

Model review: A Discussion of a Case Study
and Framework to Enhance Research Ethics
Review of Research Involving Gender Non-
Conforming, Genderqueer, and Transgendered
Youth

CAREB-ACCER 2016 National Conference and AGM
1:30 pm to 2:45 pm
Thursday, May 26, 2016

Overview

- “ Procedural ethics issues and an institutional perspective from SFU (Sarah, 10 min)
- “ Substantive ethics issues (Holly, 10 min)
- “ Interactive workshop discussion around a series of CIHR cases (Holly and Sarah, 55 min)

Acknowledgements

Presenters

- “ Sarah Bennett, Manager of the Office of Research Ethics at Simon Fraser University
- “ Holly Longstaff, Partner at the Engage Associates Consulting Group and Ethicist at the BC Cancer Agency Research Ethics Board

Case study co-authors with Holly an Sarah

- “ Jaime Flamenbaum, Senior Advisor, CIHR Ethics Office
- “ Aaron Devor, Chair in Transgender Studies and Sociology Professor at the University of Victoria



- “ SFU has very specific context for the ethics review of studies that involve gender non-conforming, genderqueer, and transgendered Youth.
- “ Last year, a group of like-minded activists and student protesters occupied on-campus washrooms in an effort to confront the campus community about the problem of a lack of gender-inclusive washrooms.

What do we review at SFU?

- “ SFU REB reviews clinical, socio-behavioural and health research applications
- “ Over 50% of the research reviewed at the SFU REB is student-driven with the student as the PI
- “ Out of 490 applications reviewed in 2014-2015, 21 were referred to the Full REB
- “ 20 applications were concerned with sex, gender and sexuality, and all were considered **Minimal Risk**
- “ We regularly work with researchers to address potential ethical concerns in their research with gender non-conforming, genderqueer, and transgendered participants

It wasn't always the case...

We struggled with:

- “ Lack of knowledge of this type of research
 - “ E.g., no expertise on the REB and challenges with finding it in a timely fashion even though it existed in the institution
- “ At the time, a limited definition and understanding of “Distinct Community”
- “ Institutional policy requiring parental consent for research with participants under 19-years old
- “ Few models to reference

TCPS2 (2014) and “Distinct Community”

- “ “We know it when we see it”
- “ By definition making something distinct makes it exceptional
- “ TCPS2 (2014) interpretation states REBs may also refer to Chapter 9 as an important source of guidance for research involving other distinct communities:
“Therefore: Research ethics boards and researchers can apply the articles of Chapter 9 that are relevant to the particular community involved in the research.”

