

How to Review a Protocol in Social Sciences, Humanities and Behavioural Research

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- Read the entire protocol first.
- Think about it from participant's perspective.
- Have ethical framework and review criteria in mind.

Ethical framework:

Respect for human dignity

- Respect for autonomy
- Informed Choice
 - Honesty
 - Freedom from coercion
- Respect for privacy
- Respect for vulnerable persons



Ethical framework:

Beneficence / Non-Maleficence

- Balancing benefits and harms
- Minimizing harms
- Maximizing benefits

Ethical framework:

Justice

- Fairness
- Equal access to benefits
- Equal share of burdens

Resources:

Belmont report: http://www.ncehr-cnerh.org/english/mstr_frm.html

Philosophical underpinnings & online tutorials:

http://www.mcmaster.ca/ors/ethics/faculty_educ.htm

www.pre.ethics.gc.ca



Review criteria-Areas of Focus

- Methodology
- Selection and Recruitment
- Risks/Benefits
- Informed Consent / Consent Form
- Right to Withdraw
- Privacy/Confidentiality



Methodology

- Bad research may not be ethical.
 - Puts participants at risk for no possible benefit.
 - Misleads participants.
- Better methodology increases possible benefit.



Methodology

- TCPS Article 1.5. *"(a) The REB shall satisfy itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research."*
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- TCPS Article 1.5(b) *"Research in the humanities and the social sciences which poses, at most minimal risks shall not normally be required by the REB to be peer reviewed."*



Selection and Recruitment

- Justification of exclusion of certain populations
- Special concerns if
 - “captive populations” — students, employees, colleagues
 - “vulnerable” populations—mentally incompetent, dying



Informed Consent/Consent form

- Informed consent is a process, not a form.
- Participants must be competent for particular choice.
 - Full disclosure of purpose, what will happen, risks, benefits
 - Voluntary choice



Right to Withdraw

- Without consequence
- Clearly stated to participant
- What will happen to data already collected



Privacy & Confidentiality

- Normal default=respect privacy by offering confidentiality
- Transparency about degree of confidentiality
- Best assurance is through anonymity.



Risks/Benefits

- Reasonable in relation to anticipated benefits to participant (if any) and importance of knowledge that may result.
- Forseeable harms should not outweigh anticipated benefits.
- Risk should be minimized.



Is it more than minimal risk?

“no greater than ...encountered in everyday life” re: probability and magnitude



Reading a protocol form: How to spot issues requiring thought

1. Title of the Research Project:

What?

2. Investigator Information

Who? How qualified?

3. Proposed Date (a) of commencement: (b) of completion:

When? Scale of project?



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4. **Indicate the location(s)** where the research will be conducted:

Where?

Special issues because offsite or in third world?

Will consent form be understandable?

Is it appropriate to ask for signature on consent form?



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4. **Indicate the location(s)** where the research will be conducted:

Where?

Will consent be free from coercion?

Will data be secure?

Will researcher be safe?



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5. Other Research Ethics Board Approval

(a) Is this a multi-centred study? **Yes** **No**

(b) Has any other institutional Ethics Board
approved this project ? **Yes** **No**

Should another REB be involved?

TCPS Article 1.2: [REB is mandated to approve any] "*research involving human subjects which is conducted **within**, or **by** members of the institution, ...*"

TCPS Article 1.14. "Research to be performed **outside** the jurisdiction of ...the institution which employs the researcher shall undergo prospective ethics review both

(a) by the **REB within the researcher's institution**; and

(b) by the **REB**, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the country **or jurisdiction where the research is to be done.**"



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6. Level of the Project

Faculty Research

Post-Doctoral

PhD.

Masters Faculty/Hospital Research

Other (specify)

Student or faculty?

Is part of benefit in training of student researchers?



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7. Funding of the Project

Will researcher have necessary budget?

(d) Agency or Sponsor (funded or applied for)

Will it have been peer-reviewed?

- Do not need to duplicate professional peer-review, although may request reviews.



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8. Conflict of Interest: from payments, interests, stock options to researcher or family

Might it compromise researcher's judgment?
Lead them to stretch inclusion criteria?
To underestimate risks?

