

IRB Boards and Qualitative Research: Insider Guidance for IRB Forms, Informed Consent

The IRB process was originally designed to ensure participant safety in medical research. As such, the forms are designed for experimental or quantitative methods, focusing on informed consent and research procedures that may cause a risk to human subjects. Most of the people on IRB review boards are unfamiliar with qualitative research as well as the various procedures used in qualitative projects to obtain informed consent. This poses a particular challenge for investigators as their studies may be turned down because of this unfamiliarity with qualitative research and procedures.

This webinar discusses effective strategies to fill out IRB forms for qualitative research and address questions often raised by IRB staff. The webinar starts by explaining that most qualitative projects should qualify as exempt or for expedited review. Your expert presenter will use examples to describe how to write an effective statement to justify an exempt or expedited rating.

This webinar will also focus on informed consent. Most quantitative or

experimental studies have elaborate informed consent forms that participants must sign before the study begins. While some interview and focus group studies will use consent forms, observation techniques and some interview studies will not obtain informed consent from every individual participant. The webinar will discuss when written consent is appropriate and how to write informed consent statements in language accessible to participants. The webinar also discusses obtaining oral consent, consent from agencies for observations and interviews of participants in natural settings, and when informed consent is not needed.

Key Webinar Take-Aways:

- ✓ Why methods statements are the most important and difficult part of the IRB statement, and what you can do to get reviewers to champion yours
- ✓ Clearly understand the rules for exemption and expedited review and be able to state those clearly to IRB staff
- ✓ Strategies for writing appropriate consent forms
- ✓ Strategies to explain situations where consent is not needed or blanket agency consent is appropriate
- ✓ IRB concerns often come from insufficient explanations of methods and informed consent. What you can do to gain IRB approval

Who Should Attend:

Investigators developing qualitative studies. IRB board members and staff

Presented by:

Dr. Jo Anne Schneider has successfully developed IRB statements for a wide array of qualitative studies since the mid-1980s. She wrote the guidelines for IRB approval for students and courses at one university. She has also advised multiple students about informed consent and IRB statements. A former American Association for the Advancement of Science Policy and Technology Fellow at NIH, she is currently an Associate Research Professor at George Washington University. She also has an international reputation for university/community involvement, serving as a PennServe Community Based Fellow for Service Learning involving community/researcher partnerships. Recent major projects include developing a model to reach at-risk communities for NCI, the Faith and Organizations Project (www.faithandorganizations.umd.edu), and multiple projects related to social welfare and human services (see home.gwu.edu/~jschneid).