

Samuel, Lee (CDC/OID/NCEZID)

From: Youngblood, Laura (CDC/OID/NCEZID)
Sent: Tuesday, August 01, 2017 4:01 PM
To: Kuhnert-Tallman, Wendi (CDC/OID/NCEZID); Samuel, Lee (CDC/OID/NCEZID)
Subject: FW: zika question
Attachments: Lab Communication for Recommended Additional Zika MAC-ELISA EUA QC check....docx

Dear Wendi,

I have reviewed the attached, as well as the referenced EUA instructions for use. I have confirmed that the instructions and solicitation of summary results is a standard QA/QC procedures that is consistent with the terms of the EUA.

Because this is a routine practice that involves the solicitation of only aggregate QA information, a formal written determination is not necessary. However, I am happy to provide one, if requested.

Sincerely,
Laura

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: Kuhnert-Tallman, Wendi (CDC/OID/NCEZID)
Sent: Monday, July 31, 2017 11:01 AM
To: Samuel, Lee (CDC/OID/NCEZID) ; Youngblood, Laura (CDC/OID/NCEZID)
Cc: Ades, Eddie (CDC/OID/NCIRD) (CTR) ; Kuhnert-Tallman, Wendi (CDC/OID/NCEZID)
Subject: zika question

For you both, we are intending to send the following document that outlines additional QC recommendations for the MAC ELISA to all PHLs. It dawned on us that we should speak with both of you about this.... one for a research determination and second for OMB since we are collecting data from the PHLs.

Can you both review and perhaps we could catch up later today? or if you have some initial thoughts that would be appreciated.

Thanks –wendi

Wendi L. Kuhnert-Tallman, Ph.D.
Associate Director for Laboratory Science
National Center for Emerging and Zoonotic Infectious Diseases
Building 16 rm 5119
404-639-3103 - phone
404-235-5166 - fax
wkd1@cdc.gov