Research Ethics in the Health Sciences

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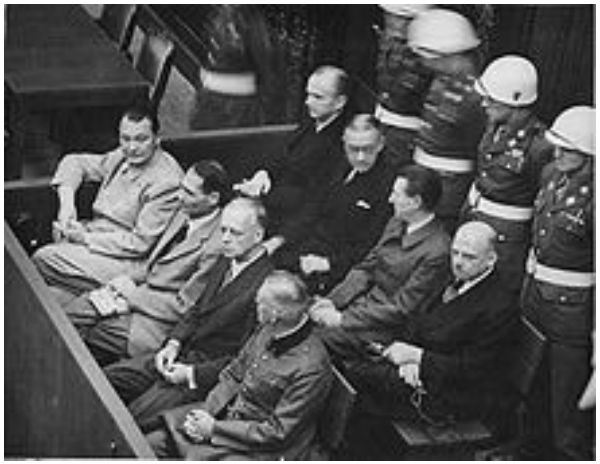
Overview

- Brief history of Research Ethics
- REB structure and processes
- Preparing a protocol
- Common REB concerns

Brief History

Nuremberg Code (1947)

- WWII crimes against humanity



http://en.wikipedia.org/wiki/Nuremberg_Trials

Declaration of Helsinki (1964)

- World Medical Association

Belmont Report (1979)

- Research scandals (e.g., Tuskegee syphilis study)

Tri-council Policy Statement (1998-2022)

- CIHR, SSHRC & NSERC

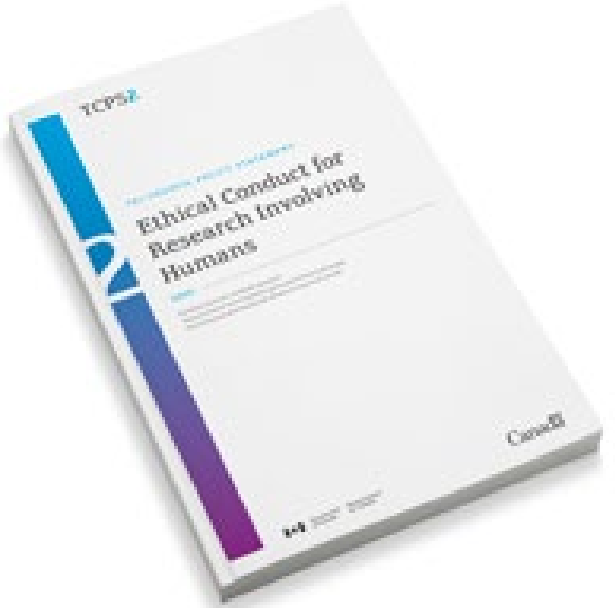
Tuskegee Syphilis Experiment

Tri-Council Policy Statement: TCPS 2 (2022)

Overarching concern: Respect for human dignity

Core Principles

- Respect for persons
- Concern for welfare
- Justice



Structure of REB

Membership requirements as per TCPS

Minimum of 5 members:

- men & women
- 2 members with expertise in the relevant research disciplines and methodologies
- 1 member knowledgeable in ethics
- 1 member who knows the relevant law
- 1 community member

U of T REBs

- U of T has 2 REBs
  - Health Sciences
  - Social Sciences, Humanities and Education

- REBs' mandate is to review the ethical acceptability of research on behalf of U of T

Life Cycle of Human Ethics Protocol

INITIATION

Undergraduate

Complete form

Submit to

Delegated Ethics Review Committee

Faculty & Graduate Student

Consultation (Optional)

Determine review type

Exempt No Review Required

Administrative Review

Delegated (Expedited) Review

Full Board Review

Submit for Review

Ethics Review

Decision is reached

More Work Needed

Ethics Approval

AMENDMENT, ADVERSE EVENT, PROTOCOL DEVIATION & RENEWAL

Complete form

Submit to

Continuing Ethics Review

Decision is reached

More Work Needed

Ethics Approval

PROTOCOL COMPLETION

Complete form

Submit to

Study Completion

Decision is reached

More Work Needed

Ethics Approval

What do you think is the rejection rate for new research ethics applications reviewed by UofT REBs?

