

NCEZID Tracking 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. 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**

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