Research Ethics in the Social Sciences & Humanities

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Outline

1. Research ethics framework & culture

2. Proportionate review & "risk"

3. Preparing a protocol: research ethics issues

History

Nuremberg Code (1947)
- WWII crimes against humanity

Declaration of Helsinki (1964)
- World Medical Association, drug trials

Belmont Report/Common Rule (1979)
- Research scandals (e.g., Tuskegee syphilis study)

Tri-Council Policy Statement (1998, 2010) & MOU
- Canadian research council guidelines

Tri-Council Policy Statement, 2nd Ed. (TCPS-2, 2010)

Research ethics: key principles and issues

- Respect for human dignity
  - Autonomy . . . e.g., consent
  - Welfare . . . e.g., privacy, confidentiality
  - Justice, fairness, equity . . . e.g., vulnerability
- Risks versus benefits

System of research participant protection

- Prior review of "protocols": Office of Research Ethics (ORE) and Research Ethics Boards (REBs)

REBs

Quorum
- 5 members, women & men
- 2 expertise in relevant disciplines, fields, methods
- 1 knowledgeable in ethics
- 1 no affiliation with the institution
- 1 knowledgeable in relevant law (biomed research)

University of Toronto: 3 boards
- "Social Sciences, Humanities & Education" (& management, law, engineering, . . .)
- Health Sciences
- HIV (for HIV-related protocols)

Research Ethics Culture:
Integral Part of Scholarly Process

Excellence in research & excellence in research ethics go hand in hand; not about authority

- Mandated by research funding bodies
- Researchers: Take possession, conception to completion: expert on groups/topics/methods -> expert on consent/confidentiality; budget for it, have models on hand, supervise/educate…push back if ill informed
- Reviewers: informed, principles based, tightly reasoned, collegial tone…open to counter-argument
- Myth that ethics/scholarship totally separate: compelled to comment if groups/topics/methods unclear, contradictory; expertise/experience/supervision inadequate

Research Ethics Culture:
Inter-disciplinarity

Myth that REBs fixated on "biomedical model"
- Dedicated boards for social sciences & humanities: researchers from psych, anthro, soc, polisci…review psych, anthro, soc, polisci...

Still, inter-disciplinarity not to be taken lightly
- Not radically discipline-centric/cheap shots
- Not radically relative/anything goes
- Good practices by those with relevant expertise
- Conceivably…new insights into own & others' disciplines

Research Ethics Culture: Evolution & Development

TCPS-2

- More open/inclusive definition of research: *disciplined, systematic…*not *generalizable*
- New qualitative research chapter—explicitly acknowledges ongoing consent process, range of methods, roles, media, open-ended/emergent designs
- Clearer explanations of exemption, delegation/reporting

Group- & methods-specific guidelines

- Aboriginal groups…Community Engagement; Ownership Control Access and Possession (OCAP) agreements
- Community-based research…conception to completion: consultative, iterative…explicit agreements on principles

Research Ethics Culture: Proportionate Approach

Exempt: program evaluation, standard professional practice/training/service learning, reflective practice

- May be high risk; discipline-specific guideline/codes help

Delegated: *minimal risk*, on par with daily life (but see risk matrix) ~90% of protocols in SSH

- Undergrad: Delegated Ethics Review Committees
- Grad & faculty: review by 1 REB member

Full REB: Greater than minimal risk (but see risk matrix)

Continuing: annual renewal, amendment, completion

Research Ethics Culture:
Nuanced, Grounded Approach to Risk?

Minimal risk…on par with daily life…*or greater*

- Blunt instrument—binary, categorical
- Inherently relativizable—e.g., PSY100 v. MTCT of HIV
- Doesn't lend itself to nuanced understanding of
  – Different groups, settings, special considerations
  – Variety of reasonably foreseeable, identifiable harms

Research might involve…

- children, international settings, aboriginal groups, LGBTQ, moderately sensitive topics, deceptive methods…and still be delegatable
- Think rigorously about vulnerability & research risk

Proportionate Review & "Risk"

Group vulnerability: diminished autonomy . . . Informed? Free?

