

Guide to Prereviews

Introduction

- Adequate justification and rationale for conducting study, citing previous research and the literature if appropriate

Methods and Procedures

Subject Characteristics and Recruitment

- Where and how subjects are being recruited and how consent/assent will be obtained
- Request for waiver of documentation of informed consent and substitution of informational cover letter, and justification
- Request for waiver of informed consent itself, citing justification (4 items from federal regs)
- Statement clarifying that subjects will all be fluent enough in English and no translations are needed, or see attachments below
- Language is in future tense and not past tense
- For those using a snowball method of recruitment, it should state that subjects will be asked to pass along information to others who might be interested, giving the researcher's contact information, rather than ask subjects to give prospective subjects' contact information without their permission.

Research Instrumentation/Material

- Adequate explanation of what the subject will be asked to do, including expected time commitment
- Adequate explanation of how the project will unfold, including administration and collection of surveys
- Clarification whether anonymous or confidential, including adequate description of how anonymity or confidentiality will be maintained

Analysis of Data

Risks

- There is always at least minimal or little risk or few risks; never “no risk” or “no known risks” or “no anticipated risks”
- There is always a risk to anonymity or confidentiality

Risk Reduction

- Repetition of how anonymity or confidentiality will be maintained
- Storage and disposition of data, consent/assent forms, tapes, etc. Items must be kept in separate, locked locations – identifiable separate from unidentifiable
- Identifiable information should be kept on campus, but tapes may be taken home to view temporarily
- If tapes are being used for transcription purposes, they may be destroyed immediately following transcription
- Tapes should specify “audiotapes” or “videotapes”

- Items must be kept for a minimum of three years following completion of the study, but may be longer
- If sensitive information is being collected, there should be a statement that subjects will be told they may refrain from answering any question that makes them uncomfortable
- If sending back anonymous questionnaires in postage prepaid envelope, the researcher should be placing his/her own return address in the return address portion and indicating that subjects will be reminded in the informational cover letter not to place any identifying information on the survey or envelope

Risk/Benefit Ratio

- Adequate comparison of risks and benefits, clearly showing that the benefits outweigh the risks
- Benefits are stated throughout as expectations, not definite outcomes, i.e. “We expect” or “We hope” rather than “The study will”
- If focus groups, they should be reminded not to share information outside the group

Attachments

- For students and NIH-funded projects: tutorial quiz score
- Survey and interview instruments
- Subject consent/assent forms, parent consent where applicable
- *Foreign language translations and back translations to English, of survey instruments, consent/assent forms, and informational cover letters, as appropriate
- For anonymous studies and studies where further assurance of confidentiality is needed, informational cover letter
- Letter of permission from external entity if project conducted elsewhere, including DCFS approval and court orders
- IRB approvals from other universities, school districts

Consent/assent forms

- If sensitive information is being collected, there should be a statement that subjects will be told they may refrain from answering any question that makes them uncomfortable
- If focus groups, they should be reminded not to share information outside the group

*Translations may be turned in later, after English versions have been approved