Should participants be told?



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SECTION B – SUMMARY OF THE PROPOSED RESEARCH

9. Rationale

Describe the purpose and background rationale for the proposed project, as well as the hypotheses(is)/ research questions to be examined.

Are objectives clear?

What are possible benefits?



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10. Methodology

Describe sequentially, and in detail, all procedures in which the research participants will be involved.... **N.B. Attach a copy of all questionnaire(s), interview guides or other test instruments.**

What will happen from participant's perspective?

Does it match purpose?

Are any personal questions necessary?

education, age, marital status, ethnic group, sexual orientation, income

Will it be described adequately to potential participants?

Special Issues in Qualitative Research

Open-ended:

- Researcher does not know where the interview may lead—cannot fully inform REB or prospective participant.
- Methodology includes everything: pauses, smiles, breaks, posture

May be done **in social context**—talking to another human

- Makes it hard to withdraw
- May create risk from loss of support at end

Can be **intimate**—risks of embarrassment, regret, guilt

REB test: Is there an interview guide?

REB test: Will these points be described clearly to the prospective participant?



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11. Experience

What is your experience with this kind of research?

How qualified are experimenters with these methods?

Can affect likelihood or magnitude of possible harms.



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12. Participants

Describe the number of participants and any salient characteristics (such as age, gender, location, affiliation, etc.)

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?



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13. Recruitment

Describe how and from what sources the participants will be recruited, including any relationship between the investigator(s) and participant(s) (e.g. instructor-student; manager-employee).

N.B. Attach a copy of any poster(s), advertisement(s) or letter(s) to be used for recruitment.

Appropriately informative?

Free from coercive elements?

Having to decline in front of peers

Having to decline when asked by someone in authority—teacher, service provider, employer

Promise of large payments



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14. Compensation

(a) Will participants receive compensation for participation?

Financial or In-Kind

Is it large enough to be respectful?

Is it so high as to create undue pressure?

Acceptable: Compensation for expenses and time

Problematic: Payment in excess of that amount



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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.



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

Will there be pressure to continue?



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

15. Possible Risks

1. Indicate if the participants might experience any of the following risks:

a) Physical risk (including any bodily contact or administration of any substance)?

Physical discomfort

Pain

Injury or disease

Electrodes, x-rays, ultrasound, MRI, exercise



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b) Psychological risks (including feeling demeaned, embarrassed worried or upset)?

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)

Altered behaviour



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c) Social risks (including possible loss of status, privacy and / or reputation)?

Loss of respect by others

Loss of status or reputation if not confidential

Disruption of family routine; loss of time

Risk to others from revelation of information
(incest, child abuse, illness disguised from employer,
corruption in NGO, “Mohawk”)—whose consent is needed?
Are there secondary subjects?



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d) Is there any deception involved?

TCPS Article 2.1c. *“The REB may approve a consent procedure which does not include...all of the elements of informed consent..., provided that:*

i. The research involves no more than minimal risk to the subject;



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d) Is there any deception involved?

ii. The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects;

REB test: would participant agree if fully informed?

How will participant react to not having been fully informed?



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d) Is there any deception involved?

iii. The research could not practicably be carried out without the waiver alteration

REB test: is deception necessary?

iv. Wherever possible and appropriate the subjects will be provided with additional pertinent information after participation; and

REB test: is the debriefing adequate?

v. The waiver or altered consent does not involve a therapeutic intervention.”



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

Is it more than minimal risk?

**REB should take 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.**



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3. Describe how the risks will be managed (including an explanation as to why alternative approaches could not be used).

Has the researcher minimized the risks?

Will participants be able to skip parts they find troublesome? Withdraw from participation without embarrassment?

Are the remaining risks acceptable *from a participant's perspective?*

Will prospective participants be informed adequately about possible risks before choosing to participate?



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16. Possible Benefits

Discuss any potential direct benefits to the participants from their involvement in the project. Comment on the (potential) benefits to (the scientific community) / society that would justify involvement of participants in this study.

Is the risk:benefit ratio acceptable?

Are the benefits described accurately to the prospective participants?



