

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

From: Youngblood, Laura (CDC/CCID/OD)
Sent: Monday, August 04, 2008 12:02 PM
To: O'Connor, Anne E. (CDC/CCID/NCPDCID)
Subject: FW: IRB determination needed for OMB Clearance package

Importance: High

Attachments: Attachment J - Maritime investigation form FINAL Burden State.doc; Attachment K - Land Border Crossing of Travelers Form FINAL Burden State.doc; OMB Maritime report form revised 50408.doc; Attachment H - Airline Illness Screening form FINAL.doc; Q Station Illness Forms Supporting Statement_August 2008.doc

Dear Anne,

I have reviewed the attached documents, and I confirm that the proposed data are collected for non-research purposes.

The proposed data collection is for routine public health monitoring and response activities, pursuant to Federal regulation. Consistent with public health practice the purpose of the data collection is to identify and control a public health threat. The activity is not designed to contribute to generalizable knowledge.

Therefore, the data collection activity does not constitute research, as defined in 45 CFR 46.102(d). IRB review is not required.

Thanks,
Laura

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From: O'Connor, Anne E. (CDC/CCID/NCPDCID)
Sent: Monday, August 04, 2008 10:49 AM
To: Youngblood, Laura (CDC/CCID/OD)
Cc: O'Connor, Anne E. (CDC/CCID/NCPDCID)
Subject: IRB determination needed for OMB Clearance package
Importance: High

Laura -

OCSO now requires an IRB determination on all information collection requests. This data collection is used by Quarantine station staff when investigating reports of a potential public health threat at the quarantine stations.

Since this is not research and IRB does not apply, I would appreciate your review and determination as quickly as possible. I am attaching the supporting statement and draft forms.

Please let me know if you have questions or comments.

Thanks
Anne

Anne O'Connor, MS, MT(ASCP)
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Attachment J -
Maritime invest...



Attachment K -
Land Border Cro...



OMB Maritime
report form revis...



Attachment H -
Airline Illness...



Q Station Illness
Forms Suppor...