

**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 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: \_\_\_\_\_