Myths & Half-Truths in Research Ethics

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Objectives

- To recognize what constitutes research & an appropriate proposal
- To clarify application questions & requirements

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Examples of What Can Go Wrong

- Ewen Cameron: the 1950s MK-Ultra ‘mind-bending’ CIA experiments
- Markingson case: University of Minnesota & the CAFÉ study (2003)

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What is Research?

- Development of new knowledge
- Systematic investigation to gain knowledge
- Studious inquiry
- Establishing facts
- Testing theories

Human Research Principles

Respect/Welfare/Justice

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What is Quality Improvement (QI)?

- Systematic investigation to gain knowledge but at a local or confined level
- Work to improve local healthcare processes/methods
- Work to improve local healthcare (eg. use of evidence-based guidelines)
- QI has its own tools; may use research tools
- PDCA cycle (Plan-Do-Check-Act)

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Quality Improvement vs Research

- QI work does NOT require ethics approval
- Involvement of patients and/or surveys
- Participants: patient/MD/staff/other
- Presenting or publication of QI projects
- Chart review/database
- Use of human tissue ('Henrietta Lacks' or HeLa)

- Contact Janice/Deborah re the need for ethics approval

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Mandate of the HiREB

- To protect the rights, safety, & well-being of any patient or healthy volunteer who participates in research conducted by a member of the staff of the Faculty of Health Sciences, McMaster University; Hamilton Health Sciences; and/or St Joseph's Healthcare Hamilton
- The HiREB conducts independent review of research to ensure it is scientifically valid & ethically sound

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Who Governs the HiREB?

- TCPS2 (2018)
- ICH-GCP
- Declaration of Helsinki
- PIPEDA/PHIPA
- Canadian General Standards Board
- Health Canada (Food & Drug Act, Division 5)
- Board of Trustees of Hospitals
  (independent of research administration)

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Research Elements

*Your Protocol

- Background information & rationale
- Previous literature
- Clinical equipoise
- Study design: how would you set this up? Cont'd…

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…Cont’d

- Outcome RCT/type of control?
- Washout period?
- Blinded?
- Inclusion/exclusion criteria?
- Sample size?
- Outcome measures?
- Time period?
- Data collection, storage and analysis?
- Recruitment/consenting?

Your Application

- Application, consent and protocol should agree with each other
- Do NOT cut and paste from protocol into application
- Should be a stand-alone document
- Do not leave everything to the coordinator; the LPI/PI is responsible
- **SPELLING and GRAMMAR**
- **EDIT YOUR WORK**

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Section 1

Student Applications

- Clinical Fellow/post-Doc/ PhD/ resident/ master's/undergraduate must ALL have a supervisor

Lay Summary

- Do not use acronyms, 'Doctor Speak', or terms like 'theoretical framework'
- Aim for a grade 8 level of understanding

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Section 2

- The Local Principal Investigator (LPI) holds the overall responsibility for the project & must have formal affiliation with our institution(s)

- Resident may be the Principal Investigator (PI); may also be a Co-investigator

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Section 8 Safety & Monitoring

- GCP requires that clinical trials be monitored
- Recent revisions in GCP focus on monitoring & risk management
- For resident projects supervision by the LPI is acceptable

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Section 9 Risks & Benefits

- All research involves some element of risk
- Loss of privacy/confidentiality is the most common
- Please think through this section carefully

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Section 11 Recruitment

- We screen this for elements of undue influence or coercion
- The LPI may approach potential participants
- CIRCLE of CARE

Section 11 Consent

- The LPI may NOT obtain consent except in restricted circumstances
- Please think through carefully *who* is obtaining consent; *when & where* this is happening

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Privacy

- Can participants be identified?
- Harms they may experience from disclosure (embarrassment/ insurance/ employment)

- Researchers are responsible for compliance with all legal and regulatory requirements concerning protection of privacy
  (PHIPA, Section 44)

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- Direct identifiers
  - Name/Address
  - Social insurance number
  - Email address
  - OHIP number
  - MRN number

- Indirect identifiers
  - Date of birth
  - Gender
  - Years of schooling
  - Medical event date
  - Profession

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How are you protecting the data?

- During the collection process
- Once it's collected
- In transit or transport
- De-identification and/or anonymization process
- Storage:
  - locked cabinet in locked institutional office
  - password protected computer on a secure network
  - encrypted

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De-identified Information

- Stripped of direct identifiers
- Code linking data to original data exists

Anonymized Information

- Stripped of direct identifiers
- No code is retained to allow re-linkage

Anonymous Information

- Information NEVER had identifiers

Is that survey truly anonymous?

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Identifiable Data

Pt ID	Pt Name	MRN	DOB	Sex	Stroke Date	Stroke Location	Stroke Type	NIHSS
001	Jane D	1234						
002	Kim L	5678						
003	Sami M	9110						

Study Key

Pt ID	Pt Name	MRN
001	Jane D	1234
002	Kim L	5678
003	Sami M	9110

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De-identified Data

(Study Key removed & kept securely in a separate location)

Pt ID	Mth/Yr of Birth	Sex	Stroke Date	Stroke Location	Stroke Type	NIHSS
001						
002						
003						

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Destroy Study Key

Pt ID	Pt Name	MRN
001	Jane D	1234
002	Kim L	5678
003	Sami M	9110

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Anonymized Data

Pt ID	Mth/Yr of Birth	Sex	Stroke Date	Stroke Location	Stroke Type	NIHSS
001						
002						
003						

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What does the Participant Need to Know?

- Procedures are in place to ensure confidentiality of data
- Measures for physical/electronic security
- Length of data retention
- Which persons or agencies can access data
- What would be disclosed and why

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Data Management

- Data management plan template: www.portagenetwork.ca

- For surveys: https://reo.mcmaster.ca/limesurvey

- Information & Privacy Commissioner: www.ipc.on.ca

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Chart Review/Database/Tissue

- A protocol is still needed but may be quite brief (1-2 pages; include references)
- What is the purpose of collecting this data/ how will it be used/ why is it important
- Chart review application used also for QI work
- Focus of these applications is privacy because you are using PHI

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- Chart review:
  - Access the data once
  - Waiver for consent must meet all conditions
- Database:
  - Clinical database may be used for chart reviews
  - Prospective database requires consent & may be used for future research
- Tissue:
  - When only human tissue is needed; may need to obtain participant consent

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You are invited to take part in this study on ….. I (we) want to …….. I am (we are) hoping to learn….. I (we) also hope to find out….

Procedures involved in the Research
[*Alternate wording: **What will happen during the study?**]*

*[Describe the procedures step by step, using **simple language, short sentences** and short paragraphs or bullets if appropriate. Put yourself in the place of the participant and **describe the procedure as you might want it explained to you**. Use the word "you" rather than the "the participant" and "I" or "we" rather than "the researcher(s)". If scientific terms are unavoidable, they should be **clearly** explained. Details such as the length of time each part of the study will take, the number of participants, assignment to study groups, frequency of procedures, where participation will take place etc. should be provided. If the study involves an interview, indicate whether you would like to take handwritten notes, audio-tape the interview or both and insert the phrase "with your permission." Provide 2-3 sample questions..]*

You will be shown….. You will be asked to do …. You might be asked to …. A XXXX will be attached to your body to monitor ….. You will be asked to complete …… You will be assigned to…. I will be asking you questions about… I will also ask you for some demographic/background information like your age and education.

[PLEASE PROVIDE A VERSION NUMBER AND/OR DATE:]

We're Here to Help!

- sancan@hhsc.ca

905-521-2100 x 44574

Application questions

- mazzedeb@hhsc.ca

905-521-2100 x 42013

- atkinsar@hhsc.ca
- 905-521-2100 x 46243

Chart review/ database/ tissue applications

- HelpDesk: eREBhelpdesk.@hhsc.ca

905-521-2100 x 70014

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