To IRB or Not to IRB? That Is the Question!

Presented by
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Why Did Human Subjects Research Become an Issue?

- Nazi Experiments (1933 – 1945)
- Willowbrook Hepatitis Experiments (1950)
- Milgram's Obedience Studies (1960s)
- Tuskegee Syphilis Study (1932 – 1972)

What was the response to the ethical lapses?

- 1947: The Nuremburg Code (Allied Judges in Trials of German War Criminals)
- 1964: The Declaration of Helsinki (World Medical Association)
- 1974: Title 45, Part 46 in the Code of Federal Regulations (45 CFR 46)
- 1978: The Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research)
- 1991: Common Rule (U.S. Dept. of HEW, now HHS and 16 other federal agencies)

Nuremberg Code

1) Voluntary consent
2) Research yields social benefits unobtainable in other ways
3) Anticipated results justify the research
4) Avoid all unnecessary physical or mental suffering
5) No *a priori* reason for potential death or disability
6) Risks should never exceed humanitarian import of problem studied
7) Preparations and facilities protect subjects from harm
8) Qualified investigators
9) Subjects free to withdraw
10) Investigator will terminate research if potential for harm arises

The Declaration of Helsinki

"Concern for the interests of the subject must always prevail over the interests of science and society."

Code of Federal Regulations, Title 45: Public Welfare, Part 46: Protection of Human Subjects (45 CFR 46)

- Requirements for institutional assurances of compliance with federal requirements related to protection of human research subjects
- Requirements for obtaining and documenting informed consent
- Requirements for Institutional Review Boards (IRB) including membership, function, operations, review of research, and record keeping.

The Belmont Report

- Respect for Persons
  - Individuals are autonomous agents
    - Informed consent
    - Privacy and Confidentiality
  - Those with diminished autonomy entitled to special protection
- Beneficence
  - Do not harm
  - Maximize possible benefits and minimize potential harm
- Justice
  - Equitable distribution of research burdens and benefits

Important 45 CFR 46 Definitions

- Research: ". . . a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." (102.d)
- Human Subject: ". . . a living individual about whom an investigator (whether professional or student) conducting research obtains
  - data through intervention or interaction with the individual, or
  - identifiable private information . . . [i.e.,] information about behavior in a context in which an individual can reasonably expect that no observation or recording is taking place or information provided for specific purposes that the individual can reasonably expect will not be made public." (102.f)

Important 45 CFR 46 Definitions

- Minimal Risk: "The probability and magnitude of harm or discomfort anticipated in the research are not greater . . . than those encountered in daily life or the performance of routine physical or psychological examinations or tests." (102.i)
- Children: ". . . persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." (402.a)

Important 45 CFR 46 Definitions

Institutional Review Board (IRB): "An independent administrative body established to protect the rights and welfare of human research subjects . . . ." (S. Sapp)

- At least five members
- Varied disciplinary backgrounds
- Qualified to review research
- Diverse
- At least one member with scientific background and at least one with nonscientific background
- No conflicts of interest
- May invite people with specialized expertise to advise on specific reviews where the IRB lacks expertise

Categories of IRB Review

- Full Review: Research that potentially poses more than minimal risk to human research subjects must be reviewed by the entire IRB.
- Expedited Review: Certain kinds of research can be reviewed more quickly by one or more experienced IRB members either because
  - the research is found by the reviewer(s) to involve no more than minimal risk, or
  - it involves minor changes in previously approved research during the period (one year or less) for which approval was authorized.

and . . .

Categories of IRB Review

Exempt: Determined by the IRB, NOT the Researcher

- Research conducted in established or commonly accepted educational settings, involving normal educational practices.
- Research involving the use of educational tests, survey procedures, etc., unless the information is identifiable and disclosure would place the subject at risk. (Survey and interview research with children are NOT EXEMPT!)
- Research involving educational tests, surveys, interviews or observation of public behavior if the subjects are elected or appointed public officials unless federal statutes require confidentiality without exception.
- Research involving the collection or study of existing data if the sources are publicly available or the information is recorded in a manner in which the subjects cannot be identified.
- Research and demonstration programs designed to study, evaluate, or examine Federal public benefit or service programs.

Why do IR professionals sometimes overlook their obligations to protect human subjects?

- IRB guidelines contain exemptions for many activities in IR, so some assume that all IR activities are exempt.
- IRB review adds an additional layer of bureaucracy, which may slow a project requiring quick turnaround.
- IR professionals often have backgrounds outside the scholarly disciplines where human subject protection is more commonplace.
- Some institutions do not have mechanisms for reviewing human subjects research and assume external review of research is not necessary.

