EDD and the IRB

I. When is a protocol submission required?

- Exclusion Worksheet
- HSR vs. Quality Improvement (QI) and Case Studies
- Outcomes based on the HSR/not HSR decision

II. What are the common issues/problems raised during IRB review?

- Quality of writing → poor writing or excessive jargon; lack of clarity about the purpose of the study or the purpose of certain methods (e.g., observations)
- Quality of research design
- Internal inconsistencies between documents
- Privacy issues → records subject to additional regulations beyond IRB requirements
- Inadequate info about security and confidentiality of data
- Small sample sizes → lack of anonymity
- Positional authority of researcher → conflicts of interest, undue influence

III. Resources

Web:

IRB website: http://www.sjsu.edu/research/irb/index.html
Most current forms and templates, educational material

CITI training: https://about.citiprogram.org/en/homepage/
Online training courses for responsible conduct of research and human subjects research. For instructions on how to access the student-specific CITI course see:
http://www.sjsu.edu/research/irb/irb-researcher-training/index.html

Print:

The Sage Handbook of Action Research (2008). Edited by Peter Reason and Hilary Bradbury.
Relevant Chapters:
Chapter 13 "Ethics and Action Research: Deepening Our Commitment to Principles of Social Justice and Redefining Systems of Democratic Practice."
Chapter 41 "Negotiating the Challenges of Participatory Action Research: Relationships, Power, Participation, Change and Credibility."

Walking the Tightrope: Ethical Issues for Qualitative Researchers (2002). Edited by Will C. Van Den Hoonaard.

IV. Questions?

Crucial Definitions

The Three E's: Exclusion, Exemption, Expedited

Exclusion: The work is not subject to any regulatory oversight because it does not meet the regulatory definition of human subjects research; this is determined by faculty supervisor using the exclusion worksheet. Use the worksheet to see what restrictions apply to student work that is not HSR (e.g., must be minimal risk).

Exemption: The work *does* meet the regulatory definition of human subjects research but is subjected to limited oversight because it fits into one of the prescribed exemption categories and the work is minimal risk. Requirements: a complete protocol submission, consent process in most cases, ethical and regulatory oversight BUT the protocol is reviewed by the Office of Research IRB Analyst and does not go to the committee.

Expedited Review: The work does not fit into any of the exemption categories but is otherwise considered to be minimal risk. The protocol is evaluated by an individual IRB member. If the reviewer believes the activities pose greater than minimal risk to subjects, a full review is selected where all committee members convene and must evaluate and vote on the research proposal.

For exempt, expedited, full review refer to the review criteria that IRB members must apply for more information on what types of considerations go into evaluation of a proposal.

Minimal Risk (regulatory definition): The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life.

Research (regulatory definition): A systematic investigation designed to contribute to generalizable knowledge.

Activities that are similar to research but usually do not meet the regulatory definition:

Case Study: In-depth examination of a specific person, group, or situation – the focus is on a single unit. Case studies may contribute to generalizable knowledge even with one subject, though there is room for interpretation. Often generalizability or transferability is up to the researcher's ability to draw inferences that apply to a broader population or issue. Researchers may choose a case because it is representative. However, case studies are sometimes not a systematic investigation. For example, a medical case study may examine the characteristics of a patient with a specific unique/rare condition by collecting all available medical data on the subject (which can advance knowledge about that condition in general), but there may be no analysis component – the case may be solely descriptive and data may not be used to answer a specific research question or to prove a set of hypotheses.

Quality Improvement: Consists of systematic and continuous actions that lead to measurable *improvement* in services that target specific groups. QI is typically a systematic investigation, but it is typically not designed to contribute to generalizable knowledge. When QI involves people, the idea is to change behavior within a specific institution rather than to study behavioral phenomena more generally.

Class Exercise: Is this Human Subjects Research (HSR)?

Example 1: "Benchmarking Cybersecurity Preparedness in California Cities"
For her master's thesis, a student investigator wants to evaluate how well prepared California cities are in being able to prevent cybersecurity breaches and whether or not they follow the standards for cybersecurity preparedness developed by the Department of Homeland Security. She will do this by contacting IT professionals (head of IT departments, lead programmers, etc.) of 30 California cities of varying sizes and ask them to fill out a survey and follow up with an interview. The survey measures city practices against the developed standards, while the interview questions solicit opinions on best practices and the challenges and strengths of their cybersecurity strategy.

Is this HSR?

Example 2: "The Effects of Cell Phone Use on Prospective Memory"
For his master's thesis, a student investigator wants to examine if using cell phone reminders or calendar prompt functions have adverse effects on prospective memory (remembering to do something in the future). The study would build on previous research that shows prospective memory tends to decline with age and that also shows how technology can benefit those with prospective memory loss. But this study asks the converse question: can technology also contribute to such memory loss? The study design includes a survey on cell phone use. At the end of the experiment participants are asked to send an email to the investigator 3-4 hours after meeting in the lab under the pretense that the investigator needs to find an "information sheet" meant for them. Participants are not primed to know the purpose of the study, but are debriefed after the 4 hour timeframe. Participants are recruited by posting flyers around campus advertising the study as well as from the psychology department's research subject pool.

Is this HSR?

Example 3: "Migrant and Seasonal Farmworkers: Needs Assessment for the Center for Employment Training"
A student investigator conducting a class project wants to examine what knowledge the Center for Employment Training in her community needs to improve services they provide to migrant farmworkers in helping them to secure a new career path. She does this by conducting a survey and focus groups with migrant farmworkers designed to determine and prioritize their needs and to measure the effectiveness of the services that clients have utilized.

Is this HSR?

Example 4: "Health Literacy Outreach: The Role of Libraries"
A faculty investigator wants to understand how libraries are providing health information outreach to the public that aims to raise health awareness literacy. She does this by sending out a nation-wide survey to librarians in consumer health libraries around the country. While the investigator compiles a list of contacts from online sources, the survey itself is anonymous and does not collect either the name of the libraries nor the name of the respondents. The questions on the survey focus on general library practices during health outreach activities.

Is this HSR?