

# Do I need to get an IRB Exemption for a Usability Study?

From: Shafer, Sharon

Sent: Friday, November 21, 2008 9:31 AM

To: Brunt, Wendy

Subject: Request info re archiving and use of data acquired via IRB exempt studies

Dear Wendy,

You have been so helpful to me when I have applied for and received IRB exemption. I hope you do not mind if I ask you a few more questions. Please feel free to point me to various OPHS documentation.

Goal: Establish and maintain an archive of data from library usability studies to be used by library staff for improving library products and services.

Concern: I am sure there are restrictions on the use of data gathered from IRB exempt studies and I hope to gather information on the restrictions so as to ensure that the UCLA Library is complying and that we are respecting our participant's privacy and expectations.

Some specific questions:

1. Can we archive data?
2. Are there different levels of use of the data (processing, transcribing (can it be outsourced?))
3. What type of access is permissible; under what conditions?
4. We never associate names with the data, but are some data (video vs. audio vs. text) subject to more stringent archiving/use policies?
5. If we can't archive video, can we archive a transcript? Or video, with a black smudge on the face?

Perhaps, I need to write this use of the data in to standardized language to be included in all IRB applications?

Perhaps, I need to submit an IRB application for each new use of the data?

Thanks in advance for pointing me to the correct path concerning archiving and use of IRB exempt gathered data.

-Sharon

Sharon Shafer

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From: Brunt, Wendy

Sent: Wednesday, November 26, 2008 1:36 PM

To: Shafer, Sharon

Subject: RE: Request info re archiving and use of data acquired via IRB exempt studies

Dear Sharon,

Let me see if I can answer some of your specific questions with some general information.

Please note that, if a library usability study will be conducted solely for the purposes of improving library products and services, the study does not need to be submitted to the OPRS/IRB for review. The OPRS/IRB only reviews "research"; research is defined by the federal regulations as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." [45 CFR 46.102(d)] If a library usability study is not intended to contribute to generalizable knowledge through formal publication or presentation, then neither IRB approval nor certification of exemption of the library usability study is required.

Data collected under a protocol that has been certified exempt from UCLA IRB review must be maintained, stored, accessed and archived as described in the application that was reviewed by the OPRS/IRB. If the data will be maintained in an archive for use by library staff for improving library products and services, the protocol should indicate such. If an investigator wanted to modify the procedures for maintaining, storing, accessing or archiving the research data collected under an exempt protocol, the investigator should submit an amendment to the OPRS for review. The investigator should consider what the subjects were told in the consent document about the procedures for maintaining the confidentiality of the data when proposing to modify the confidentiality procedures for a project.

Regarding your last two questions... Yes, this use of the data should be described in all applications submitted to the OPRS/IRB. Each proposed use of the data solely for the purposes of improving library products and services would not require submission to the OPRS/IRB.

Please let me know if you have any additional questions.

Sincerely,  
Wendy

Wendy Brunt  
Administrator  
Office for the Protection of Research Subjects  
University of California, Los Angeles

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