



MAY 27 2010

Indian Health Service
Rockville MD 20852

John Redd, M.D., MPH, FACP
Chief, Infectious Diseases Branch / CDC field Assignee
IHS Division of Epidemiology
5300 Homestead Road, NE
Albuquerque, NM 87110

Re: "Risk for Death from Influenza A (pH1N1) among American Indians and Alaska Natives (AI/AN)" --EXEMPT

Dear Dr. Redd:

The National Indian Health Service (IHS) Institutional Review Board (IRB) reviewed the research protocol entitled "Risk for Death from Influenza A (pH1N1) among American Indians and Alaska Natives (AI/AN)". The IHS IRB **approved** the study protocol effective from the date of this letter. Because it met the criteria of category of being "**Exempt**" from an IRB review under the provision of 45CFR46, it will be not require the monitoring of the IRB and require no additional information to proceed. This decision was based on the information provided that shows this project is a Public Health Practice/Response rather than Research in its intent and purpose.

Work on this project may begin, with the understanding that it will adhere to the Health Insurance Portability and Accountability Act (HIPAA) guidelines, which it currently meets as proposed. This study will not require a continuation annual approval during the duration of the study.

If you make any major changes to the submitted protocol during the period of this study, you must submit a revised protocol to the National IHS IRB for review before implementing the changes. Furthermore, when the results of the research are used to prepare papers for publication or oral presentations at professional conferences, manuscripts or abstracts must be submitted to the IHS Publication and Review committee for pre-publication approval.

If you have any questions about the IRB's decision, please contact me at phone (301) 443-1549, or by e-mail at psmith@hqe.ihs.gov. Thank you for submitting this study proposal to the National IHS IRB. We appreciate your interest in providing the benefits of health research and evaluations to American Indian and Alaskan Native individuals and communities.

Sincerely,

Phillip Smith, MD, MPH
Chair, National IHS IRB/00000646
FWA00008894

cc: File