

**Determination of Non-applicability of Human Subjects Regulations
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)**

Project title Interim Local Health Department Strategy for Response, Control, and Prevention of Healthcare Associated Infections (HAI) and Antibiotic Resistance (AR)

Primary contact Wendy Vance

Division/Branch DHQP/SSET

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. This authority is delegated to the CDC Centers, Institutes, and Offices under CDC Policies SSA-2010-01 and SSA-2010-02.

Determination

- Project is neither conducted nor supported by a Common Rule agency. IRB review is not required. [45 CFR 46.101(a)]
- Project does not meet the definition of research under 45 CFR 46.102(l). IRB review is not required.
- Project is deemed not to be research under the following provision. IRB review is not required.
- Select, if applicable
- Project does not involve human subjects under 45 CFR 46.102(e). IRB review is not required.
- CDC's role in the project does not meet the threshold requiring submission to HRPO. *Investigator has provided documentation of appropriate local review.*

Rationale

The purpose of this activity is to: network with local health departments (LHDs), building capacity for hospital acquired infection and antibiotic resistance, and evaluating and improving program impact. To improve impact, SSET will conduct a structured data collection, including interviews and surveys among participating LHDs that will capture feedback on the strategy's usability and effectiveness via process and outcome evaluation questions. As the purpose of this project is to evaluate a standard programmatic networking activity, it is consistent with non-research program evaluation. This activity is not designed to contribute to generalizable knowledge.

Additional considerations

Additional requirements

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 James Peterson, PhD

Title Human Subjects Advisor

Signature S James M. Peterson -S
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Date: 2022.03.30 13:08:54 -04'00'

Date 3/30/2022