Ethical Considerations in Operations Research and HSSR

CFAR Operations Research Mini-Course

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Key Issues for Discussion

- Defining research vs. non-research
- Appropriate review processes and mechanisms
- Ethics issues in “non-research” activities

Defining Research vs Non-research

- Generalizibility is key defining characteristic of resarch (not methods)
- Routine program evaluation is not research
- Non-research is publishable
- Need rules, algorithms to help define

Need code of ethics for both

Belmont Ethical Principles (for research)

- Respect for persons – maximize autonomy, protect privacy
- Benificence – weighing of cost-benefit
- Justice – benefits and burdens shared equally

Research vs Non-Research

CDC Definition

“Research means a systematic investigation,

including research development, testing and evaluation,

designed to develop or contribute to generalizable knowledge.”

Distinguishing Research from Non-Research Public Health Practice - Draft Guidelines

(Adapted from P. Brentlinger, M. Mercer, D. Eaton 2003)

1. What is the aim of the project?
2. Categories of public health practice
3. Vulnerable populations
4. Risks to participants

Declaring projects to be non-research

1. What is the aim of the project?

- Is the primary aim to “develop or contribute to generalizable knowledge,” or to answer or generate a research question?

If yes – research.

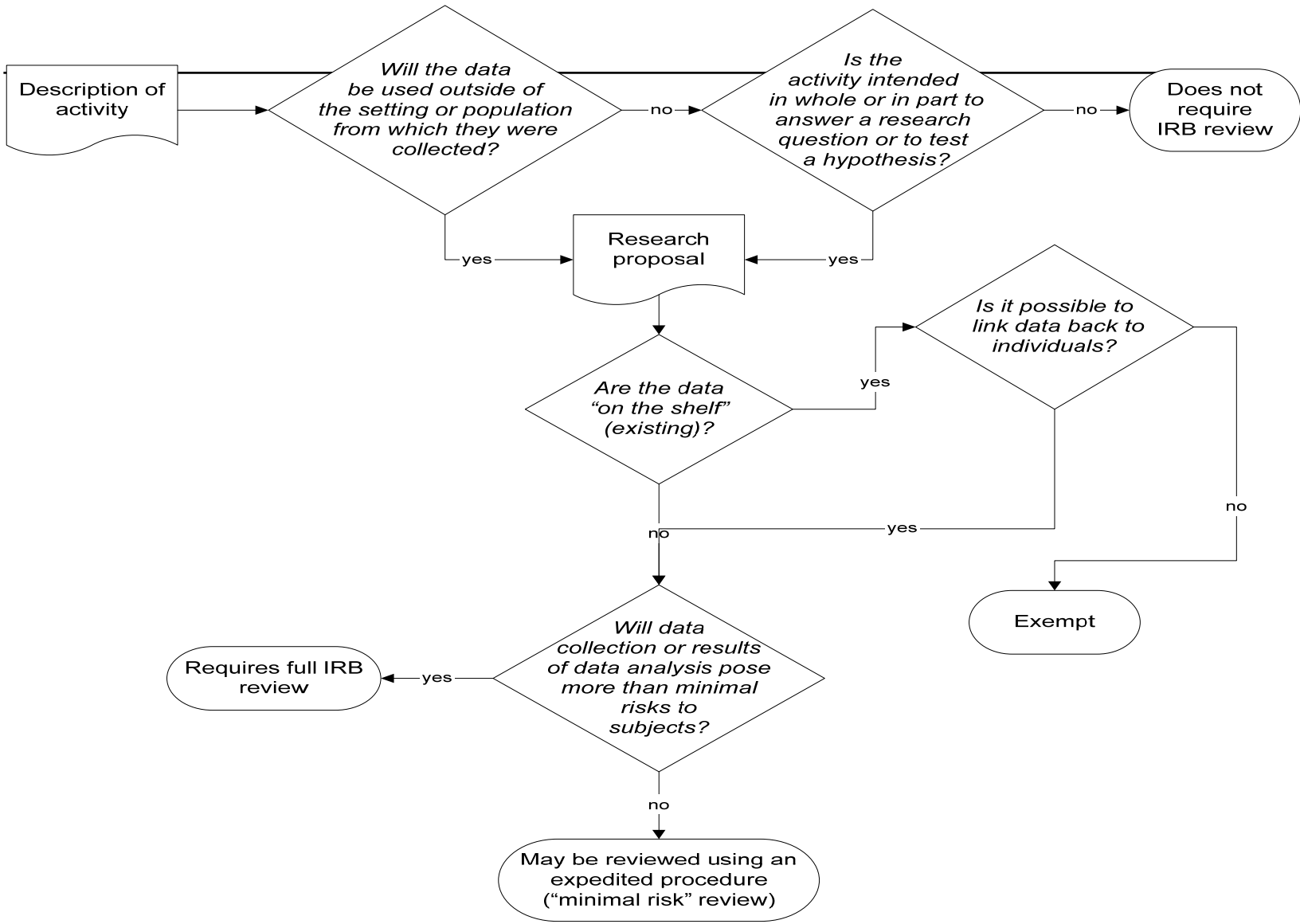
- Is the primary aim to “identify and control a health problem with potential benefits for the project participants or their communities”?

