

Horovitch-Kelley, Vivian (NIH/NCI) [E]

From: Pursley-Crotteau, Suzanne (NIH/OD) [E]
Sent: Monday, May 18, 2009 12:23 PM
To: Horovitch-Kelley, Vivian (NIH/NCI) [E]
Subject: Form 1572 - OHSR not needed

Good Afternoon Vivian,

Based on the information you have provided and our discussion over the collection of this data, OHSR would say this is not research since this data is being collected to meet FDA requirements prior to the investigation of FDA regulated products. In the event that you would want to analyze and publish all or part of the data you have collected then it would be prudent for OHSR to review your project.

Please let me know if you have any questions.

Best regards,
Suzanne

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From: Horovitch-Kelley, Vivian (NIH/NCI) [E]
Sent: Monday, May 18, 2009 10:40 AM
To: Pursley-Crotteau, Suzanne (NIH/OD) [E]
Subject: OHSR exemption?

Hi Suzanne. I just left you a message. I have an information collection that is more of an administrative, record-keeping collection than it would be considered research. The IC is collecting investigator's names, etc. in accordance with FDA policy. I have attached an overview along with the questionnaires that will be sent out to the investigators to complete. My question is – does this need OHSR review? If not, can you send an email in that regard? Thanks.

Vivian Horovitch-Kelley
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For more information about PRA/OMB clearance:
<http://omaa.cancer.gov/policy/clearances/omb>