

**From:** Campbell, Scott (CDC/ONDIEH/NCBDDD)

**Sent:** Wednesday, December 07, 2016 10:51 AM

**To:** Bitsko, Rebecca (CDC/ONDIEH/NCBDDD) <dvk2@cdc.gov>

**Cc:** Campbell, Scott (CDC/ONDIEH/NCBDDD) <sic3@cdc.gov>; Fox, Michael H. (CDC/ONDIEH/NCBDDD) <imv9@cdc.gov>; Bertolli, Jeanne (CDC/ONDIEH/NCBDDD) <jub7@cdc.gov>

**Subject:** Research Determination 26781: Assessment of Developmental Outcomes in Infants Born with Congenital Zika Infection: An Amendment to Follow-up the Assessment of the association of Zika virus infection and microcephaly

Dear Becky:

The proposed project titled “**Assessment of Developmental Outcomes in Infants Born with Congenital Zika Infection: An Amendment to Follow-up the Assessment of the association of Zika virus infection and microcephaly**” was reviewed by the NCBDDD Human Subjects Contact and determined to be:

**PUBLIC HEALTH PRACTICE: surveillance**

The scope of all activities should be limited to public health practice and must not involve research. Since the project is not considered to be research, no further action is required by CDC for human subjects protections in accordance with federal regulation for the protection of human subjects in research.

RE-REVIEW REQUIRED: The activities of this award should be monitored closely by the CDC project officer to ensure the activities do not involve research. The CDC project officer should request re-review of the activities periodically by the NCBDDD Human Subjects Contact to ensure the scope of the activities are still considered Public Health Practice.

Please save this email as documentation of the original research determination.

Signed,

**Scott**

Scott Campbell, BSN, MSPH

Health Scientist

Centers for Disease Control and Prevention

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**From:** HSR HelpDesk (CDC)

**Sent:** Wednesday, December 07, 2016 10:41 AM

**To:** Campbell, Scott (CDC/ONDIEH/NCBDDD) <[sic3@cdc.gov](mailto:sic3@cdc.gov)>

**Subject:** HSR Protocol: Assessment of Developmental Outcomes in Infants Born with Congenital Zika Infect



The HSR IRB Form (PDF) and associated documents you requested are attached to this email.

## Research Determination - 0.684

<b>System Number</b>	26781
<b>Funding ID</b>	200-2010-37203/N/A/017 ((Contract))
<b>Project Title</b>	Assessment of Developmental Outcomes in Infants Born with Congenital Zika Infection: An Amendment to Follow-up the Assessment of the association of Zika virus infection and microcephaly
<b>Status</b>	Approved By Center
<b>Division</b>	DHDD
<b>Lead Staff Member</b>	Rebecca Bitsko
<b>Subtype</b>	Initial
<b>Project Type</b>	Public Health Practice
<b>Human Subjects</b>	Unknown Type
<b>Exempt Research</b>	Unknown Type

[Email HSR Help Desk](#)