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.		
<u>Determination</u>		
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(I). 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 me appropriate local review.	eet the threshold requiring submission to HRPO.	Investigator has provided documentation of
Rationale		
Additional considerations		
Additional requirements		
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Changes in the nature or scope of this your NC Human Subjects Advisor before	activity may impact the regulatory determina re they are implemented.	tion. Please discuss any changes with
Reviewed by	Title	
Signature	Date	