

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

A presentation by

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Why did protection of the human subjects of scientific research ever become an issue? Isn't this something responsible scientists do as a matter of course? Why do we need to worry about it?

- NAZI Experiments (1932 – 1945)
- Atomic Weapons Testing (1945 - 1962)
- Willowbrook Hepatitis Experiments (1950)
- Jewish Chronic Disease Hospital Cancer Studies (1963)
- Milgram's Obedience Studies (1960s)
- Humpheries' Tearoom Trade Study (mid-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)
- 1962: *Human Guinea Pigs* (Maurice Papworth)
- 1964: The Declaration of Helsinki (World Medical Association)
- 1966: “Ethics and Clinical Research” (Henry K. Beecher)
- 1974: National Research Act (U.S. Congress)
- 1974: The Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research)
- 1974: 45 CFR 46 (U.S. Dept. of Health, Education & Welfare, now the U.S. Dept. Health & Human Services)
- 1991: “Common Rule” (15 U.S. Federal Departments and Agencies)



# Key Points of the Nuremberg Code

- 1) Voluntary consent of subjects
- 2) Research must yield 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.”

# Key Points of the Belmont Report

- Respect for Persons
  - Individuals as 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

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.



# Important Definitions

## 45 CFR 46

- **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 Definitions

## 45 CFR 46

- **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 Definitions

## 45 CFR 46

- **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 or 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.



# Final Contextual Point

- Whether an individual or an institution engages in research that is covered under the auspices 45 CFR 46 and complies with its requirements is not the issue.
- The issue is ethical, not regulatory!
- The issue is that anyone who engages in research involving human subjects has an ethical obligation to ensure the well-being of those human subjects.

# Resources (1 of 3)

- “Directives for Human Experimentation: Nuremberg Code,” 1949, <http://www.nihtraining.com/ohsrsite/guidelines/nuremberg.html>.
- “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.nihtraining.com/ohsrsite/guidelines/helsinki.html>.
- “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. <http://www.nihtraining.com/ohsrsite/guidelines/belmont.html>.

# Resources (2 of 3)

- 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), <http://www.nihtraining.com/ohsrsite/guidelines/45cfr46.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.nihtraining.com/ohsrsite/guidelines/GrayBooklet82404.pdf>.
- “IRB Guidebook,” Office for Human Research Protections (OHRP), U. S. Department of Health and Human Services, [http://www.hhs.gov/ohrp/irb/irb\\_guidebook.htm](http://www.hhs.gov/ohrp/irb/irb_guidebook.htm).



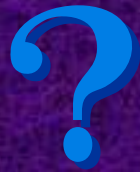
# Resources (3 of 3)

- OHRP Online Training Modules related to (1) DHHS Regulations & Institutional Responsibilities, (2) Investigator Responsibilities & Informed Consent, and (3) Human Research Protections Program (free, but requires login),  
<http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>.
- U.S. National Institutes of Health Online Investigator Training and IRB Member Training (free, but requires login),  
<http://ohsr.od.nih.gov/cbt/cbt.html>.
- U.S. National Institutes of Health Online Training Module, “Human Participant Protections Education for Research Teams,” (free, but requires login),  
<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>.



# Questions and Answers Relating to IRBs





# Do surveys and focus groups conducted by an institutional research (IR) or other administrative offices need IRB approval?

Answer:

- First Criterion: 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 accepted.
- Second Criterion: 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 HSR from QA?

Answer:


- Research: “systematic investigation,” “research development, testing and evaluation,” intended to “contribute to generalizable knowledge”
- Audience external rather than internal (sharing publicly is recognized as an aspect of “generalizable knowledge”)
- Federal agency revisiting definitions in Common Rule, including “research,” and may rewrite regulations or issue guidance



## **What do you do if your institution does not have an IRB?**

Answer:

- An IRB at another institution can review your research.



## **If your institution neither has an IRB nor generates much research, why do you need an IRB, and how do you organize an effective one?**

Answer:

- All human subjects research should have IRB review.
- Get commitment of senior leadership and key researchers.
- Ask an IRB at a nearby institution for help.





**If a project does not have IRB approval, can results be published in a professional publication?**

Answer:


- Definitely not!



**If a project does not have IRB approval, can results be presented at a professional meeting?**


Answer:

- Definitely not! (Even though not published in print, generalizable knowledge is being shared at the meeting.)