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17. The Consent Process

Describe the process that the investigator(s) will be using to obtain informed consent (including a description of who will be obtaining the informed consent; if there will be no written consent form, explain why not).

N.B. Attach a copy of the Letter of Information (if applicable), the Consent Form (if applicable), the content of any telephone script (if applicable) and any other material which will be utilized in the informed consent process.



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17. The Consent Process

Is information complete?

Is it comprehensible to the target population?

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



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17. The Consent Process

How will the process be documented?

Usually by signature on written consent form.

BUT sometimes better to avoid signature to provide anonymity or because culturally inappropriate.

Still needs to be documented.



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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, including any permission / information letter to be provided to the person(s) providing the alternate consent.

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

TCPS Article 2.5. "*individuals who are not legally competent shall only be asked to become research subjects when:*

(a) the research question can only be addressed using individuals within the identified groups; and

(b) free and informed consent will be sought from their authorized representative(s); and

(c) the research does not expose them to more than minimal risks without the potential for direct benefits for them."

TCPS Article 2.7. *"...and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential subject's dissent will preclude his or her participation."*

Annotated sample Consent form and checklist
Questions about Informed consent

<http://www.ncehr-cnerh.org>



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20. Debriefing (Participant feedback)

Explain what feedback/ information will be provided to the participants after participation in the project. (For example, a more complete description of the purpose of the research, access to the results of the research). **N.B. Please provide a copy of the written debriefing form, if applicable.**

Part of benefit to participant.

Is it comprehensible?

Is it appropriately complete?



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21. **Participant withdrawal**

- a) Describe how the participants will be informed of their right to withdraw from the project. Outline the procedures which will be followed to allow the participants to exercise this right.

- b) Indicate what will be done with the participant's data and any consequences which withdrawal might have on the participant, including any effect that withdrawal may have respecting participant compensation.

- c) If the participants will not have the right to withdraw from the project, please explain.

TCPS Article 2.1a. *"Research may begin only if (1) prospective subjects, or authorized third parties, have been given the opportunity to give free and informed consent about participation and (2) their free and informed consent ...is maintained throughout their participation in the research."*

REB test: Is provision for withdrawal appropriate?

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



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SECTION E – CONFIDENTIALITY

22. a) Will the data be treated as confidential?

b) Describe the procedures to be used to ensure anonymity of participants or confidentiality of data both during the conduct of the research and in the release of its findings.

c) Explain how written records, video/audio tapes and questionnaires will be secured, and provide details of their final disposal or storage.

d) If participant anonymity/confidentiality is not appropriate to this research project, explain, including providing details of how all participants will be advised of the fact that data will not be anonymous or confidential.



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SECTION E – CONFIDENTIALITY

22. a) Will the data be treated as confidential?

Are researcher's intentions appropriate?

How might they go astray?

Would that put participants at risk?



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Possible violations of promised confidentiality

- From researcher's lapses: participant's photo will be part of "anonymous" file; computer will be in public place.
- From revelations by other participants (focus groups)
- From researcher's obligation to report child abuse, infectious disease, threat of harm to self or others
- From identifying information present in aggregate data (thanks to xx school; breaking down data into cells with n=1)
- From court orders (re: illegal activity)

REB test: could design be altered to ensure greater confidentiality?

REB test: will participants understand limits to confidentiality before agreeing to participate?

REB test: Would any violation of confidentiality put participants at risk?

Is there relevant law? e.g., PIPEDA



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SECTION F -- MONITORING ONGOING RESEARCH

23. Annual Review and Adverse Events

a) Minimum review requires the completion of a “Renewal/Project Completed” form at least annually. Indicate whether any additional monitoring or review would be appropriate for this project.



Survey for Adolescents

- Thanks to:
 - Sociologist Sarah Phillips
 - Laurel Evans, Senior Research Ethics Officer, McMaster University
- **WE ALTERED IT TO MAKE IT A TEACHING TOOL.**

1. Title: Adolescent Attitudes and Behaviours related to HIV/AIDs prevention

4. Location: Jean Chretien High School, Brian Mulroney High School, and Pierre Trudeau Secondary School

5d: No other REB to approve.

