

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

From: Subbarao, Shambavi (CDC/CCID/NCHHSTP)
Sent: Wednesday, July 29, 2009 7:06 PM
To: O'Connor, Anne E. (CDC/CCID/NCPDCID)
Cc: Subbarao, Shambavi (CDC/CCID/NCHHSTP)
Subject: IRB determination for LMPB package

Anne,

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

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 and if this information is sufficient.

Regards,

Shambavi

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From: O'Connor, Anne E. (CDC/CCID/NCPDCID)
Sent: Wed 7/29/2009 2:29 PM
To: Subbarao, Shambavi (CDC/CCID/NCHHSTP)
Cc: O'Connor, Anne E. (CDC/CCID/NCPDCID)
Subject: IRB determination for LMPB package

Shambavi -

Based on the conversation we just had with ICRO, would you please provide an IRB determination for the LMPB information collection request? Here's the supporting statement.

<<OMB Supporting Statement LMBP_ao_07 27 2009 (final).doc>>

thanks
Anne

Anne O'Connor, MS, MT(ASCP)
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