A. 30%

B. 10%

C. 1%

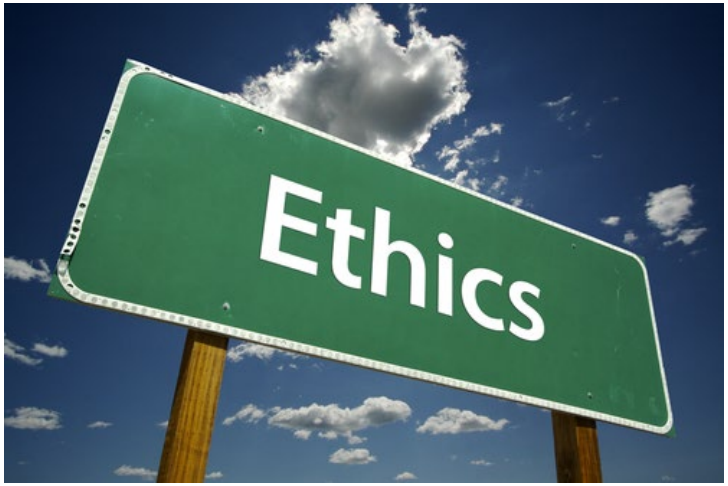
D. 1/1000

E. 50%

Research requiring Ethics Review

Research involving

- Living human participants
  - Interventions, interviews
- Human biological materials
  - Teeth, saliva, tissue, blood
- Secondary analysis of data from human participants
  - Chart reviews



http://provocativecopy.com/tag/integrity

Exemptions from ethics review

- Exclusive use of publicly available information
- Observing people in public places
- Secondary use of anonymous information
- Program evaluation/quality improvement studies

Administrative review:
Research involving TAHSN hospitals

University's Role	Type of review
Human participants research taking place at the University	Ethics review
Funds administered through the University	Administrative review
Storage/analysis of personal Information (data)	Administrative review
Storage or analysis of biological samples	Administrative review (MTA required)
Graduate student involvement	Administrative review

Delegated vs. Full review

- Delegated (expedited) review:
  - Protocol does not exceed *minimal risk*
  - *Minimal risk*: the probability and magnitude of possible harms on par with everyday life of participant

- Full review: if protocol presents more than minimal risk

Evaluation of risks

Group vulnerability: diminished ability to safeguard own interests

- Physiological (e.g., health crisis)
- Cognitive/emotional (e.g., age, capacity, recent trauma)
- Social (e.g., stigma, economic/legal status)

Research risk: possibility of harm

- Physiological/health issues (e.g., injury, side effects)
- Cognitive/emotional (e.g., stress, anxiety)
- Social/legal (e.g., privacy, reporting, subpoena)

Risk Matrix

Group Vulnerability	Research Risk		
	Low	Medium	High
Low	1	1	2
Medium	1	2	3
High	2	3	3

Risk Level: 1 (delegated review)

Risk Level: 2 and 3 (full review)

Can you think of examples of groups who may be considered vulnerable?

REB Protocol Submission

- My Research Human Protocol (MRHP)
- Protocol must be initiated by a faculty member
  - UTORID is required to access system
- Students can be PI
  - protocol requires approval by supervisor and departmental chair

Preparing a Protocol

- Each section should be brief, clear, consistent, focused on ethics
- Append all recruitment & consent scripts, flyers, letters, interview questions, questionnaires, surveys and any other instruments
- Give the REB a complete and carefully prepared ethics protocol

Consent Process

Essential components

- Voluntariness
- Information
- Competence

"Personally, I wouldn't have signed it."

http://www.wolfescape.com/Humour/MedPicts/ConsentForm.gif

Consent Process

- Describe how informed consent will be obtained
  - Usually written form
- Variations, as appropriate, with clear rationale:
  - Verbal (literacy, criminality, cultural appropriateness)
  - Implied (online survey)
  - Authorized third party- assent if feasible

