

STARS Project ID Number:

NCEZID Tracking Number:

STARS Accession Number:

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

Project title

Primary contact

Division/Branch

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.

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

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

Title

Signature:

Date: