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)

- Canadian research council guidelines

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
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

<table>
<thead>
<tr>
<th>Group vulnerability</th>
<th>Research Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Del. Del. Full</td>
</tr>
<tr>
<td>Med</td>
<td>Del. Full Full</td>
</tr>
<tr>
<td>High</td>
<td>Full Full Full</td>
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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
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://tcps2core.ca/welcome
• http://tcps2core.ca/login