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The IRB reviews research involving human subjects

• Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. 45CFR46.102(d)

• Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains
  (1) Data through intervention or interaction with the individual, or
  (2) Identifiable private information. 45CFR46.102(f)

If a project doesn’t meet both conditions, then the IRB should NOT review it.
Processing applications

When the IRB staff receives a new protocol they ask 2 questions:
• Is the investigation systematic and designed to develop or contribute to generalizable knowledge?
• Does it involve human subjects?
Generalizability is not defined in the regulations

*Working definition.* The knowledge would be applicable to groups drawn from groups different from the one that supplied the original test sample.

*Indicators of intent to develop generalizable knowledge:*

- Discussion of potential importance of the knowledge to society
- Explicit discussion of potential applicability of the results beyond the researcher’s immediate environment

But *intent* is not enough. There must also be an appropriate *design*
Generalizability in quantitative research

- Closely related to the concept of **external validity**.
  - Statistical methods are used to draw inferences about a population based on measurements made on a sample.
- Design also includes elements to address **internal validity**:
  - Hypothesis driven
  - Conditions are manipulated to reduce variability, *eg*
    - Randomization
    - Blinding
Generalizability in qualitative research

• There is a difference of opinion among investigators in the field about whether qualitative research is generalizable.

• Majority view: “…if qualitative research is not considered to be generalizable, then it is arguably of little use (and is unlikely to be funded).” Morse 1999

• Minority view: “…qualitative research cannot be generalisable because it treats data qualitatively. That is, the sample generally is small because the researcher needs detailed information about a number of individuals/group.” Anon

• Further complicating things, some qualitative researchers define different kinds of generalizability. Kim 2011
Generalizability and Transferability

• Some qualitative researchers use the term *transferability* instead of generalizability.

• Others hold that transferability and generalizability are distinct but related concepts.

• Colorado State has an *interesting discussion* of these concepts.
Projects that are (usually) not designed to be generalizable

• Evaluation of a new course at CMU
• Evaluation of a commercially available program to improve scholastic performance of students
• Evaluation of a training program for a state agency
• Evaluation of a plan to reduce waiting time in a hospital emergency department
  • If you’ve seen one ED, you’ve seen one ED!
• Journalism projects
• Classroom projects to teach research methods
Generalizability: Gray Areas

• Oral history
  • Most OH projects are not designed to develop or contribute to generalizable knowledge.
  • The US Office for Human Research Protections (OHRP) has issued an opinion letter agreeing with the position of the Oral History Assn and the American Historical Assn.
  • However, it is possible to design an OH project with the intent of developing generalizable knowledge.

• Small studies or pilot studies
  • Not designed to generate generalizable knowledge per se, but are often intended to determine whether a project is feasible.
When uncertain ...

- We choose the conservative option (IRB review)
  - Typically, the research can be considered for exemption
- If the intent is not clear, we invite an investigator to articulate how the knowledge would be “generalizable”
- However, the definitions of *generalizable* and *human subjects* should not be manipulated to make an end run around the IRB
Human Subject: A living individual about whom an investigator obtains:

- **Data through intervention or interaction**
  - Interviews
  - Clinical examinations
  - Therapeutic interventions such as surgery or nontherapeutic interventions such as sham surgery
  - Administration of drugs or placebos

- **Identifiable private information** – There is a reasonable expectation that certain information about a person will be kept confidential, for example,
  - SSN
  - Credit card PIN
  - Credit history
  - Medical records
Research involving humans who are not human subjects

Identifiable information that is NOT confidential

• information that is publically available; or

• information that one would have no reasonable expectation of being confidential, such as:
  • Birth, marriage, adoption, or divorce records
  • Court records (unless sealed) including DUI convictions and bankruptcies
  • Permits for gun carry, hunting, fishing
  • Business records
  • Property deeds
Research involving humans who are *not* human subjects

- Translating into English publically available lists of victims of a civil war in another country as a preliminary step to interviewing survivors
- Mapping addresses of known sex offenders to see whether they cluster in certain neighborhoods
- Research involving secondary data sets or de-identified data (if the data are scrubbed by someone who will *not* analyze the dataset)

- These projects meet the generalizability condition, and they involve humans, but they do not involve human subjects as defined in the regulations
Human Subjects: Gray Areas

Publically available information that was obtained illegally:
• Stolen credit card numbers
• Medical records of celebrities admitted to hospitals

An application to the IRB to study this information should probably be considered as eligible for exemption 4:

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
The Great Myth About IRB Review

In need IRB review if I want to publish my work

• Intent to publish (disseminate) is not necessarily the same as intent to generalize

• Many journals publish reports of improvement projects and case studies that do not meet the definition of Human Subjects Research
  • The work may use sophisticated analytic techniques
  • The work may be recognized as “scholarly activity” within a discipline and be credited toward promotion and tenure. For example, oral history projects.

• A determination of NHSR is not a bar to publication or presentation
  • The Compliance Office sends the investigator a letter with the determination.
    • This letter should satisfy journal editors and reviewers who might ask about IRB review.
  • Unfortunately, program officers at NIH and NSF may insist on IRB review for projects that don’t meet the definition of HSR. (We don’t argue!)
On the other hand...

• A specific statement of lack of intent to publish or otherwise disseminate the results can be taken as lack of intent to generalize.
  • The report will be submitted to a sponsor or contracting agency
  • “I’m doing this to fulfill course requirements”

• However, caution should be exercised when declaring that publication or dissemination of results is restricted, as such restrictions may conflict with the academic exemption from export control regulations.
Playing it safe

• It is not absolutely necessary for an investigator to obtain prior review from the IRB if an investigation does not meet the definition of research or involve human subjects.
  • If necessary, a letter can be issued after the research was conducted, but only if it is clear that the research did not meet the criteria for research involving human subjects.
• Investigators are advised to contact the IRB office before starting their research for a formal determination of whether the project meets the regulatory definition of human subjects research.
Current practice in the office: Dialog with investigators

• If the generalizability criterion is not met, then the investigator is invited to consider the implications of a NHSR determination.

• If there is an intent to create or contribute to generalizable knowledge, then the investigator is invited to submit additional documentation that speaks to generalizability.
If the IRB does not review a project ... then what?

- A determination that an investigation does not require IRB review does not mean that the project is free of risk to humans or does not present ethical challenges.

- Investigators are advised that:
  - Basic ethical principles of research should be considered - respect for persons, beneficence, and justice
  - Professional codes of ethics still apply
  - An ad hoc oversight body or ethics review panel may be useful
Questions?

*Feel free to contact me at any time.*

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References

- 45CFR46 - Policy for Protection of Human Research Subjects
- Generalizability and Transferability (Colorado State University)
- Qualitative Research and the Generalizability Question
- American Anthropological Association Statement on Ethnography and Institutional Review Boards
- IRB Review of Oral History Projects (Columbia University)
  The appendix of the Columbia policy contains a letter from OHRP stating that oral history activities, in general, are not designed to be generalizable.