

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

Project title National Hypothesis Generating Questionnaire for multistate foodborne disease outbreak investigations

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Division/Branch DFWED/ORPB

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 standard questionnaire was developed for use in the initial interview of patients during multistate suspected foodborne disease outbreaks. The use of this form for data collection as described above during an outbreak would not be considered a research activity per CDC guidance since it would be undertaken to identify, characterize, and solve an immediate health problem and the knowledge gained will directly benefit those participants involved in the investigation or their communities. As a non-research activity, this use would not require IRB review.

Additional considerations While no specific individual project is specified, a determination of the need for IRB approval is required for the OMB application.

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 Wendy Carr, PhD

Title Human Subjects Advisor, NCEZID

Signature: _____
wlc

Date: _____
6.14.12