What the IRB Reviews

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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. 45 CFR 46.102(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. (45 CFR 46.102(f)

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

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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 the investigation involve human subjects?

Generalizability is not defined in the regulations

Quantitative and qualitative researcher define generalizability differently because they operate according to two different research paradigms.

- Quantitative research is based on deductive reasoning and hypothesis testing.
- Qualitative research is based on inductive reasoning and hypothesis seeking.

Generalizability in quantitative research

- *Working definition*. The knowledge would be applicable to groups drawn from groups different from the one that supplied the original test sample.
- Closely related to the statistical concept of **external validity**.
  - Statistical methods are used to draw inferences about a population based on measurements made on a sample.

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 generalizable 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

Generalizability in qualitative research

- Further complicating matters, some qualitative researchers define different kinds of generalizability.
- Kim (2011) speaks of analytic generalization in qualitative research:

  Analytic generalization may be defined as a two-step process. The first involves a conceptual claim whereby investigators show how their study's findings are likely to inform a particular set of concepts, theoretical constructs, or a hypothesized sequence of events. The second involves applying the same theory to implicate other similar situations where similar concepts might be relevant.

Transferability

Transferability refers to the process whereby a body of knowledge created for a particular purpose or under a particular set of circumstances is applicable to different purpose or set of circumstances.

- Some qualitative researchers use the term transferability instead of generalizability.
- Others hold that transferability and generalizability are distinct but related concepts.

  The researcher designs a project with the intent that the results will be generalizable; the reader recognizes that results of a project are transferable to another set of circumstances.

- Colorado State University has an interesting discussion of these concepts.

Projects that are (usually) not designed to be generalizable

- Evaluation of
  - A new course at CMU
  - A commercially available program to improve scholastic performance
  - A training program for a state agency
  - A plan to reduce waiting time in a hospital emergency department
- 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. Rather, they are intended to preserve the stories of a specific cohort of people.
  - However, it is possible to design an OH project to develop generalizable knowledge.
- Pilot studies
  - Pilot studies are usually intended to determine whether a project is feasible. They are not designed to develop generalizable knowledge per se.

When uncertain…

- We choose the conservative option: IRB review.
- If intent is not clear, we invite an investigator to discuss how the knowledge would be “generalizable”.
- The definitions of generalizable and human subjects should not be manipulated to make an end run around IRB review.

Human Subject: A living individual about whom an investigator obtains:

- *Data through intervention or interaction*
  - Interviews
  - Clinical examinations
  - Administration of surveys or drugs
- *Indentifiable 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

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Research involving humans who are *not* human subjects

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 confidential information available of internet sites:
  - 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
I 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 quoting the relevant regulatory definition.
  - 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.
  - In these special circumstances we don't argue; we observe the Golden Rule (The one with the gold makes the rules!)

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)
- 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.