

What Works: Evidence-Based Ethical Problem Solving

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Acknowledgement

Most of the ideas presented here
are based on articles published in
*Journal of Empirical Research on Human Research
Ethics (JERHRE)*

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acknowledged. For details, visit:*

www.csueastbay.edu/JERHRE/notes

and

UC Press at <http://caliber.ucpress.net/loi/jer>

You suspect that your IRB
will mess up your study to
“protect human subjects”
aka

“protecting the institution from OHRP.”



The IRB's concerns should also be methodological concerns of yours:

- Review the relevant literature on the ethical issues and solutions! Include it in your protocol!
- Will the subject population actually understand the informed consent? (20 pages of legalese or understandable language)
- How will subjects feel about their participation? (Guess at perceived benefits or harms, or empirically ascertain them)
- Are you asking subjects questions that are too sensitive? (Censor the ones the IRB dislikes, or ask a focus group of your subjects)
- Will subjects participate if they have to sign a consent form and get paid with a check rather than cash? (Argue with the IRB or ask a sample of the subjects.)
- Will youngsters participate if you have to have parental permission? (Argue with the IRB or ask the kids. Find out what risks to the kids inhere in getting parental permission.)
- Are you paying your subjects so much that it is coercive? (Ask, in a focus group, how much they need to be paid before they will participate.)

You plan empirical inquiry. So..

- Should you ask for funding to cover the pilot inquiry? (Write rationale into grant. Demonstrate competence and ethical concern.)
- Should you do the pilot inquiry even if you don't have funding for it? (Essential, but not necessarily very expensive.)
- Should your inquiry be rigorous enough to be published? (If not, it may persuade no one, least of all the IRB.)

Staying discovered



- *“Columbus wasn’t the first to discover America—but when he discovered it, it stayed discovered.”*
- *Many have discovered **effective ways** to study AIDS and substance abuse but have failed to publish it. Publish what you learn so that others can benefit. Join those who share results of evidence-based ethical problem solving.*

Discussion Topics

- **Informed consent**
 - Learning their language
 - Using analogies to explain, e.g., random assignment, placebos
 - When the lawyers insist on 20 pages
 - Parental permission
 - Signed consent
 - Tribal cultures
- **Risk and benefit**
 - How do subjects feel about participating (before and after)? RRPQ Scale (Newman)
 - Sensitive questions – Newman, et al; Fendrich, et al
 - Learning who should opt out with the RRPQ
 - What benefits do subjects want? (relationship, informational resources, education)
 - Risk of suicide (Gould, et al, 2006)
- **Certificates of Confidentiality & the standard disclosure**
- **Mandatory reporting**
- **“Snowball” sampling – what are the risks?**
- **Ethnography – explaining it to your IRB.**
- **Sharing data & with whom? A requirement or a risk?**
- **Deception**

If We Run Out of Time

All of the topics are cited on the next pages. Keep that and find the information on the web, look it up in JERHRE, or JERHRE Notes, or contact joan.sieber@csueastbay.edu

Informed Consent

Use cognitive interviewing to learn the language your subjects use:

- “Think aloud method” ask a sample of subjects to think aloud about what they think you mean by the terms you use in an “official” consent to identify misunderstanding.
- Verbal probing – to learn what people think something means, and how they would describe it in their own words.

See Gordon Willis (2006). Cognitive interviewing as a tool for improving the informed consent process. *JERHRE*, 1(1), 9-23.

This article can be accessed free of charge from UC Press at:

<http://caliber.ucpress.net/loi/jer>

A brief description of “Cognitive Interviewing” can also be accessed as a JERHRE Note online at:

www.csueastbay.edu/JERHRE/notes

Using Analogies to explain difficult concepts, e.g., random assignment



See: Amy Corneli, et al (2006). Using formative research to develop a context-specific approach to informed consent in clinical trials. *JERHRE*, 1(4), 45-60.

Or see: www.csueastbay.edu/JERHRE/notes "Using Analogy to Explain Research Methods"

Tribal Cultures

Applying communal concepts and other local cultural norms to the informed consent process:

African experience: See

- Woodsong, et al (2006). Women's autonomy and informed consent in Microbicides Clinical Trials, *JERHRE*, 1(3), 11-26.
- Sidle, et al. (2006). An international needs assessment for building capacity in research ethics: Creating a viable research collaboration. *JERHRE*, 1(2), 23-38.

Native American experience: See

- Glass & Kaufert (2007). Research ethics review and aboriginal community values: Can the two be reconciled? *JERHRE*, 2(2), 26-40. See also "Aboriginal Community Values" at www.csueastbay.edu/JERHRE/notes

When Lawyers Insist on 20 Pages

Contact Martin Tolich for his document “Enhancing Informed Consent in 472 words” martin.tolich@otago.ac.nz; or phone: 03-479-8755.

Parental Permission

See: Diviak, et al, (2004). Human participants challenges in youth tobacco cessation research: Researchers’ perspectives. *Ethics & Behavior*, 14(4), 321-334.

Risk & Benefit

Perceived risks and benefits. See:

- Newman, et al (2006). Ethical issues in trauma-related research: A review. *JERHRE*, 1(3), 29-49.
- See also: “Reactions to Sensitive Research” at www.csueastbay.edu/JERHRE/notes
- Fendrich, et al. (2007). Respondent reactions to sensitive questions. *JERHRE*, 2(3), 31-38.

Risk of Suicide. See:

- Gould, et al (2005). Evaluating iatrogenic risk of youth suicide screening programs: A randomized clinical trial. *JAMA*, 203(13) 1635-1643.

Certificates of Confidentiality

- See: Catania, et al. (2007). Research Participants' Perceptions of the Certificate of Confidentiality's Assurances and Limitations. *JERHRE*, 2(4).

Mandatory Reporting

- See: "Mandated Reporting" *JERHRE*, 2(1), 61-64.

Respondent Driven (Snowball) Sampling

- See: "Stigma" *JERHRE*, 2(1), 65-67.

Explaining Ethnography to your IRB

- See: Tolich & Fitzgerald (2006). If ethics committees were designed for ethnography. *JERHRE*, 1(2), 71-78.

Sharing Data: A Requirement or a Risk?

- Cooper (2007). Sharing data and results in ethnographic research: Why this should not be an ethical imperative. *JERHRE*, 2(1), 3-19.
- O'Rourke, et al. (2006). Solving problems of disclosure risk while retaining key analytic uses of publicly released microdata. *JERHRE*, 1(3), 63-83.
- Rodgers & Nolte. (2006). Solving Problems of disclosure risk in an academic setting: using a combination of restricted data and restricted access methods. *JERHRE*, 1(3), 85-97.