

Research Ethics in the Social Sciences & Humanities

Dean Sharpe, Ph.D.
Office of Research Ethics
University of Toronto
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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, 2010/2014) & MOU

- Canadian research council guidelines

Tri-Council Policy Statement, 2nd Ed. (TCPS-2, 2010/2014)

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” (incl. management, law, computer science, . . .)
- 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

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...
- Qualitative methods, emergent themes, but tight parameters regarding group, topic, method; meaningful discussion, what types of issues reasonably foreseeable
- Nonetheless, element of inter-disciplinarity; shouldn't write with such technical jargon that only people in your sub-sub-discipline would understand. Write for reasonable person, or educated lay person standard

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 renewals, amendments, adverse events, completions, small chance of a site visit

Research Ethics Culture: Nuanced, Grounded Approach to Risk?

Minimal risk...on par with daily life...or greater

- Blunt instrument: binary, categorical, inherently relativizable
- Many complexities regarding groups, topics, methods need to be taken into account

E.g., merely by virtue of involving . . .

- Children; low-income country; talking to adults about moderately sensitive topics; using deceptive methods . . .
. each in and of itself doesn't necessarily trigger full-REB review
- Need to think rigorously about vulnerability & research risk

Proportionate Review & “Risk”

Group vulnerability: narrow & broad construals; diminished autonomy? Base rates for risk?

- Physiological (e.g., health crisis, service for 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

- 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

	<u>Research Risk</u>		
<u>Group vulnerability</u>	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, or MRHP if no local DERC coordinator
- Grad/faculty submission: through MRHP
 - 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 process & language: researcher identity, affiliation, research topic, nature of participation, voluntariness, risks, confidentiality (or not)
- Variations, as appropriate, with clear rationale:
 - Verbal (literacy, criminality, cultural appropriateness), phone, web
 - Capacity-appropriate assent, proxy consent (e.g., parent, substitute decision maker)
 - Deception & debriefing
 - Admin consent, community consultation, ethics approval

Deception & Debriefing

Not inherently unethical: good vs. bad practices

- See TCPS-2, Article 3.7A & B 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

Collection, use, disclosure though life of project

- Some projects: name participants, attribute quotes; most projects: maintain confidentiality
- Recruitment: e.g., snowball, distribution/disclosure?
- Data collection: e.g., notes/recording; 1-on-1/groups
- Data management plan:
 - Identifiable information (collected/separated/de-linked?)
 - Safeguards (double locking/encryption?)
 - Retention/destruction (identifiability, sensitivity, richness, disciplinary standards? 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? Typically
role-based: concurrent dual roles, undue influence

- E.g., researcher + instructor/minister/manager
- Real, potential or perceived, should inform REB and participants of non-research roles
- May have to manage—e.g., avoid direct recruitment, remain 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

- Clear, consistent basis for inclusion/exclusion
- Sometimes multi-step process for recruitment, screening, inclusion/exclusion (e.g., diagnostic categories, cut-off scores on standardized measures)

ORE Website Links

Forms, Procedures, Guidelines

Submit through MRHP, see user guide, FAQs, help desk (416-946-5000, RAISE@utoronto.ca)

- <http://aws.utoronto.ca/services/my-research-mr/>

UT resources, procedures, guidelines, boards & dates

- <http://www.research.utoronto.ca/faculty-and-staff/research-ethics-and-protections/>
- <http://www.research.utoronto.ca/faculty-and-staff/research-ethics-and-protections/humans-in-research/>
- <http://www.research.utoronto.ca/policies-and-procedures/>
- <http://www.research.utoronto.ca/about/boards-and-committees/research-ethics-boards-reb/>

ORE

Contacts

Delegated review specialist—new submissions

- sasmita.rajaratnam@utoronto.ca, 416-978-6899

Quality assurance analyst—renewals, amendments, completions, site visits

- joshua.vanry@utoronto.ca, 416-946-5606

Manager, Social Sciences, Humanities and Education
Research Ethics Board

- dean.sharpe@utoronto.ca, 416-978-5585

References

Tri-Council Policy Statement, 2nd Ed. (TCPS-2, 2014), 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>