


Informed Choice: More than a Consent Form

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The Tri-Council Policy Statement: Article 2.1

(a) Research governed by this policy 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 has been given and is maintained throughout their participation in the research.**

Guiding Principles of the TCPS

- Respect for human dignity
- Respect for free and informed consent
- Respect for vulnerable persons
- Respect for privacy and confidentiality
- Balancing harms and benefits

Issues About Consent to Think About

- Free?
- Informed?
- Choice?
- Maintained?

The Tri-Council Policy Statement

Article 2.2

- Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion

Free?

Undue influence or coercion?

- From inducements
- From adverse consequences of non-participation
- From power relationships

Free?

Undue influence or coercion?

- From inducements
 - *Any payment should be respectful (appropriate for participants' circumstances)*
 - *and not large enough to distort decision about participation*
- From adverse consequences of non-participation
 - *Losing access to counselling or support group*
 - *From embarrassment in front of peers of not participating in sex survey*

Free?

Undue influence or coercion?

Problematic Power Relationships

- Therapeutic
 - MD to patient
 - Social Worker to client
 - Counsellor to client
- Prisoner
- Teacher to student
 - *Teacher out of room during sex survey*

REB TEST: would participant agree without that influence?

- If questionable, requires more scrutiny:
 - consistent with participant's values?
 - adequately informed about risks and benefits?
 - is influence compatible with respect for human dignity?

Issues About Consent to Think About

- Free?
- Informed?
- Choice?
- Maintained?

Informed?

- *Complete information?*
 - What will happen
 - Possible harms
 - Possible breaches of confidentiality
 - Partial disclosure
- *Comprehensible information?*
 - Accessible explanation
 - Re: competence of prospective participant

Informed?

- What will happen *from participant's perspective*
 - Type of questions will be asked
 - What will see, hear, be asked to do
 - What substances, what those substances are, nature, severity, and probability of any side effects
 - How long it will take
 - Which parts are standard medical care; which are research components
 - Who will find out.

Physical Harms

- Discomfort
- Pain
- Injury
- Disease

Psychological Harms

- Loss of self-confidence or self-esteem
 - *Sex survey: no sex yet; unusual or risky practices*
- Regret or guilt about what disclosed; anxiety
 - *Sex survey: details of private life, including incidents that may have been stressful (date rape, incest)*
- Altered behaviour

Social/economic Harms

- Embarrassment
- Loss of respect by others
- Negative labeling
- Loss of wages
- Disruption of family routine
- Loss of time

Harm from Loss of guaranteed confidentiality

- From revelations by other participants (e.g., other members of focus groups)
- From researcher's obligation to report threats to society (child abuse, infectious disease, intent to murder)
- From identifying information in aggregate data
- From researcher's mistakes--*branching questions in sex survey*

Are risks minimized?

- Collected in sealed box; all done in short period; careful about branching.
- Able to skip questions; doodle on survey instead of filling it out; desks moved apart.
- Male and female research assistants.
- Could ask anonymous questions.
- Contact numbers for questions and counselling.
- Treated heterosexual and homosexual experience equivalently

Temporary exceptions to full disclosure

- i.e. consent not fully informed

The Tri-Council Policy Statement

Article 2.1 (C)

- The REB may approve a consent procedure¹ which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the REB finds and documents that:

The Tri-Council Policy Statement

Article 2.1 (C)

- i. The research involves no more than minimal risk to the subject;
- ii. The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects;
- iii. The research could not practicably be carried out without the waiver alteration
- iv. Wherever possible and appropriate the subjects will be provided with additional pertinent information after participation; and
- v. The waiver or altered consent does not involve a therapeutic intervention.

REB TEST: *participants' perspective* on partial disclosure

- Would participant agree if fully informed?
- How will participant react to not having been informed?
- Is it necessary?

Informed?

- *Complete information?*
 - What will happen
 - Possible harms
 - Possible breaches of confidentiality
 - Partial disclosure
- *Comprehensible information?*
 - Accessible explanation
 - Re: competence of prospective participant

Comprehensible information

- Words or phrases to avoid: Waggoner

Sponsor

Protocol

Sequelae

Subsequent care

Baseline visit

Investigator

Double-blind

Efficacy

Placebo

Random (assignment)

Prorated (payment)

Comprehensible information

- Software indices of reading difficulty
- Style of presentation
 - Flowchart, pictures, video
 - Boldface and italics
- Consent concepts
 - Research
 - Forseeable risks: how far in the future?

Informed?

- Complete information?
 - Possible harms
 - Special issues in qualitative research
 - Possible breaches of confidentiality
 - Partial disclosure
- Comprehensible information?
 - Accessible explanation
 - Competence of prospective participants

TCPS Article 2.5 – 2.6 Incompetent Individuals

- Special Issues
 - Ethical
 - Legal
- Competence to participate is not all-or-nothing. Varies with:
 - Choice and circumstances
 - Time

Potential benefits

- Be explicit if no potential benefits to the prospective research participant.
- Be transparent by respecting the dignity and autonomy of prospective subject

Commercialization and conflict of interest

- Describe any apparent, actual, or potential conflict of interest on the part of the researchers, their institutions or sponsors, and any possibility of commercialization of the research findings.
 - Could compromise judgment (increase risk)
 - Respect for dignity of prospective participant

Issues About Consent to Think About

- Free?
- Informed?
- Choice?
 - Respect voluntary choice
 - Whose choice is it? Risk to others
- Maintained?

The Tri-Council Policy Statement, Article 2.1a

Research May begin only if

- ...(2) their [subjects'] free and informed consent has been given and is maintained throughout their participation in the research.

Maintained?

- No undue influence or coercion to continue
- Informed of right to withdraw and consequences
 - Data already collected
 - Compensation
 - Ongoing relationship with researcher

Documentation of informed choice

- Usually by signature on written consent form
 - BUT in some cases, it is better to avoid written signature: guarantees anonymity
 - Implied consent: "by filling out this survey you indicate that you have consented...")
 - Concealing identity: allowing participant to fill in an X on the signature line
 - Written consent can be culturally inappropriate (telephone interview of immigrants; interview with CEO)
 - REB should insist on documentation of consent process

Issues About Consent to Think About *from participant's perspective*

- Free?
- Informed?
- Choice?
- Maintained?

How to Get Your Protocol through the McMaster Research Ethics Board

- Monday, November 28 9:30-11:30 A.M.
- Council Chambers, Gilmore Hall