NCEZID Tracking Number:

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

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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.

<u>Determination</u>				
☐ Project does not meet the definition of research under	er 45 CFR 46.102(d). IRB review is not required.			
☐ Project does not involve human subjects under 45 C	FR 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. <i>Investigator has provided documentation of appropriate local review.</i>				
Rationale				
Additional considerations				
Additional requirements				
Changes in the nature or scope of this activity may in discuss any changes with your NC Human Subjects				
Reviewed by Laura Youngblood, MPH, CIP	Title Human Subjects Advisor, NCEZID			
Signature:	Date:			