“Research” Can Include

- Formal investigations
- Surveys
- Pilot projects
- Exploratory studies, including manipulations of data files
- Student independent studies, theses, or dissertations
- Some demonstration activities
- Some service programs

Generally, "Research" Does NOT Include

- Classroom activities that teach research methodologies or simulate research activities.
- Activities conducted to improve the quality of teaching in a particular course or classroom.
- Activities required for quality assessment (QA) or quality improvement (QI), including those activities designed for institutional evaluation/improvement.

What Triggers an IRB Review?

- The study is a systematic investigation about individuals,
- The study involves interactions with persons,
- Individuals are identifiable (note, studies tracking respondent participation—even if only in a database—can fall under the purview of the IRB)
- The findings are generalizable to others,
- The findings will be published or shared publicly outside the institution.

Benefits of IRB Oversight

- Helps protect subjects from harm; researchers may not recognize potential threats and risks inherent in the study (e.g., coercive protocols or letters of consent)
- Provides objective/outside review of the researcher's work; sometimes we're too close to the project to see its flaws; easy to overlook ambiguous or confusing protocols, offensive or biased questions, etc.
- Ensures researcher adheres to commonly accepted standards; provides guidance and encourages good practice
- "Seal of Approval" that comes with successful IRB review helps with recruitment of subjects and gaining cooperation
- Reassures stakeholders that study will be conducted with integrity

If Your Institution Doesn't Have an IRB

- All "research" involving human subjects should undergo IRB review.
- If your institution has no IRB, ask an IRB at a nearby institution for help.
- Get commitment of senior leadership and key researchers.

Becoming Certified

- Most universities and a growing number of community colleges require everyone contributing to the design of projects involving human subjects and those working with human subjects to complete human subjects training including:
  - All personnel responsible for recruiting subjects, obtaining informed consent, conducting procedures, and analyzing data
  - All investigators listed on a grant proposal
  - Subcontractors
  - Consultants
  - Students conducting research
  - Any new investigators or other staff added during the project
- Local training includes institution-specific requirements in addition to federal regulations.
- A variety of online training modules are accessible via the Internet.

Key Considerations

- The opportunity to conduct research using human subjects is a privilege granted by the participants.
- With privilege comes responsibility, including recognizing the potential to do harm—either directly or indirectly.
- "Harm" may be social, psychological, financial, or physical.
- The subject, researcher, institution, and community may be harmed.
- Researchers must seriously consider risks and exercise due diligence (e.g., IRB review).
- The issue is ethical rather than regulatory: anyone who engages in research involving human subjects has an obligation to ensure the well-being of those subjects.

Implications for Institutional Researchers

- Become familiar with federal guidelines and standards for research.
- All staff members who have major contact with data should be certified.
- Public institutions: Become familiar with federal and state freedom of information laws which have implications for cover letters and consent forms (e.g., respondents will need to know that their responses could be released under freedom of information laws).

Implications for Institutional Researchers

- Work with your IRB in advance to determine which categories of activities are likely to fall under exempt, expedited, or full review.
- Most IR surveys, focus groups, and interviews will qualify for exempt or expedited review.
- Anonymous surveys qualify as exempt, but you still need to submit to IRB, which determines if project is exempt.
- Remember: decisions about which activities should be reviewed by the IRB belong to the IRB, not to IR.

Implications for Institutional Researchers

- ALL material (survey instruments/focus group protocols, instructions to subjects, invitations and follow-up communications, flyers) must be approved in advance by an IRB.
- ALL changes must be submitted as amendments.
- Plan ahead: seek IRB approval **BEFORE** you do research, it cannot be granted retroactively.

National Surveys and Working with Vendors

- Just because an outside organization conducting a national survey (e.g., the federal government, its contractor, or another university overseeing the survey) has approval from its own IRB does not mean you do not need your own IRB review.
- If data from your students or faculty will be included in a national research project (e.g., CIRP, NSSE), your project is considered an affiliate of the larger research program and requires IRB approval at your institution.
- Check with your IRB—rules on affiliates may vary.

Under-age participants

- Students under legal age for consent (in Texas, 18 years of age) are defined as “children” and therefore fall into the category of “vulnerable” populations, requiring permission from their guardians before participating in any survey.
- It’s usually easier to exclude all students under 18 from your sample.
- Note, prisoners and pregnant women are also considered vulnerable population.

