“IS THIS RESEARCH, OR NOT?”

ALBERTA COLLEGE OF FAMILY PHYSICIANS

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DISCLOSURE

- Employee of Alberta Innovates
- Manager of the A pRoject Ethics Community Consensus Initiative (ARECCI) program, but no financial interests. Everything is free.
- www.aihealthsolutions.ca

EXAMPLE FROM REB DISCUSSION FORUM

A Family Nurse Practitioner is conducting the study to see if an educational session on prescribing hypertension meds will increase provider adherence. The study is being conducted at an urgent care where b/p meds are normally not prescribed b/c those clinics don't normally address hypertension. She is going to go through 300 existing charts and see how many times b/p medications were prescribed.

EXAMPLE (CONT'D)

Then she will do the educational session. After the educational session she is going to review 300 more charts to see if the number of times b/p medications prescribed increased. My thought was that this is a type of research. My primary viewer says it's a quality improvement project because you are looking at provider adherence therefore the study is exempt [from ethics review].

RESPONSE #1

Your primary (re?)viewer is partly correct: This project is a QI; but it does not meet the regulatory definition of research, namely a systematic investigation designed to develop or contribute to generalizable knowledge.

RESPONSE #2

Why isn't this a systematic study designed to contribute to generalizable knowledge? Measure, intervene, re-measure sounds quite systematic. and if the results are anticipated to be publishable, that too suggests that others might care if the method works...

RESPONSE #3

To me this is research, expedited research but research for several reasons, and it does not meet the current criteria for exemption [from ethics review]:
- there is a research intervention i.e. educational session or sessions
- there will be identifiable information collected (I suspect)
-there is no mention that ALL of the data is "on the shelf", and already in existence at the time of IRB application

RESPONSE #3 (CONT'D)

- is not completely retrospective because the FNP is comparing (before/after) the educational session
-given that FNP access the patients charts to see who is on bp meds, now the FNP knows who the patients are, now the FNP can consent the participants, plus wouldn't the participants be attending the educational sessions as well, there seems to be plenty of time to consent.

RESPONSE #4

I agree the project is systematic, BUT the project will be carried out in ONE urgent care unit. There is no way to tell whether it is "representative" of all or many other urgent care units. Anybody in health care knows how different institutional operations are, even if everybody is wearing the same logo on their lab coats.

RESPONSE #5

The description did not include enough information to determine if the study was "designed" to contribute to generalizable knowledge. Depending on that determination, the study could either be QI or research. At our institution, we do stuff like this all the time. It's part of a "Learning Health System".

ARECCI ASSUMPTIONS

- Risks ALWAYS exists when using people's information
  - Research (primary data)
  - Data initially collected for clinical purposes, but now for research, quality improvement, program evaluation, "learning health system" (secondary data)
- All projects need risk assessment and strategies to minimize and mitigate risks

ARECCI ASSUMPTIONS

- Need the **appropriate** type of review
  - Research ethics boards for research
  - ARECCI for non-research
  - Develop another process

A PROJECT ETHICS COMMUNITY CONSENSUS INITIATIVE (ARECCI)

- Two online **decision-support tools**
  - ~ 16,000 hits
- Training opportunities
  - ~1600 participants
- "Ethics consultation" called Second Opinion Review
  - ~50 per year

ARECCI SCREENING TOOL

- Steps 1 and 2
  - Determine if it's research or not
  - Thirteen "Yes" and "No" questions
  - **Primary purpose of the projectis the key consideration**
- Step 3
  - Helps identify the risks
  - Twenty-two "Yes" and "No" questions
- Step 4
  - Suggests type of review

STEP 1

Step 1: Preliminary Questions

1. Is there an explicit requirement for review of this project by a Research Ethics Board as part of its funding arrangements? Yes No

2. Are there any local policies that require this project to undergo review by a Research Ethics Board? Yes No

3. Does the project involve use of a pharmaceutical device, drug or natural health product under Health Canada Food and Drug Act regulations or guidelines? Yes No

STEP 2

4. Is the project designed to test a specific hypothesis or answer a specific quantitative or qualitative question?	Yes	No
5. Does the project involve a comparison of control groups?	Yes	No
6. Is the project designed to support generalizations that go beyond the particular population the sample is being drawn from?	Yes	No
7. Does the project impose any additional burdens on participants beyond what would be normally expected or normally experienced during the course of care, program participation or role expectations?	Yes	No
8. Is the primary purpose of the project to produce the kind of results that could be published in a research journal?	Yes	No

STEP 2 (CONT'D)

9. Will project participants also likely be among those who might potentially benefit from the result of the project as it proceeds?	Yes / No
10. Is the project intended to develop a better practice within your organization or setting?	Yes / No
11. Would this project still be done at your site even if the results might not be applicable anywhere else?	Yes / No
12. Does the language used in the project description refer specifically to features of a particular program, organization, or locale, rather than using more general terminology such as rural vs. urban populations?	Yes / No
13. Is the current project part of a continuous process of gathering or monitoring data within an organization?	Yes / No

NEXT 21 QUESTIONS TO IDENTIFY RISKS (STEP 3)

IN CONCLUSION

- Assume that there are ethical risks whenever using people's data
- Need to have a process to assess and mitigate them
- Appropriate type of review depends on **primary purpose**
- I will gladly do presentations in person or by distance