

Vice, Rudith (CDC/NCEZID/OD)

From: Youngblood, Laura (CDC/NCEZID/OD)
Sent: Tuesday, January 30, 2024 3:54 PM
To: Vice, Rudith (CDC/NCEZID/OD); Vera Garcia, Carlos (CDC/NCEZID/DGMH/SBHMB)
Cc: NCEZIDHumanStudies (CDC)
Subject: FW: Non-research: CureTB Information Collection
Attachments: 081716KM-NR-signed.pdf

Dear Rudith,

I have reviewed the original project, and I confirm that the determination of Non-Research continues to apply to this health monitoring project. This information collection is for purposes of public health service delivery, and it does not involve research, as defined at 45 CFR 46.102(l). IRB review is not required.

Thank you,

Laura

Laura Youngblood, MPH, CIP

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From: Peterson, James M. (CDC/OID/NCEZID) <iyr1@cdc.gov>
Sent: Wednesday, August 17, 2016 3:41 PM
To: Moser, Kathleen (CDC/OID/NCEZID) <kzm5@cdc.gov>
Cc: NCEZIDHumanStudies (CDC) <NCEZIDHumanStudies@cdc.gov>; Beltrami, Elise MD (CDC/OID/NCEZID) <ebj4@cdc.gov>; Diaz, Pamela (CDC/OID/NCEZID) <pdd4@cdc.gov>; Khan, Nomana M. (CDC/OID/NCEZID) (CTR) <hyu4@cdc.gov>
Subject: Non-research: CureTB Information Collection

Hi Kathy,

I have reviewed the attached project and determined that it does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required. Documentation of this determination is attached.

This activity involves collecting information on tuberculosis (TB) patients for the purposes of continuity of care after migration or travel. Contact and TB treatment data will be collected and used to ensure that patients are linked to the necessary care after migration or travel. As this project is consistent with non-research public health practice, IRB review is not required per CDC policy. This project is not designed to contribute to generalizable knowledge.

Changes in the nature or scope of this activity may impact the regulatory determination. Please discuss any changes with your NC Human Subjects Advisor before they are implemented.

Good luck to you with this project,

James

James Peterson, PhD
Human Subjects Advisor
National Center for Emerging and Zoonotic Infectious Diseases

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From: Diaz, Pamela (CDC/OID/NCEZID)
Sent: Friday, July 15, 2016 5:29 PM
To: Peterson, James M. (CDC/OID/NCEZID) <iyr1@cdc.gov>
Cc: Khan, Nomana M. (CDC/OID/NCEZID) (CTR) <hyu4@cdc.gov>
Subject: Cure TB determination needed for OMB package

Hi James,

We talked about this effort when we conferenced call this week. It is the CureTB program that I mentioned that is moving from San Diego HD to our US-Mexico unit (DGMQ-USMU) in San Diego. The OMB package is pretty much done. They are just waiting on the forms to get finalized. I've include the San Diego forms for your awareness as the CDC forms will be pretty much the same.

Can you take a look at the OMB package and provide a response with your determination? There is one section in it that I highlighted (in yellow) that would like you to take a look at and make sure it is accurate in representation. Feel free to suggest edit as needed.

Regard,
Pam

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