Informed Consent

- All subjects must provide informed consent before participating.
- Since obtaining written consent is often impractical, consider requesting waiver of signed consent and include a statement such as, “Completion and return of the enclosed questionnaire indicate your consent to participate in this study.”
- Instructions should include all elements of informed consent (e.g., participation is voluntary, risks & benefits, contact person). Consider saying something like “Federal regulations require that we inform you of the following:” and then list the elements.

Web Surveys

- Subjects must be allowed to skip items on a Web survey.
- Avoid Web-based surveys that require a response to proceed.

Do surveys and focus groups conducted by IR need IRB approval?

Answer depends on two criteria:

1) Is the project "Human Subjects Research" (HSR) or "Quality Assurance" (QA)?
   - QA doesn't need IRB approval, but HSR does.
   - This distinction is not in regulations or guidelines, but is generally accepted.
2) If the project is QA, will the results be used internally or externally?
   - If it is strictly internal, IRB involvement is not needed.
   - If it is external or includes sensitive questions, it is prudent to consult your IRB.

What distinguishes Human Subjects Research from Quality Assurance?

Answer:

- Research: systematic investigation, research development, testing and evaluation, intended to "contribute to generalizable knowledge"
- Research: Audience external rather than internal (sharing publicly is recognized as an aspect of "generalizable knowledge")

If a project does not have IRB approval, can results be published in a professional publication or presented at a professional conference?

Answer:

Definitely not! (Note: Information shared at a conference it “generalizable knowledge” even though it’s not published in print.)

If a project started as a QA customer satisfaction survey but you want to share results at a conference, can you do it if there was no prior IRB approval?

Answer:

- No. Once you skip the IRB process, you cannot share findings at conferences or in publication.
- There is no such thing as “retroactive approval” for human subject research.

If a project does not have IRB approval, can results be shared with a colleague at another institution?

Answer:

This is a gray area. It would depend on what the colleague is planning to do with data.

If a project does not have IRB approval, can results be published as part of marketing material?

Answer:

- Probably not, because marketing is intended for an external audience rather than just QA.
- It's safer to check with IRB.

If a project does not have IRB approval, can results be used to draw conclusions to develop questions for follow-up research that will be published?

Answer:

- Yes. This is a good option for research that might lead to conclusions you want to share publicly.
- Just don't use any pilot data in follow-up research.

If a project does not have IRB approval, can results be shared in a presentation/report to the Board or senior leadership?

Answer:

Yes. This is QA for an internal audience.

Resources

- "Directives for Human Experimentation: Nuremberg Code," 1949, https://ori.hhs.gov/chapter-3-The-Protection-of-Human-Subjects-nuremberg-code-directives-human-experimentation
- "Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects," World Medical Association, adopted June 1964, amended 1975, 1983, 1989, 1996, 2000, http://www.wma.net/en/30publications/10policies/b3/
- "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research," The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979, U.S. Department of Health, Education, and Welfare. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

Resources

- Code of Federal Regulations, U.S. Department of Health And Human Services, Part 46 Protection of Human Subjects, Revised June 23, 2005, Effective June 23, 2005, (45 CFR Part 46), https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
- "Guidelines for the Conduct of Research Involving Human Subjects at the National Institutes of Health" (Gray Booklet), U.S. Department of Health and Human Services, 5th Printing, August 2004, http://www.nccamwatch.org/research/human_guidelines.pdf
- "IRB Guidebook," Office for Human Research Protections (OHRP), U. S. Department of Health and Human Services, https://archive.hhs.gov/ohrp/irb/irb_guidebook.htm

Resources

- U.S. Department of Health & Human Services, Office for Human Research Protections, E-Learning Modules, https://www.hhs.gov/ohrp/education-and-outreach/online-education/e-learning-modules/index.html
- U.S. National Institutes of Health, Office of Extramural Research, Protecting Human Research Participants, online training (free, but requires login), https://phrp.nihtraining.com/users/login.php
- U.S. National Institutes of Health, Research Involving Human Subjects "Resources." https://humansubjects.nih.gov/resources

Resources

- YouTube, “Office for Human Research Protections (OHRP)” https://www.youtube.com/view_play_list?p=5965CB14C2506914
- YouTube, “When the Regs Come a' Knockin': Nuts and Bolts of 45 CFR part 46,” https://www.youtube.com/watch?v=ET3Sv4esu2w&list=PL5965CB14C2506914&index=5

Questions?

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