HiREB Applications and Resubmissions

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Objectives

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

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What is Research?

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

TCPS2 (2018) Human Research Principles

Respect/Welfare/Justice

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Proportionate Review

- Degree of risk that is conferred on the participant
- Consider this in view of the participant's situation
- The level of scrutiny applied to a study is determined by the level of risk posed to participants
- Use of surveys/ interaction with patients

Quality Improvement vs Research

- QI work does NOT require ethics approval
- Work to improve local care: process/knowledge
- Involvement of patients and/or surveys
- Participants: patient/MD/staff/other
- Presenting or publication of QI projects
- Chart review: Student QI project needs to submit chart review application
- Chart review: QI project initiated by the department/ program generally does not need ethics review

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QI Exemption

- Send a copy of your proposal/project outline to Janice or Erin
- Include the purpose of the project/ how you will use the data/ what do you hope to learn
- If QI then we send you an exemption email
- Use that email for publishing as evidence of ethics contact

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Miscellaneous

- Waivers:
  - If it's research, then it requires review
- In-principle (pro-tem) approvals are used when you need REB support to show ethics review in order to release study funds/ contact HiREB manager
- Case reports are not research so no ethics review/ you are required to obtain patient consent

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Recruitment

- We screen this for elements of undue influence or coercion
- Consider *who* is recruiting; also *when, where* & *how*
- Circle of Care (PHIPA)

Consent

- Please think through carefully *who* is obtaining consent; *when & where* this is happening
- Implied consent
- May use email/fax/mail/verbal
- Videoconferencing guidelines on www.hireb.ca
- Signed written consent is the default

Verbal Consent Guide

- There should be a formal method of tracking a verbal consent process. To obtain verbal consent, the research member would need to document the following:
- -That the participant had a copy of the consent form
- -That the participant appeared to understand what the study entailed
- -That the participant was given the opportunity to ask questions
- -That the questions were answered to their satisfaction
- -That the participant provided verbal consent
- -This record should then be signed & dated by the person obtaining consent
- The participant may also sign & email/mail a copy of the consent form to the researcher.

Privacy

- Can participants be identified?
- Harms they may experience from disclosure (embarrassment/ insurance/ employment/ effect on grades/ social media/ performance evaluation)
- Why are you collecting those datapoints—do you really need them?

- Compliance lies with the investigator

- 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 (encryption needed?)
- Once it's collected (who can see this data in storage?)
- In transit or transport (who can see this data?)
- De-identification and/or anonymization process
- Storage:
  - locked cabinet in locked institutional office
  - password protected computer on a secure network
  - encrypted
- Identifiable data MUST be encrypted
- Check the security levels of the app you wish to use

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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						

De-identified Data

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

- The data collection form (DCF) must NOT contain identifiers
- The DCF is what you use for analysis
- You may NOT analyze identifiable data

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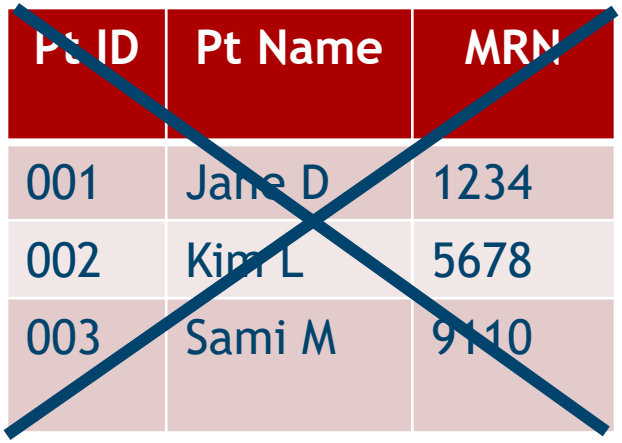
Study Key

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



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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Amendment

- TCPS requires that substantive changes be submitted to the REB (Article 6.16)
- Ethics review is determined by the ethical implications & associated risk with the change
- Any change in any document available to the public require ethics approval
- ‘Sub-forms’: amendment form
- Must include a cover letter
- Usually delegated review in 7-10 days

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Annual Renewal

- TCPS requires that annual review of research must be done as a minimum (Article 6.14)
- Is the project still ethically acceptable?
- The HiREB will determine if review is needed more frequently, eg. every 6 months
- ‘Sub-forms’: annual renewal form
- May include a cover letter
- Usually delegated review in 7-10 days

We're Here to Help!

- sancan@hhsc.ca

905-521-2100 x 44574

- belle@hhsc.ca

905-521-2100 x 42013

Application questions

- HelpDesk: eREBhelpdesk.@hhsc.ca

905-521-2100 x 70014

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