If yes, more likely to be non-research.

- Would the project be conducted exactly as proposed if there would be no academic recognition for then project, including publication in a peer-reviewed journal or presentation at academic meetings?

If yes, more likely to be non-research.

Distinguishing QA/QI from Research



2. Categories of practice with research overlap

There are research non-research attributes of:

- Surveillance
- Program and other evaluation
- Emergency response
- Policy analysis
- Quality assurance/Improvement

Example: Program Evaluation

Non-research attributes

- Assesses success of an established program, and use findings as feedback to that program
- Program to be assessed is not new, and is known to be effective in its setting or similar settings
- Pre-intervention evaluation provides information on how to modify a proven-effective intervention

Research attributes:

- Tests new, previously untested intervention.
- Extends findings to dissimilar settings or populations.
- Designed as systematic comparison using experimental-type design (e.g. RCT of two different interventions.)

3. Vulnerable populations

- If study participants are members of vulnerable populations, additional protections and review are advisable
- IRB is not necessarily required.
- Vulnerable populations include, but are not limited to, the following:
  - Children
  - Pregnant women
  - Fetuses
  - Prisoners or detainees
  - Persons who are not legally competent
  - Refugees or displaced persons
  - Residents of war and conflict zones
  - HIV+ persons

4. Risks to participants

If participation in the project may place participants at risk of harm, additional review is advisable, but IRB is not necessarily required

Potential risks include

- physical harm
- psychological harm (including to professional, financial, social standing, emloyability, reputation)

(example: Assessment of operational interventions to improve antenatal syphilis or HIV testing – results may pose risk to positive women when they disclose to partners)

Health Alliance International Approach

Ethical Review Committee

- Membership: investigators and staff
- Reviews all data gathering activities
- Distinguishes research from non-research
- Research sent to UW IRB
- ERC addresses ethical concerns of non-research activities
- Appeal process available

Review processes and mechanisms

- Initial review process to determine research vs. non-research
- OR staff training in ethics review criteria
- External expert advice
- Database review and approval
- National IRB considerations
- Publication
- Documenting review decisions

Ethics issues in “non-research” activities

- Applying professional ethics codes, guidelines, and principles (e.g. APHA, AMA, CDC, WHO) without IRB oversight.
- Internal ethics oversight processes.
- Potential informed consent requirements.
- Documentation of ethics compliance.
- Whistle-blowing protection.

Thank you!

Some useful websites on ethics:

- **Guidelines for Defining Public Health Research and Public Health Non-Research** http://www.cdc.gov/od/ads/opspoll1.htm
- **Distinguishing Research from Non-Research Public Health Practice** http://sphcm.washington.edu/research/human_subjects_guidelines.pdf
- **Protection of Human Subjects - Code of Federal Regulations, Department of Health and Human Services, National Institutes of Health** http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm.
- **Ethical Principles for Medical Research involving Human Subjects, Declaration of Helsinki, World Medical Association** http://www.dvincitbt.com/ohsrsite/guidelines/helsinki.html.