

Ellington, Sascha R. (CDC/ONDIEH/NCBDDD)

From: Youngblood, Laura (CDC/OID/NCEZID)
Sent: Tuesday, August 15, 2017 2:12 PM
To: Newsome, Kimberly (CDC/ONDIEH/NCBDDD)
Cc: Ellington, Sascha R. (CDC/ONDIEH/NCCDPHP); Honein, Margaret (Peggy) (CDC/ONDIEH/NCBDDD); Reynolds, Megan (CDC/ONDIEH/NCBDDD); NCEZIDHumanStudies (CDC)
Subject: FW: US Zika Pregnancy Registry Non-Research Determination Change Justification
Attachments: Justification_ExtraTime_Aug14_2017_USZPRUpdate_CLEAN_SRE.docx; Protocol_US Zika Virus Pregnancy Registry_amendment_7_3_2017_TRACK_EP_....docx

Thanks, Kim.

I have reviewed the revisions to the Zika Pregnancy Registry Protocol, as well as the associated justification for extending the timeframe for infant follow-up. These revisions are reasonable in the context of the recent revisions to CDC's recommendations for infant testing, as well as the growing recognition of outcomes manifesting after 1 year of age. These revisions serve to monitor the outcomes associated with this outbreak, in order to get a full picture of the magnitude and scope of the threat to public health. They also serve to identify the needs of the population.

The extension of the follow-up timeframe remains consistent with original non-research objectives of this project.

Please continue to keep me apprised of any changes as this project progresses.

Laura Youngblood, MPH, CIP

Human Subjects Advisor

National Center for Emerging and Zoonotic Infectious Diseases

lyoungblood@cdc.gov | Office: (404) 639-6394 | Mobile: (404) 510-0093

I will be on part-time assignment to the Office of Scientific Integrity through December 31, 2017. Please continue to copy the NCEZID Human Studies mailbox, NCEZIDHumanStudies@cdc.gov during this time.

I will continue reviewing Zika-related human subjects inquiries during this time. Please continue to copy your home division and the appropriate task force lead on all human subjects requests.

From: Newsome, Kimberly (CDC/ONDIEH/NCBDDD)
Sent: Monday, August 14, 2017 2:05 PM
To: Youngblood, Laura (CDC/OID/NCEZID) <zfk9@cdc.gov>
Cc: Ellington, Sascha R. (CDC/ONDIEH/NCCDPHP) <frk5@cdc.gov>; Honein, Margaret (Peggy) (CDC/ONDIEH/NCBDDD) <mrh7@cdc.gov>; Reynolds, Megan (CDC/ONDIEH/NCBDDD) <xah6@cdc.gov>
Subject: US Zika Pregnancy Registry Non-Research Determination Change Justification

Good afternoon, Laura-

Thank you for your valuable feedback and direction on the US Zika Pregnancy Registry (USZPR) Non-Research Determination (NRD). I have attached a clean version of the justification document which incorporates your latest comments, but please let us know if you have any further suggestions. Our suggestion for the USZPR NRD change is in RED below.

NRD EXCERPT:

Zika virus disease and congenital infection are nationally notifiable conditions, and the WHO has declared the Zika virus outbreak a public health emergency of international concern. The purpose of this activity is to

monitor the frequency and types of adverse birth outcomes for women in the US infected with Zika virus during pregnancy. The registry aims to include all pregnant women with Zika virus infection. Women may be identified through multiple mechanisms. Follow-up information will be requested at the time of birth, and periodically through the first **two** years of the infant's life to monitor for adverse birth outcomes and developmental delays. As an activity designed to monitor the frequency of occurrence of adverse birth outcomes in the context of a public health emergency to provide situational awareness and inform appropriate public health measures, this activity is consistent with the attributes of non-research surveillance and public health response, as described in current CDC policy.

In addition, we will connect with Lee Samuel about the changes to the OMB package that are necessary, and we will update the information on the DVBD contacts in this submission. Please let us know if you need any further input from us in order to approve the changes to the Non-Research-Determination. If not, please provide an updated NRD.

Again, many thanks for all of your support and advice.

Very best regards,
Kim Newsome