Privacy & Confidentiality

- Outline procedures to maintain confidentiality
  - Anonymization or de-identification
  - Encryption
  - Storage of hard copy data in locked cabinets in a locked room
  - Present data in aggregate form, pseudonyms
- Data management plan?
- Limitations
  - duty to report- child abuse, suicide, subpoena
  - breach by other participants (e.g. focus groups)

Common REB Concerns

- Is what the participant being asked to do clear?
- Are inclusion/exclusion criteria clear and fair?
- Is recruitment coercive? Are there power issues?
- Is compensation fair and appropriate?

Common REB Concerns, cont'd.

- Are risks fully and realistically described?
- Have adequate steps been taken to mitigate the risks?
- Is the researcher's experience adequate?

Common REB Concerns, cont'd.

- Is consent free and informed?
- Is the information in the consent form the same as in the protocol?
- Are data safely stored and is confidentiality protected?

Review process and timelines

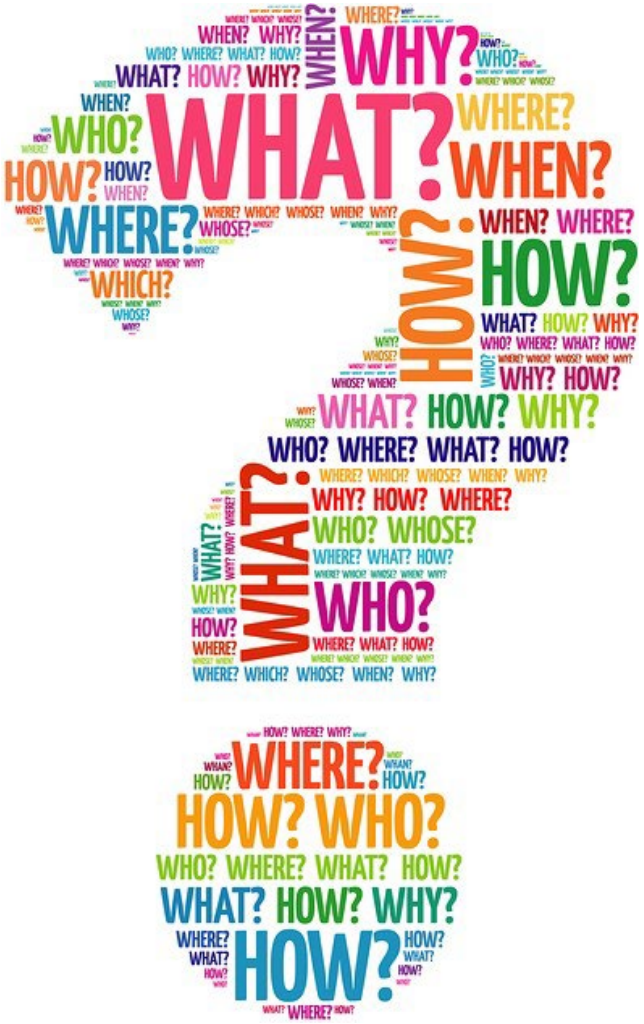
Delegated (Expedited) Review:

- Reviewed by a delegate of the REB
- Protocols submitted by Monday (4pm) will go out to reviewers within the week
- First response in approx. 4-6 weeks

Full Review:

- Protocols reviewed by full REB
- Submit before deadline (check website)
- First response within 2 weeks of meeting

Questions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Resources

- TCPS 2 (2022)

https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html

- Human Research Ethics Unit

https://research.utoronto.ca/ethics-human-research/ethics-human-research

- Informed Consent Guide

http://www.research.utoronto.ca/wp-content/uploads/documents/2014/10/GUIDE-FOR-INFORMED-CONSENT-V-Oct-2014.pdf

- Working Securely: Remote Data Collection and Storage

https://cris.utoronto.ca/spotlight/secure_remote/