6. Post-doctoral research.

7. No funding.

8. No conflict of interest.

9. Rationale.

This is a study to determine **adolescents attitudes and behaviours related to HIV/AIDS prevention. ...**

We hope to determine **what adolescents think about using condoms during sexual intercourse, and how what they think influences their decisions to use or not to use condoms during sexual intercourse...**

Participants will complete a **paper and pencil questionnaire (attached)**.

The participants will be high-school students who will complete the questionnaire **in their regularly scheduled health classes**.

.... will take approximately **30 minutes**.

The questionnaire will be administered by the researcher and the research assistants, and the student's **teacher will not be present**.

.... any students who object to participating or whose parents do not wish them to participate will be provided with an **alternative activity in another room**

12. Participants.

....**approximately 400 high-school students between the ages of 13 and 18**, attending health classes at the participating high-schools.

13. Recruitment.

...The principals have given me permission to administer the survey and the teachers have agreed to include their classrooms.

.... Parents will have been sent a letter of information and a consent form and given the option of withdrawing their child from the study, all they have to do is let us know.

Prior to administering the survey, I or my research assistants will read a "letter of assent" to the class, and then have an informal discussion to answer the student's questions....,

There is no relationship between myself or my research assistants and the students.

14. No compensation.

15.Risks: None.

This is a **paper and pencil survey**, which does not pose any risk to the participants,

as the data collected will be **anonymous**, no-one will know how /what each participant answered,

and if any student did feel uncomfortable with the survey, they **could choose NOT to complete it, or not to answer any question that they didn't feel comfortable with.**

22. Confidentiality: YES

a) Permission has been obtained from the teachers for the students to **move their desks and/or selves any place in the room to give them the maximum personal space.**

b) Design of the questionnaire: The questionnaire has been designed as booklet with a cover so that students can **fold a page back, not leaving completed pages exposed.**

c) Administration of the questionnaire: Students will be pointedly told **NOT to put their names** or any other identifying marks on the surveys. Surveys will be collected by having the students drop their completed questionnaires into **a large sealed box with a slot.**

No questionnaires will be removed until all of the surveys from the entire school have been collected.

The teacher will NOT be in the classroom while the survey is being administered.

d) Coding: Questionnaires will be **coded numerically** so that the researchers will be able to identify the school and the date of the administration, but **will not be able to identify any individual respondents.** The research assistants and the researcher will be the only people who actually see the actual questionnaires.

e) **Secure storage.**



Survey for Adolescents

- Read sample questions.
- Read letter to parents.
- Read letter of assent for students.
- Complete reviewer's form.
- Think about possible solutions.



Sex Survey Application– Concerns

Methodology

- 1. Questionnaire design may compromise privacy by making it obvious when students skip questions.
- 2. No justification given for asking for personal information and if some cells are small, this information could compromise confidentiality.
- 3. Questions don't match rationale.



Sex Survey Application– Concerns

Selection and Recruitment

- 1. Has the researcher assured that these schools represent a range of knowledge about HIV/AIDSs?



Sex Survey Application– Concerns

Consent

- 1. Problematic passive consent process for parents. A child could participate without the parent's knowledge.
- 2. Not enough information in the letter to parents to truly convey sensitive nature of survey.
- 3. Public: peer pressure may lead to participate or not to withdraw



Sex Survey Application– Concerns

Right to withdraw

- Not explained clearly.



Sex Survey Application– Concerns

- ## Privacy and Confidentiality

- 1. Branching questions may allow classmates to figure out how a student is responding.
- 2. Feedback to schools may allow teachers to figure out who made low frequency responses.



Sex Survey Application- Concerns

Risks and Benefits

1) Psychological risks

- Discomfort over being asked about sexual practices.
- Embarrassment or guilt about what revealed.
- Issues of rape or incest could arise.

2) No follow-up is provided for distressed students.



Sex Survey Application- Concerns

Risks and Benefits

3) Social risks

- Other students may figure out answers for a particular participant.
- Students who do not participate will be conspicuous and may be teased.

4) Deception--true purpose is disguised.



More than minimal risk?



Working with researcher to find solutions

- Making suggestions consistent with researcher's objectives
- Look at article by Sarah Philips about her solutions and protocol reflecting these solutions