

Nuts and Bolts: How to Complete the Research Ethics Application

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Governing documents

- Tri-Council Policy Statement (2nd edition, 2010)
- McMaster policies

www.pre.ethics.gc.ca

www.mcmaster.ca/ors/ethics

Research Ethics Board= arm's length body

Values research, but no particular interest

From perspective of participants

Staffed with research expertise and community perspective

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"How would you feel if the mouse did that to you?"

How would you feel if the mouse did that to you?

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Trust me. It's not a God-given right.

WHO? Membership 2011 (diverse—to gauge participants' perspective and evaluate research from many disciplines)

Daphne Maurer, Psychology, Neuroscience & Behaviour, Chair

Tina Moffett, Anthropology, Vice-Chair

Bruce Milliken, Psychology, Neuroscience & Behaviour, Vice-Chair

Dorothy Pawluch, Sociology

Violetta Igneski, Philosophy; Communication Studies, *Ethicist*

Maroussia Ahmed, French

Tony Porter, Political Science

Marshall Beier, Political Science

Isik Zeytinoglu, Business

Niko Yiannakoullas, Geography

Carol Wood, Chaplaincy

Giannie Parise, Kinesiology

Mirna Carranza, Social Work

Jeannie An, Library

Michelle Donnelly, Sociology, graduate student

Yaro Konar, Psychology, graduate student

Nick Caric, Divinity College, graduate student

Linneth Maride, graduate student & community member

Debra Clinton, *Community member*

Cindy McCormack, *Community member*

Renata Kis, lawyer, *Community member*

Inas Garwood, *Community member*

STAFF SUPPORT: Michael Wilson, Karen Szala-Meneok

What requires review: Tri-Council Policy Statement

Research

An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation

Involving human subjects or their remains

Or records from human subjects (private papers; use of data for new purpose)

What does not require review

Use of public records

Naturalistic observation in public places (when don't expect privacy and won't be identifiable)

Quality assurance or quality improvement studies

Secondary use of anonymous information

Creative practice

Usual process

- Submitted to ethics office
- Reviewed by Chair (or Vice-Chair), two other members
- Letter from chair (or Vice-Chair)
- Correspondence by email
- MREB meetings: protocols with challenging issues

What? Reviewer's form

Methodology

Selection and Recruitment

Risks/Benefits

Informed Consent / Consent Form

Right to Withdraw

Privacy/Confidentiality

How to fill out protocol form

I. Key Sections

SECTION B – SUMMARY OF THE PROPOSED RESEARCH

9. Rationale: purpose of your research.

Reviewers' questions:

What does the researcher hope to accomplish?

Are objectives clear?

What are possible benefits?

Tip: state objectives clearly; include ***brief*** rationale

Trap: say too little or too much.

Methods

10. Describe sequentially and in detail.

Reviewers' questions:

What will happen from participant's perspective?

Does it match purpose?

Are any personal questions necessary?

Will it be described adequately to potential participants?

Tip: explain how it relates to purpose, if not obvious, why demographic questions needed.

Special Issues that may arise in Qualitative Research

Open-ended

May be done in social context—talking to another human

Can be **intimate**

Tip: Provide an interview guide as part of protocol.

Tip: Indicate how these points will be described clearly to the prospective participant.

Tip: Reconfirm consent; give outs as go along; offer info on follow-up support

Methods

Trap: say too little.

I will interview teachers about their union. This is qualitative research and I will follow leads.

Trap: ask for personal information that isn't needed
age, job, income, sexual orientation

Tip: indicate *why* you need the information.

Trap: write it for academics.

11. **Experience:** *with this kind of research*

Reviewers' questions:

How qualified are experimenters with these methods?

Does their inexperience make risk more likely?

Decrease likelihood of benefit?

Tip: Mention relevant experience by those who will be involved with participants; mention how students will be supervised

12. **Participants:** number, age, gender, location, etc.

Reviewers' questions:

Is the number within the range of appropriate?

Enough to learn something but not more than needed.

Do the characteristics match the rationale?

Are exclusion criteria justified?

Trap: don't mention number or location.

Method of recruitment



*"I don't usually volunteer for experiments,
but I'm kind of a puzzle freak."*

*I don't usually volunteer for experiments,
but I'm kind of a puzzle freak.*

Recruitment

13. Describe how, who will recruit, any pre-existing relationships, attach draft recruiting ad

Reviewers' concerns:

Sufficiently informative?

Are most sensitive parts mentioned?

Free from coercive elements?

