

# Best Practices for IRB Approval: Four Perspectives

Janice E. Cuny, Mark Guzdial, Amanda Holland-Minkley, Clifford A. Shaffer

Michael S. Kirkpatrick (moderator)

# Panelists

- Amanda Holland-Minkley
  - Washington & Jefferson College
- Clifford A. Shaffer
  - Virginia Tech
- Mark Guzdial
  - Georgia Tech
- Janice E. Cuny
  - National Science Foundation

# Definitions

## Belmont Report

- Department of Health, Education, and Welfare (1979)
- Basic ethical principles
  - Respect for persons, beneficence, justice

## U.S. 45 CFR 46 (“Common Rule”)

- Department of Health and Human Services (1991)
- Protection of human research subjects

# Definitions

## Human subjects research (HSR)

“a systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge”

U.S. 45 CFR 46

# Definitions

## Institutional Review Board (IRB)

“ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice”

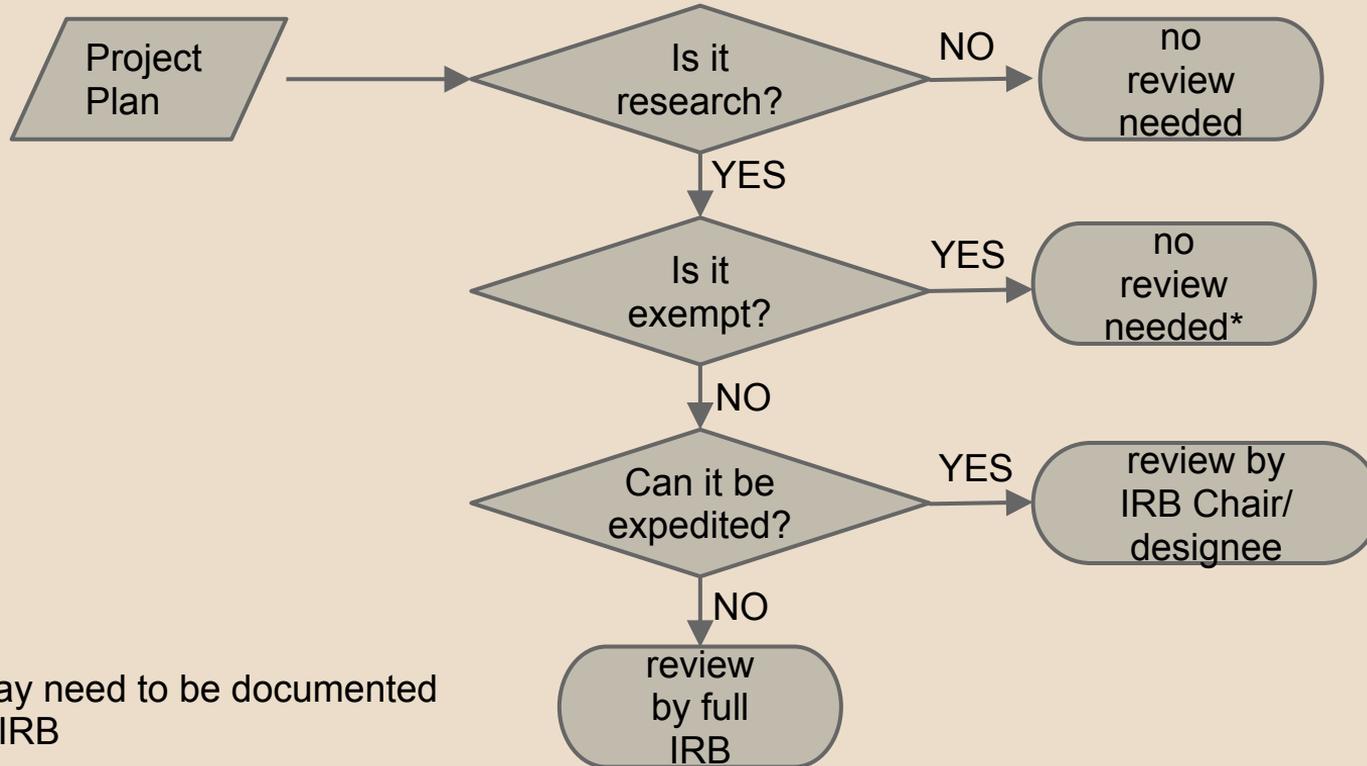
U.S. 45 CFR 46

Amanda Holland-Minkley, Washington & Jefferson College

# IRB Perspective: Approval Criteria

- Risks to subjects are minimized and reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent (or its waiver) will be sought and appropriately documented
- Research plan makes adequate provision for monitoring the data collection process and protecting privacy and confidentiality of subject data
- Investigators have necessary qualifications relative to the degree of protocol complexity and risk to subjects

