Responsible Conduct of Research : Brief Introduction

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Responsible Conduct of Research: Key Terms

- Research Integrity
  - strive for the best research practices "honestly, accountably, openly and fairly"
  - report suspected instances of misconduct

- Financial Responsibility
  - responsibility and accountability for managing research monies and resources

- Research Ethics
  - principles that balance the protection of research participants with the legitimate goals of the research enterprise.

- Animal Care
  - "ground rules and basic requirements for oversight of animal care and use."

Ethics Considerations for Educational Human Participant Research at Queen's University

Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB)

October 5, 2016

Agenda

- ✓Two REBs - GREB and HSREB
- ✓HSREB Ethics Office
- ✓HSREB Review Process
- ✓Guiding Principles
- ✓Important Considerations
  - Informed Consent
  - Risks
  - Privacy and Confidentiality

Research Involving Human Participants

Two REBs: GREB and HSREB

1. General Research Ethics Board (GREB)
2. Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB)

"There now. We get our wish of continuing our work unimpeded, and they get their wish of being in a position of direct oversight at all times."

HSREB Ethics Office

HSREB Chair

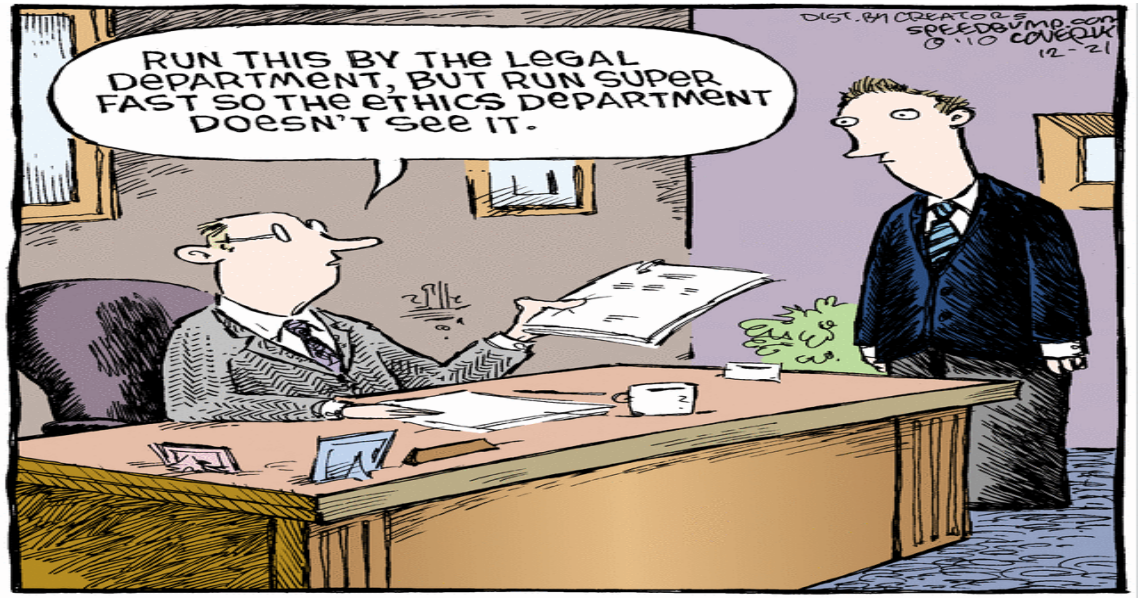
- Dr. Albert Clark

Office Staff

- Ethics Office Assistant - Ms. Elizabeth Heinricks
- Ethics Coordinator - Ms. Kathy Reed
- Ethics Compliance Advisor - Ms. Jennifer Couture
- Director of Research

Ethics Compliance –

Dr. Andrew Winterborn



HSREB Guiding Principles

HSREB Guiding Principles

- **TCPS2 (2014)— the latest edition of *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans***
- Course on Research Ethics (CORE)
- Students are required to submit their CORE certificate

✓Queen's policies (OCASP, Integrity of Research, Electronic Information Security Policy Framework, etc.)

✓Canadian laws (e.g., HC, FIPPA, PHIPA, PIPEDA)

✓USA laws, as applicable (e.g., US CFR, FDA)

✓Industry standards

✓Professional best practices

HSREB Review Process

Full Board Review:

- High risk research projects – complete full application form
- Ethics submission deadline - two weeks in advance of the full board meeting date
- http://www.queensu.ca/urs/research-ethics

Delegated Review:

- Minimal risk research
- No submission deadline
- Use short form for critical enquiry, chart reviews, questionnaires, and survey research

Important Considerations

Of course it's anonymous! ... just make sure you lick the envelope, ok?

Informed Consent

- How will informed consent be obtained?
- Voluntary nature of consent
- No coercion
- Invitation to participate in a research study
- Explain what participants will be asked to do in plain language
- Outline time commitment
- Process for withdrawal and withdrawal of data

Informed Consent

- Appropriate letterhead
- Approval required from the School of Medicine for data collection during class time (Theresa Suart/Dr. Tony Sanfilippo)

Required statement:

- *"If you have questions about your rights as a research participant you can contact the Board Chair Dr. Albert Clark at clarkaf@queensu.ca or by calling 1-844-535-2988."*

Risks and Benefits

Risks:

- All research poses some level of risk
- Our responsibility is to ensure that the risks, whether social, physical, emotional, economic, or legal, have been adequately communicated to the participant(s)
- The researcher must have a plan to mitigate any risks
- Risks must be outlined on consent form

Privacy and Confidentiality

Participants should be informed about:

i. What personally identifying or confidential information will be collected?

ii. What will happen to the information during the full lifecycle of the data?

