

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

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**From:** Beltrami, Elise MD (CDC/CCID/NCPDCID)  
**Sent:** Wednesday, September 30, 2009 6:22 AM  
**To:** O'Connor, Anne E. (CDC/CCID/NCPDCID)  
**Subject:** RE: IRB determination for OMB package

Anne,

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

The purpose of this activity is to verify the testing capabilities of laboratories participating in the Laboratory Response Network (LRN). LRN laboratories report biological and chemical agent testing results to CDC and participate in proficiency testing challenges, exercises, and/or validation studies. These actions are used to ensure that there is an integrated national and international network of laboratories that is ready to respond to suspected acts of biological, chemical, or radiological terrorism or other public health emergencies.

As the intent of this project is to evaluate a standard public health practice (i.e., laboratory practices) and not to contribute to generalizable knowledge, this activity does not meet the definition of research.

Please let me know if you have any questions or concerns.

Thanks, Elise

Elise M. Beltrami, MD, MPH  
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**From:** O'Connor, Anne E. (CDC/CCID/NCPDCID)  
**Sent:** Tuesday, September 29, 2009 3:53 PM  
**To:** Beltrami, Elise MD (CDC/CCID/NCPDCID)  
**Cc:** O'Connor, Anne E. (CDC/CCID/NCPDCID); Dieterich, Laurie (CDC/CCID/NCPDCID) (CTR)  
**Subject:** IRB determination for OMB package  
**Importance:** High

Elise -

Would you please provide an IRB determination on this package. It still has some holes, but I don't think the incomplete sections will effect your determination.

<< File: LRN Supporting Statement\_09 29 2009.doc >>

Thanks  
anne

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