Research in Anesthesia: Does this project need to go through ethics?

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Consider the following Cases: Does each need ethics approval?

- **Case 1: Opportunistic Assessment of new technologies for Quality Improvement**
  - Chart review of hospital cases to assess the performance of a new analgesic agent
  - Prospective assessment

- **Case 2: Quality improvement initiatives using surveys**
  - Post-discharge patient satisfaction survey
  - Post-discharge telephone interview

- **Case 3: Descriptive analysis of the characteristics or features of patients on some pain treatment**
Outline

- What is research ethics?
- What types of investigations require ethics approval?
  - Research vs Practice
  - Quality Assurance vs Quality Insurance
  - Criteria for assessing whether an investigation is research
- REB Process at SJHH and HHS/FHS
Ethics and Research Ethics Guidelines

- Ethics are principles of the right conduct, guiding what ought to be done.

- Importance of research ethics is embodied in several guidelines:
  - Nuremberg Code
  - The Declaration of Helsinki
  - The Belmont Report
  - CIOMS
  - Tri-council Policy Statement (TCPS)
The Role of a Research Ethics Board

- To advance the protection or safety of human or animal subjects in research
- To foster high ethical standards for the conduct of research
- To ensure that research follows appropriate research ethics guidelines
What is considered Research?

- **Research** is defined as any systematic activity designed to contribute to **generalizable knowledge** (expressed as theories, principles or statements about relationships). Includes
  - Research development
  - Testing
  - Evaluation

- **Important References**
  - Belmont Report, 1979
  - CIOMS, 2002
What is Practice?

- **Practice:** interventions (that have a reasonable chance of success) designed solely to improve the well-being of an individual patient or client (Belmont Report, 1979)

- **Non-research:** activities designed for (Bioethics advisory Commission Report, 2001)
  - Patient treatment
  - public health practice
  - program evaluation
  - population health surveillance
Quality Assurance vs Quality Improvement

- **Quality Improvement (QI):**
  - Activities are designed to improve health care

- **Quality Assurance (QA):**
  - Activities are designed to assess the adequacy of current care
Types of QI Research

- **Research-type QI initiatives**
  - Primarily aimed at improving understanding of phenomena presumed to be generalizeable to other settings
  - May involve some level of risk or burden to patients
  - There some expected benefit to patients

- **Non-research QI initiatives**
  - Improvement of specific processes, structures or systems within specific organizations
  - Very minimal or no risk involved
  - Majority of patients are expected to benefit
When Should a QI Initiative be considered research?

(The Casarett Criteria: JAMA 200;283:2275-80)

Criterion 1: Are the majority of patients expected to benefit from the knowledge gained from the study?

Criterion 2: Are there any additional risks or burdens imposed to make the results generalizeable?
When should a QI activity be reviewed for ethics approval?
(The Casarett Criteria: JAMA 2000;283(17): 2275-80)

Criterion 1: Direct Benefit to patients

- Are the majority of patients expected to benefit directly from the knowledge gained?
- Clinical practice is the benchmark against which to measure benefit

Criterion 2: Imposition of Additional Burdens or Risks

- Will generalizeability require subjecting patients to additional risks or burdens?
- Clinical practice is the benchmark against which to measure
PHIPA 2004

- **Ontario-based legislation**
  - Establishes a set of uniform rules for collection, use or disclosure of personal health information for (among others)
    - Research purposes
    - Marketing activities or marketing research

- **Definition of Research:**
  - A systematic investigation designed to develop or establish principles, facts or **generalizable knowledge** or any combination of them
  - Includes the development, testing and evaluation of research
The Alberta Research Ethics Community Consensus Initiative (ARECCI)

- It is a collaborative effort to improve ethics screening and review processes in Alberta, Canada

- Funded by the Alberta Heritage Foundation for Medical Research (AHFMR)
  - Website: http://www.ahfmr.ab.ca/

- Context: Alberta privacy legislation
  - Health Information Act (HIA): April 2001
ARECCI Recommendations

1. Ethics screening (Recommendation 1)
   - Screen all projects to determine if ethics review is needed

2. Sort by Purpose (Recommendation 2)
   - Screen according to purpose:
     • Research: contribution to generalizeable knowledge
     • Quality and Evaluation

3. Sort by Risk (Recommendation 3)
   - Screen according to level of risk:
     • More than minimal risk
     • Minimal risk

4. Building Capacity (Recommendation 4)
   - Build capacity and build on existing practices
     • Structural components
     • Resource components
     • Networking components

5. Progressive Implementation (Recommendation 5)
   - Implement recommendations in all organizations involved in enhancement of health
What is the Government of Canada’s position? (update website)

- The Interagency Advisory Panel on Research Ethics (PRE)
  - Body of external experts
  - Established in November 2001 by three Canadian Research Agencies –
    - CIHR, NSERC, SSHRC

- To support the development and evolution of their joint research ethics policy
  - Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)
  - TCPS was adopted in August 1998
All research that involves living human subjects requires review and approval by an REB.

Includes research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses.

Exemptions:
- Research about a living individual .... based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews.
- Quality assurance studies, performance reviews or testing within normal educational requirements.
My General Views

- **Institutions need to educate researchers about**
  - Research methodology
  - Research Ethics/REB process
  - International Ethics guidelines on research involving human subjects

- **Research Ethics boards**
  - Agree on basic principles on determining when QI/QA will considered research
  - Guided by ethics guidelines
  - Establish ways to communicate guiding principles/REB process to researchers

- **Country legislatures**
  - Address the issues through legislation
  - Empower REBs to deal with the issues
Basic Rule of Thumb

- Decide *apriori*
  - Will QI/QA results will be submitted for peer-review publication?

- If so,
  - Then treat activity as research
  - Go through ethics review
REB Process at SJHH and HHS/FHS
What type of studies need REB approval

- Any study that involves human subjects
  - Prospective studies
  - Chart reviews (retrospective)
  - Surveys
  - Clinical database (pro/retrospective)
REB Submission at SJHH/HHS/FHS

- **Deadline for REB submission**
  - 4:00 p.m. on last Monday of each month (SJHH)
  - 4:00 p.m. on last Tuesday of previous month (HHS/FHS)

- **REB meetings**
  - 3rd Monday of each month – **no meeting in August** (SJHH)
  - 3rd Tuesday of each month (HHS/FHS)

- **REB fee: $3,000**
  - industry sponsored projects

- **REB submission includes**
  - 3 copies of application + supporting documents (eg Research Protocol)
  - 1 electronic copy of application and consent forms:
REB Submission at SJHH/HHS/FHS

- **REB Forms**
  - [http://fhs.mcmaster.ca/healthresearch/sjhhreb/forms.html](http://fhs.mcmaster.ca/healthresearch/sjhhreb/forms.html)

- **Consent checklist**

- **Reviewer checklist**

- **Only at SJHH**
  - All submissions are reviewed for statistical and methodologic issues by a statistician