Laura Youngblood, MPH, CIP **Title** Human Subjects Advisor, NCEZID

Signature: _____ **Date:** 2/4/11