

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

Project title LRN Special Data Calls

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Division/Branch OD

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 This activity involves the periodic polling of network laboratories to assess preparedness needs. It is not designed to contribute to generalizable knowledge, but rather to assess the particular needs of the laboratories participating in the laboratory response network.

Additional considerations This information collection request is being submitted to OMB.

Additional requirements None.

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 Laura Youngblood, MPH, CIP

Title Human Subjects Advisor, NCEZID

Signature: _____



Date: _____

6/7/10