# Is review required? What kind?



\*may need to be documented by IRB

# Educational Research and Exemption

“Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

(i) research on regular and special education instructional strategies, or

(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.” (45 CFR 46)

# Making a Case for Expedited Review

Illustrate through application:

- Minimal risk of harm
- Only eligible procedures are used (e.g. review of existing data or documents, surveys, focus groups, human factors evaluation)
- Minimal risk of exposure to legal liability or damage to employability, reputation, etc. through revealing subject participation or responses

# Collaborating with your IRB

- Be familiar with your institution's procedures
- Be in touch early and often with questions
- Be as detailed as possible about protocols, consent forms, instruments, etc.
- Be thoughtful about personally identifiable information and whether it is required
- Be thoughtful of your processes for protecting subject data, particularly in digital forms or when partnering with third party service providers

Cliff Shaffer, Virginia Tech

# Philosophy on Working with the IRB

- Don't treat them as the enemy or an obstacle
  - Doing so won't help you to get done what you need to get done
- Keep a positive attitude about the process
  - They have a job to do
  - Make it easy on both of you

# Keys to Success

- Don't raise red flags (unless you mean to)
- Examples:
  - Not being clear how you will maintain data privacy
  - Not using informed consent when you reasonably can
  - Not giving sample documents (surveys, etc.)
- Whenever possible, sell your study as "standard educational practice"
  - Might get exempt status, or at the least easy approval

# Engage your IRB

- They can help you with difficult aspects
- They are more likely to accept controversial provisions that result from an engagement process
- Point of contact is most likely the IRB chair

# Dealing with Controversy

- Don't shy away from standing your ground if you need to
  - But don't do this frivolously!
- Examples: See the red flags issues

# Process Issues

- Assume you must re-submit at least once
  - Its usually pretty easy to do the response
- At start, you might not know what your survey or test instrument will look like
  - Submit something reasonable, and then amend
  - Amendments to update documents should be easy
- IRB at non-research schools are less experienced
  - Help them with interpretation, interact more to start

Mark Guzdial, Georgia Tech

# IRB at the Cross-Institutional Level

Two examples:

- Research projects across the University System of Georgia
- Expanding Computing Education Pathways alliance

# IRB at the Cross-Institutional Level

- Do what you need to do, and no more
- Rules differ between institutions
  - You have to apply for IRB at the institutions that require you to apply
- Beware of non-virtuous cycles!

# ECEP IRB

We run a lot of events with similar structures

- Teacher workshops, statewide summits, etc

Wanted an umbrella IRB to cover all of them

- To avoid amendments for each event
- UMass-Amherst was unwilling; Georgia Tech was willing
  - We did it with Georgia Tech

# Working with Schoolchildren

- Consent/Assent is the rule
- If they're on campus, you can recruit
  - But a self-selected population
- Reaching them *in their schools* may be more work than you might imagine

# NOT replicating “Stuck in the Shallow End”

Wanted to interview Atlanta students and teachers. Are the barriers in Atlanta like the ones in LAUSD?

- Two district research offices said no, and wouldn't take our calls
- Finally got Dekalb County schools to say yes
  - By listing *undergraduate researchers* as the “PI's”
- But then none of the school principals would take the calls of the undergraduate researchers!

Three years and we have to be able to do one interview

Jan Cuny, National Science Foundation

# NSF Role

- NSF supports research involving human subjects when:
  - Certified by a responsible body
  - Compliance with the federal government's "Common Rule" for the protection of human subjects.

# Requirements for Funding

## IRB approval or official notice of Exemption

- Not needed for submission
- Must be in place before funding
  - In the past, there was some leeway here but that's been tightened up considerably
  - Especially in the case of awards that will be made late in the fiscal year (*i.e.*, summer), make sure you have them underway even if not yet submitted

# Who says?

- Institutions have discretion  $\Rightarrow$  LOCAL variations
  - NSF can help with explanations of regulations but the final arbiter is your organization
  - Which institutions in a collaboration need to have their own approvals? Is an expedited review is possible?

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<http://github.com/kirkpams/CSEdIRB>