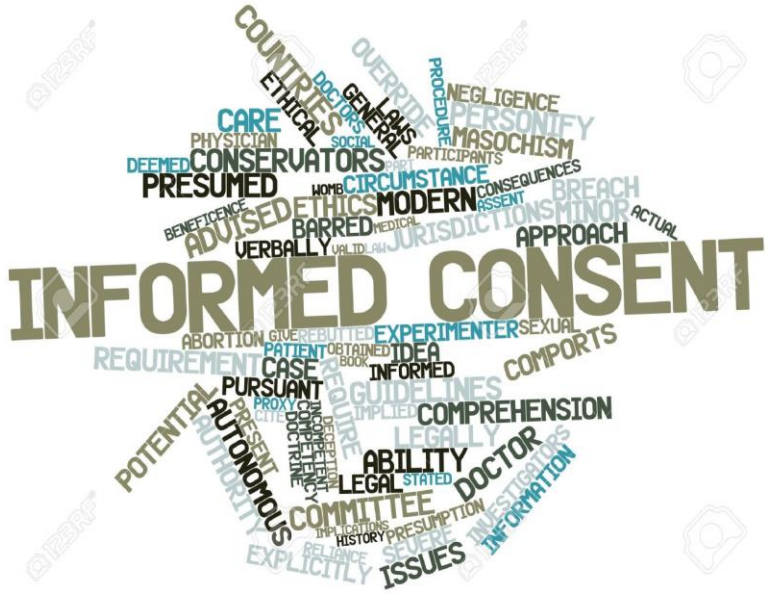
iii. Who will have access to the information?

iv. How will the information be disseminated?

v. What will happen to the information after the research is finished? (retention = minimum of 5 years for Queen's & 25 years for all clinical trials)

Documentation for Student HSREB Applications

1. CORE Certificate
2. Supervisor Sign off (for all students)
3. Protocol
4. Letter of Information/Consent Form
5. Recruitment Materials
6. Questionnaires, surveys, etc.,
7. Sample interviews, scripts, etc.,
8. Debriefing materials



Thanks for your time!

Research Integrity

"You are completely free to carry out whatever research you want, so long as you come to these conclusions."

The Lab – Demonstration

Office of Research Integrity USA

http://ori.hhs.gov/TheLab/TheLab.shtml

Kim Park : Graduate Student

- Is there an issue?
- What should she do?

Senate Policy on Integrity in Research

- **Access on the Senate Website at**

  http://www.queensu.ca/secretariat/sites/webpublish.queensu.ca.uslcwww/files/files/policies/senateandtrustees/research_integrity.pdf

- **Applies to faculty, staff, students*, post docs**

- **Compliant with Tri-Council requirements – National Standard**

- **Policy outlines expectations, definitions, and processes for reporting and investigating potential misconduct**

***except when an integrity issue relates to research associated with a course**

Expectations
Senate Policy on Integrity in Research

- Deal fairly with colleagues and students
- Adhere to relevant ethical principles
- Carry out research in an honest and rigorous search for knowledge
- Interpret findings according to scientific, scholarly and/or creative principles
- Make results of work accessible
- Identify affiliations and contributions accurately
- Retain research records in accordance with relevant protocols
- Honestly comply with funding agency requirements
- Be proactive in rectifying integrity breaches

Misconduct in Research or Scholarly Activity
Senate Policy on Integrity in Research

- **Fabrication of data (making up data)**
- **Falsification (manipulating data/equipment/processes to affect data)**
- **Plagiarism**

Lying, Cheating, Stealing

- **Financial misconduct**
- **Failure to disclose conflicts of interest**

Misconduct Definitions cont'd
Senate Policy on Integrity in Research

- Failure to comply with ethics or other regulatory requirements
- Failure to recognize others' contributions or to obtain permissions
- Mismanagement of authorship
- Providing incomplete or false information in applications
- Submission of same article in multiple venues without notice
- Destroying records to avoid detection of wrongdoing

Moral Decision Making

- 4) Moral Action : Need to carry out the act
  - Presence of others is largest factor in not acting

- 3) Moral Intention: Decide what to do or not to do
  - Find the courage to act, possibly in face of peer pressure

- 2) Moral Judgement: Identify right/wrong or better/worse
  - Degree of harm or benefit
  - Likelihood of harm or benefit
  - Peer pressure

- 1) Moral Awareness: Feel something is wrong, have an emotional reaction
  - Would your social group think it is wrong?
  - How do you feel about the people affected?

The Lab – Demonstration

Office of Research Integrity USA

http://ori.hhs.gov/TheLab/TheLab.shtml

2015 Queen's Policy: Stages in the Investigation

- Informal Discussion with Trained Advisors
  - No action needed under the Integrity Policy
  - Yes Initial Review
- Initial Review
  - No Investigation needed based on further fact finding
  - Yes Investigation needed
- Investigation
  - No Finding of misconduct based on full investigation by Committee
  - Yes Finding of misconduct
- Post Investigation
  - If relevant, sanctions fall to the Provost
  - Post reporting to external agencies as required

Research Integrity Resources

- Secretariat for the Responsible Conduct of Research
  - Tri Agency body responsible for ethics and integrity in Canada
  - http://www.rcr.ethics.gc.ca/eng/

- Office of Research Integrity
  - https://ori.hhs.gov/