Having to decline in front of peers

Having to decline when asked by someone in authority—teacher of class student is taking, service provider, employer

Could it compromise confidentiality?

Knowing who else is likely to have participated if numbers are small, recruitment by snowball sampling, or participation is too public

Recruitment

13. Recruitment

Trap: *I'll ask my friends.*

Trap: *It will be conducted during an optional class.*

Trap: *The agency will give me a list of clients.*

Trap: *I will use a snowball technique whereby each interviewee identifies others.*

Trap: *I will test 100 teachers (no **how**).*

Recruitment

Tip: describe *how* you will get the names

Tip: use a third party if power relationship

Tip: give easy outs if social or power relationship (*I know you are busy*)

Tip: make non-participation invisible to others to avoid social or economic pressure (e.g., allow to turn in blank survey)

Tip: get many more referrals than needed; tell participants will use only fraction

14. **Compensation**:provide details

Reviewers' questions:

Is it large enough to be respectful?

Is it so high as to create undue pressure?

(c) If participants choose to withdraw, how will you deal with compensation?

Reviewers' questions: Will there be pressure to continue?

14. Compensation

REB test: Would participant consent without the compensation (or other influence)?

- consistent with values
- adequately informed about risks
- influence is consistent with respect for human dignity.

SECTION C – DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH

15. Possible Risks

a) Physical risk

Physical discomfort

Pain

Injury or disease

Electrodes, x-rays, ultrasound, MRI, exercise

b) Psychological risks

Loss of self-confidence or self-respect

Embarrassment from personal questions

Stress from memories of unpleasant events

Regret or guilt over what revealed (or hidden)

Tip: Acknowledge possible unpleasant effects.

Tip: Minimise by warning about risks in advance; allowing to skip questions; offering follow-up support (e.g., list of agencies).

Trap: Check none to avoid trouble or because haven't thought about.

c) Social risks

Loss of status or reputation if not confidential

Loss of employment

Tip: Acknowledge possible social risks.

Tip: Mitigate by warning, allowing to skip questions, keeping participation confidential.

Trap: Check none to avoid trouble or because haven't thought about.

Risk to others from revelation of information
(illness disguised from employer, corruption in
NGO, “Mohawk”)

*Reviewers’ questions: whose consent is needed? Are
there secondary subjects or risks to third parties?*

e) Are any possible risks to participants greater than those the participants might encounter in their everyday life?

Reviewers' questions: Is it more than minimal risk?

Proportionate approach: some social and psychological risks are part of everyday life-- participants are willing to assume them if informed clearly in advance about:

(a) those risks and

(b) possible benefit of research.

Tip: Explain how this applies to your research.

3. Describe how the risks will be managed

Tip: How can risks, however small, be mitigated from *participant's* perspective?

Skip parts find troublesome? Withdraw from participation without embarrassment? Offer of follow-up support? Review transcript for accuracy or second thoughts?

Reviewers' questions: Are remaining risks acceptable from a participant's perspective? Informed adequately before consent?

16. Possible Benefits: to participants and to society

Reviewers' questions:

Is the risk:benefit ratio acceptable?

Are the benefits described accurately to the prospective participants?

Trap: claim too much

Trap: don't say anything

17. The Consent Process: describe *process* and attach any letter of information/consent form

Reviewers' questions:

Whose consent is needed? Individual? Authorised representative? Community?

Is information complete?

Is it comprehensible to the *target* population?

Who will get consent? How? Is the process appropriate?

How will the process be documented?

17. The Consent Process

Tip: leave information with participant--so can follow up later if desired.

Tip: signature on consent form is not only option--but consent should be documented.

Trap: *Subjects will be required to sign the attached consent form.*

Trap: Complex language, academic jargon.



You...hereby grant the entire, complete rights to everything you've ever thought, made, or done to Acme Co., in perpetuity and throughout the Universe, and even if one day they find a door in the Universe that leads to a whole new non-Universe place, or somebody invents a time-stopping machine so that "perpetuity" no longer exists, or everything falls into a black hole and nobody knows which end is up and we're all dead anyway, so who cares—we'll STILL own all these rights....



"A handshake is as good as a thirty-page contract, eh, Mr. Harrison?"

A handshake is as good as a thirty-page contract, eh, Mr. Harrison?

21. **Providing study results:** describe; attach debriefing form, is appropriate.

Reviewers' questions:

Is it comprehensible?

Is it appropriately complete?

Tip: Think of as part of benefit to participant.

Tip: Allow subject to review transcript of interview, if appropriate.