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


Answer:

- A gray area—would depend on what the colleague is planning to do with it

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


Answer:

- Probably not, because it is no longer really QA, but is intended for external audience
- Whether marketing is truly “HSR” may be questioned, but 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 might be published?**

Answer:


- Yes. This is a good option for data that might lead to conclusions you want to pursue and 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 only?**

Answer:


- Yes. This is QA for an internal audience.



 **Does IR or another administrative office need IRB approval if there are no intentions of ever publishing results of a survey or focus group?**

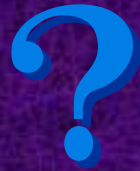
Answer:

- Not if project is for QA (e.g., customer satisfaction survey), unless other generalizable use is foreseen.
- When in doubt, let IRB decide.

 **Is IRB approval needed for SACS assessment, in particular the QEP?**


Answer:

- Probably a good idea. Suppose the QEP is successful and you want to share results publicly?

 **If results of a QA customer satisfaction survey turn out well and you want to share them at a national conference, can you do it if there was no 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 HSR.

 **If a testing center wants to pilot test a new instrument for the College Board, does it need IRB review?**

Answer:

- Yes, but project should be exempt.



## **Do anonymous surveys (with no way to connect data with subjects) need IRB review?**

Answer

- Yes, but anonymous surveys qualify as exempt.
- You still need to submit to IRB, which determines if project is exempt.
- At least there's no need for ongoing IRB review (but do need to reapply next time you do study).



## **Do IR projects need full IRB review?**

Answer:

- Most IR projects probably qualify as either exempt (if anonymous) or expedited, both of which receive faster review by a designated individual rather than the full IRB.

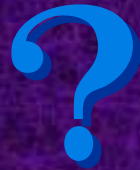




**If using a survey developed by another institution or by the government for national administration, is IRB approval still needed at each institution administering the survey? What if the originating institution already obtained IRB approval?**

Answer:


- This is a “local option,” depending on each institution’s policies and procedures.
- At the University of Miami, we require local IRB approval if a study involves UM personnel in any way.
- Just because an outside organization obtained approval from their IRB doesn’t mean you don’t need it.
- If data from your subjects will be included in national research, the project could be considered an affiliate of a larger research program requiring IRB approval at your institution.



# Is there any way to treat college students who are under 18 years of age the same as those over 18 years?

Answer:

- No!
- Adulthood is defined by state statute. Depending on what state your institution is in, students under 18, or in a few instances students under 21, are considered “children.”
- Children fall into the category of “vulnerable” subjects and require permission from their parents before participating in research.
- Usually it is easiest to exclude all students (or other human subjects) who are legally defined as children from your sample, though this may create biases in your research. Each researcher must decide how to handle this sensitive issue on a project by project basis.




# What should IR or other administrative offices do if they have not obtained IRB approval for past projects?

Answer:

- Most important: Take training for human subjects certification so you understand what is required.
- Contact your IRB and discuss the types of research your office does.
- In conjunction with the IRB, develop a written agreement about guidelines for projects needing IRB review (e.g., purpose, use, type of data).
- Specify criteria for exemption from review, expedited review, and full review.
- Remember that decisions about which activities should be reviewed by the IRB belong to the IRB, not IR or any other administrative office.






# What do IR and other administrative offices need to know about Human Subjects Research? (Part 1)

Answer:

- Public institutions should check freedom of information laws for impact on wording of cover letters (e.g., may need to warn that responses could be released under freedom of information laws).
- Subjects under 18 years old, prisoners, and pregnant women are considered vulnerable populations, so check for special rules relating to them.



# What do IR and other administrative offices need to know about Human Subjects Research? (Part 2)

Answer:

- All staff members who have major contact with data should be certified.
- All material (survey instruments/focus group protocols, instructions to subjects, invitations and follow-up communications) must be approved in advance by an IRB; changes must be submitted as amendments.



# Do IR or other administrative research projects need written informed consent from survey participants?

Answer:

- All subjects must provide informed consent before participating.
- Written consent is often impractical and may reduce response rates, so consider requesting waiver of informed consent.
- Consider including a phrase such as: “Your completion and return of the enclosed questionnaire indicate your consent to participate in the study” (or similar wording). Some IRBs are comfortable with this approach, while others see it as falling short of informed consent.
- Instructions should state that participation is voluntary and that lack of participation will not lead to adverse consequences.
- All subjects must be allowed to skip any item(s) on a survey.
- Web-based surveys must not require a response to one item before a subject can proceed to the next item.



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