

**From:** Youngblood, Laura (CDC/OID/OD)  
**Sent:** Tuesday, March 30, 2010 3:52 PM  
**To:** Nguyen, Lyn (CDC/OID/NCZVED) (CTR)  
**Cc:** Ford-Knights, Paulette (CDC/OID/OD); Beltrami, Elise MD (CDC/OID/NCPDCID); Youngblood, Laura (CDC/OID/OD)  
**Subject:** FW: IRB Determination for the EARS new Data Collection

Lyn,

I have reviewed the attached activity and determined that it is not subject to the requirements of 45 CFR 46, as it is not a research activity as defined in §102(d). Therefore, IRB review is not required.

Thank you,  
Laura

Laura Youngblood, MPH, CIP

Human Subjects Advisor | NCEZID (proposed) | [lyoungblood@cdc.gov](mailto:lyoungblood@cdc.gov) | MTh: (404) 639-6394 | TWF: (404) 510-0093 | MS E-07

**From:** Beltrami, Elise MD (CDC/OID/NCPDCID)  
**Sent:** Tuesday, March 30, 2010 3:45 PM  
**To:** Youngblood, Laura (CDC/OID/OD)  
**Cc:** Nguyen, Lyn (CDC/OID/NCZVED) (CTR); Ford-Knights, Paulette (CDC/OID/OD)  
**Subject:** FW: IRB Determination for the EARS new Data Collection

Laura,  
Could you please respond to the question below?

Thanks,  
Elise

Elise M. Beltrami, MD, MPH  
CAPT, U.S. Public Health Service  
Acting Deputy Associate Director for Epidemiologic Science  
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**From:** Nguyen, Lyn (CDC/OID/NCZVED) (CTR)  
**Sent:** Tue 3/30/2010 3:28 PM  
**To:** Beltrami, Elise MD (CDC/OID/NCPDCID)  
**Cc:** Ford-Knights, Paulette (CDC/OID/OD)  
**Subject:** IRB Determination for the EARS new Data Collection

Hi Elise,

We were wondering if this new request for approval of a new data collection needs an IRB determination. We are requesting OMB approval to have a new registration module component to the current Early Aberration Reporting System (EARS) application. The electronic registration form will be required before the EARS download. The data collected during the electronic registration form submission will be stored in a SQL database. This database is stored on CDC servers and will only be used for user tracking and/or broadcast messages regarding future application releases and/or user surveys. Our identified

user are classified as an organization (entities). Please see the drafted supporting statement, EARS proposed data form, and the FRN 60 day notice for a better overview of this request.

Let me know if you have any further questions.

Thanks.

-Lyn

<<60 day FRN\_DBPR\_EARS\_03\_22\_10.docx>> <<Supporting Statement.doc>>  
<<EARS\_Registration\_Form clean.doc>>