Trap: None or *they can call me later to ask for a copy of my thesis.*

22. Right to withdraw: how informed; what will happen to data already collected?

Reviewers' questions:

Is provision for withdrawal appropriate?

What will happen to promised compensation? To data already collected?

Will participants be clearly informed about right to, and consequences of, withdrawal?

SECTION E – CONFIDENTIALITY

23. Procedures to ensure anonymity or confidentiality of data; security; final disposal

Reviewers' questions:

Are researcher's intentions appropriate?

How might they go astray?

Would that put participants at risk?

Will participants understand limits to confidentiality before deciding to participate?

Can design be altered to ensure greater confidentiality?

- SECTION E – CONFIDENTIALITY

Trap: Confusing anonymous and confidential

Trap: Asking for identifying information when not needed.

Tip: anonymous is better; signed consent form may be unnecessary

Trap: Forgetting that focus group members may reveal what others say. **Tip:** ask them to keep remarks confidential but warn cannot guarantee this will happen.

...con't

- SECTION E – CONFIDENTIALITY

Trap: Reporting aggregate data down to very small categories

Trap: Forgetting to warn about duty to report. **Tip:** think through what you will do in advance and what to tell subjects.

Trap: Forgetting about U.S. Patriot Act if data stored in U.S.; about company access to computers

Trap: Mistakes (losing the laptop; leaving the firewall open to a hacker).



"Just for kicks, Leon, let's shut down the F.B.I. again."

*Just for kicks,
Leon, let's shut
down the F.B.I.
again.*



"Forgive me, Doris, but some computer hacker from Roslyn, Long Island, has just gained access to my feelings."

*Forgive me, Doris, but some
computer hacker from Roslyn,
Long Island, has just gained
access to my feelings.*



Human Error. Again

- SECTION E – CONFIDENTIALITY

Trap: Thinking Ethics Board expects confidentiality even when subject wants to be identified: oral history, President of Union, Prime Minister

Tip: be transparent to Ethics Board and participant about confidentiality; let participant choose how to be identified.

Some fine points

- Deception
- Participants who are not competent to consent
- International research
- Research with Aboriginal participants
- Contract research and conflict of interest
- Research at multiple universities

Deception

15d) Is there any deception involved?

TCPS Article 3.7. *“The REB may approve..., provided that:*

i. ...no more than minimal risk

ii. ...unlikely to adversely affect the welfare of the participant

REB test: would participant agree if fully informed?

How will participant react to not having been fully informed?

Is there any deception involved?

iii. ... could not practicably be carried out without

REB test: is deception necessary?

iv. ...additional pertinent information after participation and, opportunity to refuse consent

REB test: is the debriefing adequate?

Will consent be reconfirmed?

v. ...does not involve a therapeutic intervention.”

Incompetence

18. Consent by an authorized party

If the participants are minors or for other reasons are not competent to consent, describe the proposed alternate source of consent.

Competence depends on decision to be made, when, context. Legal definition varies.

(a) researcher involves indiv in decision to greatest extent possible

(b) consent from authorized third party

(c) who is not part of research team

(d) if no potential direct benefit, must be minimal risk and burden and protect indiv's welfare

(e) If indiv regains capacity, seek consent immediately.

TCPS Article 3.10. "...shall seek to ascertain the wishes of the individual concerning participation. The potential subject's dissent will preclude his or her participation."

International research

Requires review here and where research will take place.

Tip: help us identify appropriate REB or appropriate reviewers.

Tip: start early.

Research with Aboriginal participants

- Requires documentation of consultation with community and community consent
- Chapter 9 of TCPS
- Start EARLY!

Conflict of interest

8. Tell us details of contracts re: profits to research team, restrictions on publication.

Reviewers' questions:

Does it create conflict of interest?

How can conflict be managed?

How would participant perceive conflict?

Should participant be told?

Multiple universities

4. Requires approval at each one

Tip: make one of them the lead; supply this information (form & all correspondence to us).

Tip: indicate what will happen here.

Tight timelines

Tip: tell us (Michael Wilson).

Most Important Tips

Ask for help before you submit the protocol

Michael Wilson, Research Ethics Officer, x23142

Karen Szala-Meneok, Senior Ethics Advisor, x26117

Daphne Maurer, Chair, x23030

Tina Moffit, Vice Chair, x23906

Bruce Milliken, Vice Chair, x23461

Check the webpage: <http://www.mcmaster.ca/ors/ethics/>

Start EARLY; tell us if you have time constraints.

