

O'Connor, Anne E. (CDC/CCID/NCPDCID)

From: Beltrami, Elise MD (CDC/CCID/NCPDCID)
Sent: Wednesday, June 10, 2009 12:35 PM
To: O'Connor, Anne E. (CDC/CCID/NCPDCID)
Subject: RE: IRB Determination for OMB package

Anne,

I have reviewed the attached data collection request and have determined that it does not constitute research. IRB review is not required.

This data collection is authorized under section 301 of the Public Health Service Act for the prevention of the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. Data will be collected in the event of an outbreak of public health significance. Data to be collected are not meant to be generalized or to contribute to the scientific understanding of specific infectious diseases. As such, this data collection would be considered public health practice. This data collection does not meet the definition of research under 45 CFR 46.102(d), and IRB review is not required.

Please let me know if you have any questions.

Thanks,
Elise

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