Attachment I
CDC Research Determination

From: Campbell, Scott (CDC/CCHP/NCBDDD)
Sent: Friday, October 17, 2008 1:38 PM
To: Cragan, Janet D. (CDC/CCHP/NCBDDD)
Cc: Campbell, Scott (CDC/CCHP/NCBDDD); NCBDDD Human Subjects Review (CDC)
Subject: Review of Research Determination #10660 PILOT PROJECT FOR A NATIONAL MONITORING SYSTEM FOR MAJOR ADVERSE EFFECTS OF MEDICATION USE DURING PREGNANCY AND LACTATION

Dear Dr. Cragan:

The project titled "PILOT PROJECT FOR A NATIONAL MONITORING SYSTEM FOR MAJOR ADVERSE EFFECTS OF MEDICATION USE DURING PREGNANCY AND LACTATION" was re-reviewed by the NCBDDD Human Subjects Contact and determined to be:

Research: CDC Not Engaged

As CDC is not engaged in this research, the awardees' local IRB must approve the study, or must rely on the CDC IRB via an inter-agency authorization agreement (IAA) with the CDC HRPO office. Please consult with Scott Campbell for any assistance. The CDC IRB will not review this study as CDC FTEs or on-site contractors are: 1) not intervening or interacting with living human subjects, and 2) will not have access to individually identifiable data. See the email from Jennifer McCleary dated October 8th, 2008, stating CDC HRPO's position on non-engagement in this study. Also see the memorandum from the CDC HRPO group dated July 17, 2007 for further information on engagement in research.

As this project involves CDC funds, please contact Brenda Hayes of NCBDDD RMO for further guidance as to award processing through PGO and/or FMO.

RE-REVIEW REQUIRED: The activities of this award should be monitored closely by the CDC project officer to ensure the activities do not change significantly. If they do, please consult with the NCBDDD Human Subjects Contact to ensure the scope of the activities are still considered research.

Please save this email as documentation of the original determination.

Signed,

Scott

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