

## Salazar, Silvia (NIH/NCI) [E]

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**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Friday, May 29, 2015 12:07 PM  
**To:** Ousley, Anita (NIH/NCI) [E]  
**Cc:** Bridge, Heather (NIH/OD) [E]; Salazar, Silvia (NIH/NCI) [E]  
**Subject:** RE: Follow-up on Call about IRB determination

Thanks for contacting us Anita. Based on our conversation and my review of the description below, I agree that your planned activity is solely a quality assessment or quality improvement activity, and does not falls within the scope of the definition of research under DHHS regulations (45 CFR 46). As you implied in your email, the definition of 'research' under the regulations, is the following: "a systematic investigation , including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge". Investigations designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or internal product, service or program. Accordingly, there is no need for you to submit a request for a determination to our office.

Feel free to contact us again whenever you have questions.

*Julie M. Eiserman, MA, CCRP* [C]

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**From:** Ousley, Anita (NIH/NCI) [E]  
**Sent:** Thursday, May 28, 2015 4:02 PM  
**To:** Eiserman, Julie (NIH/OD) [C]  
**Cc:** Bridge, Heather (NIH/OD) [E]; Salazar, Silvia (NIH/NCI) [E]  
**Subject:** Follow-up on Call about IRB determination

Julie,

Thank you, and thank you Heather, for talking with Silvia and I today about IRB determination for our usability testing program. It was very useful. As I mentioned on the call, we are preparing the OBM clearance package for submission and one of the items it requests is the IRB approval. Below is a description of the program.

NCI AARB plans to schedule bimonthly Open Call website usability testing sessions starting in FY 2015 to inform revisions and improvements to the NCI website. These regularly scheduled usability testing sessions will provide an opportunity for NCI web portal managers, designers, content managers, application designers, and communications practitioners, to better understand if the website information meets the needs of the users. With a regular schedule of sessions, usability testing can be easily and quickly included for testing the Cancer.gov and Cancer.gov/espanol, without creating a special project or schedule. This will also lead to a greater understanding of appropriate and effective content, structure, navigation and

presentation of information on cancer.gov pages. This is a quality assessment and improvement program and the data collected is strictly about the product/service of interest. The results will be used for improving NCI communication products and will not be generalizable.

Would you please let us know if this project needs to be submitted to your office for IRB determination?

Thank you,  
Anita

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