

From	<')">"OS OPHS OHRP (HHS/OPHS)" <OHRP@hhs.gov>
Sent	Thursday, July 13, 2006 11:49 am
To	Jan Blustein <jb81@nyu.edu>
Cc	
Bcc	
Subject	Informed consent for Exempt research

Dr. Blustein -

From a regulatory perspective, if a study is found to be "exempt," then there is no requirement for informed consent.

However, many believe there is still an ethical directive to engage in some sort of consent process for exempt research. The extent of the consent process would depend on the risk of the research, the perceptions of the potential subjects, as well as practical considerations of time and impact on subject recruitment.

Many IRBs handle this by developing guidelines to include in their SOP.

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-----Original Message-----

From: Jan Blustein [<mailto:jb81@nyu.edu>]
Sent: Wednesday, July 12, 2006 2:06 PM
To: OS OPHS OHRP (HHS/OPHS); OS OPHS OHRP (HHS/OPHS)
Subject: Request for clarification

I am hoping that you can provide some clarification on the implications of a project being deemed "Exempt", in terms of informed consent required under the federal regulations.

Suppose, for example, our committee receives an application for a random digit dialing survey on political beliefs. Calls will not be recorded; identities of the respondents will not be sought. We deem the study exempt.

Am I correct that we can decide that all of the elements of informed consent are not required - just to keep it simple, and to keep the response rate up, and for no other reason? That is, can we approve a plan whereby the caller just identifies him/herself, and states the purpose of the survey; and if the respondent stays on the phone, s/he is effectively consenting?

In other words, if a project is exempt and we're satisfied that the procedure meets our collective ethical standards, we need not insist on the investigator satisfying all of the elements of informed consent under the regs? That is my understanding based on a PowerPoint presentation entitled "IRB Flexibility" by G. Pospisil that appears:

<http://www.aera.net/aera.old/humansubjects/courses/APS.htm>

but we would feel more comfortable receiving confirmation from you.

Thank you!

-- JB

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