- Physiological (e.g., health crisis, service dependence)
- Cognitive/emotional (e.g., age, capacity, recent trauma)
- Social (e.g., stigma, under the table, undocumented)

Research risk: probability & magnitude of reasonably foreseeable, identifiable harm

- Methods invasiveness & data sensitivity
- Physiological (e.g., new diagnoses, side effects)
- Cognitive/emotional (e.g., stress, anxiety)
- Social (e.g., dismissal, deportation, reporting, subpoena)

Proportionate Review & Risk Matrix

Review Type by Group Vulnerability & Research Risk

Group vulnerability	Research Risk		
	Low	Med	High
Low	Del.	Del.	Full
Med	Del.	Full	Full
High	Full	Full	Full

Preparing a Protocol
Forms, Deadlines, Guidelines…
(see ORE website links at end)

- Thesis proposal should be approved by thesis committee
- Follow model protocol; work closely with supervisor
- Use resources: ORE website; workshops/seminars; UT guides on consent docs, data security, key informant interviews, participant observation, deception/debriefing, student participant pools
- Each section brief, clear, consistent, focused on ethics
- Append all recruitment & consent scripts, flyers, letters
- Undergrad submission: to local DERC coordinator
- Grad/faculty submission: dept. sign off, then e-mail as single attachment to new.ethics.protocols@utoronto.ca
  - Delegated: weekly, Mondays by end of day
  - Full REB: monthly (except Aug), check website for deadlines

Research Ethics Issues: Free & Informed Consent

Quality of relationship from first contact to end

- Emphasis on process: not signature on paper; not jargony; not contractual/legalistic (*I the undersigned…   I understand that..I understand that..I understand that..*)

- Group-appropriate, plain language: who researcher is, affiliation, what they're studying, what participation would involve, voluntariness, confidentiality…(check readability)

- Variations, as appropriate, with clear rationale:
  - Verbal (literacy, criminality, cultural appropriateness), phone, web
  - Age-appropriate assent, alternate (e.g., parental) permission
  - Deception & debriefing
  - Admin consent, community consultation, ethics approval

Deception & Debriefing

Not inherently unethical: good vs. bad practices

- See TCPS-2, Article 3.7 and commentary
- Is it *necessary*? Rigourously think through justification
- *Low risk*—i.e., vulnerable group? sensitive topic?
- *Immediate, full debriefing*? Clear, explicit explanation:
  - What elements were deceptive—remove any misconceptions
  - Explain why necessary; why important—not arbitrary/capricious
  - "Re"-consent option--i.e., can withdraw if not satisfied
- Report any concerns to REB

Research Ethics Issues: Privacy & Confidentiality

Some projects: name participants, attribute quotes; most projects: protect personal info

- Consider collection, use, disclosure—life of project
- Recruitment: e.g., snowball, distribution/disclosure?
- Data collection: e.g., notes/recording; 1-on-1/groups
- Data management plan:
  – identifiers (collected/separated/de-linked?)
  – safeguards (double locking/passwords/encryption?)
  – retention/destruction (sensitivity, richness, standards of discipline? Not simply: *When will you destroy…)*
- Publication: pseudonyms, generics, aggregates
- Limits: duty to report (abuse, suicidality, homicidality), subpoena (criminality)

Research Ethics Issues: Conflict of Interest

Commercialization, investment… but typically

role-based: concurrent dual roles with *power over*

- e.g., researcher + instructor/minister/manager
- real or perceived, should inform REB and participants of non-research aspects
- may have to manage—e.g., not recruit directly, stay blind to participation until after relationship ends
- May have to abandon one interest

Research Ethics Issues: Inclusion/Exclusion Criteria

Equity, justice—fair distribution of benefits/burdens

- justify basis for including/excluding
- students sometimes have trouble with complex constructs (e.g., sex/gender/sexual orientation, race/ethnicity/culture)

State consistently throughout protocol sections & appendices (e.g., recruitment, consent)

ORE Website Links
Forms, Procedures, Guidelines

http://www.research.utoronto.ca/forms/

http://www.research.utoronto.ca/faculty-and-staff/research-ethics-and-protections/humans-in-research/

http://www.research.utoronto.ca/about/boards-and-committees/research-ethics-boards-reb/

http://www.research.utoronto.ca/policies-and-procedures/

ORE Contacts

New submissions (only): **new.ethics.protocols@utoronto.ca**

General Info: **ethics.review@utoronto.ca**

Delegated Review Specialist: **sshe.coordinator@utoronto.ca, 8-6899**

Quality Assurance Analyst (renewals, amendments, completions, site visits): **shantel.walcott@utoronto.ca, 8-3165**

Research Ethics Analyst (consults): **dario.kuzmanovic@utoronto.ca, 6-3608**

Research Ethics Board Manager, Social Sciences & Humanities: **dean.sharpe@utoronto.ca, 8-5585**

References

Tri-Council Policy Statement, 2nd Ed. (TCPS-2, 2010), and TCPS-2 tutorial

- **http://www.pre.ethics.gc.ca/policy-politique/initiatives/tcps2-eptc2/Default.aspx**

- **http://tcps2core.ca/welcome**

- **http://tcps2core.ca/login**