

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

Project title Risk for death from influenza A (pH1N1) among American Indians and Alaska Natives (AI/AN)

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Division/Branch DPEI/AIPI

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 The purpose of this activity is to describe the factors contributing to increased H1N1 mortality in AI/AN population. The activity does not seek to identify new or previously undescribed risk factors; rather the intent is to identify which factors are contributing to the disproportionate burden of severe illness and death in American Indians and Alaska Natives. Results will be used to inform ongoing public health measures as this illness continues to circulate. Because H1N1 transmission continues, and because this activity is not designed to contribute to generalizable knowledge, this activity is considered part of the ongoing public health response.

Additional considerations Protocol has been reviewed by the Indian Health Service IRB and determined to be non-research/public health response. Protocol will also undergo ethical review locally by participating state health departments and tribal entities.

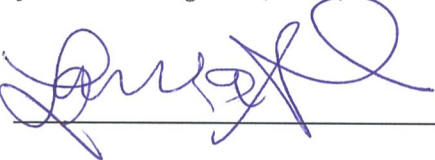
Additional requirements None.

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:

6/23/10