Policy review

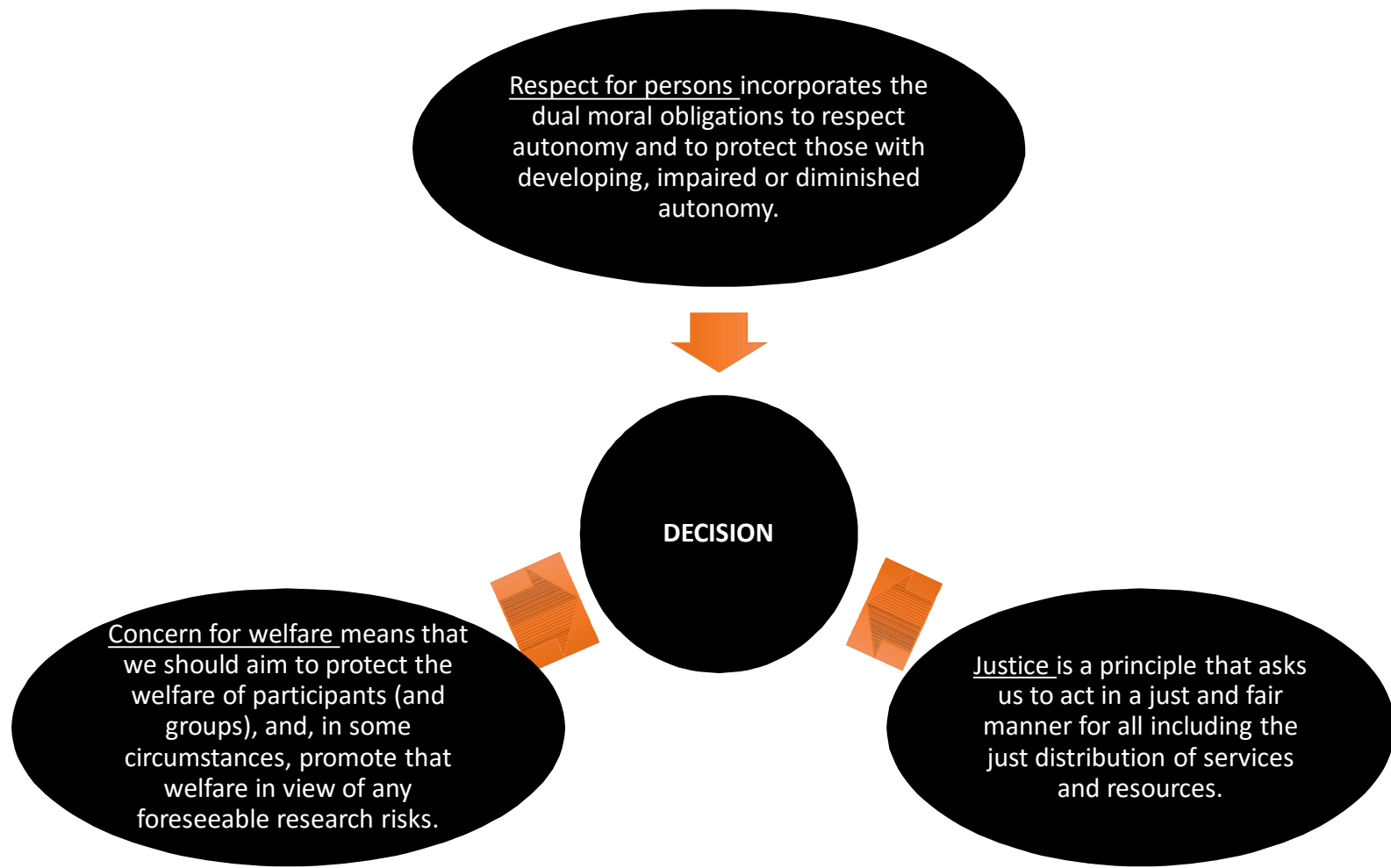
- “ Institutional policy had to be moved from being a ‘blunt instrument’ to avoid causing greater risk to participants
 - TPCS2 (2014) Interpretation: “does not specify an age of consent for children. Seeking consent from children is not based on their age, but on whether they have the capacity to understand the significance of the research and the implications of the risk and benefits to themselves – as defined in TCPS 2 Section 3.C.”
 - Link: <http://www.pre.ethics.gc.ca/eng/policy-politique/interpretations/consent-consentement/>

- “ Clarified the ‘duty to report’ in BC which only applies to a child or youth under 19 years of age being abused or neglected and the public’s obligation to notify authorities

- “ Link: http://www.bclaws.ca/Recon/document/ID/freeside/00_96046_01#section14

Procedural and substantive ethics in human research participant protection

Applied ethics principles



Research ethics exceptionalism

- “ Calls for different procedural and substantive reviews.
- “ Uncontested example:
Research with Aboriginal peoples in Canada, including First Nations, Inuit and Métis peoples

Ethics exceptionalism is not static

Centering the human participant in
REB review: *Consent relationship is intended to be
a flexible process and participant specific*



Consent

➔ Full disclosure, individualistic models or consent to good governance?

"My view is that the focus on consent in contemporary biomedical research has become the modern equivalent of a fetish"- Barbara A. Koenig

Michigan BioTrust for Health - Consent Options

Engaging the relevant publics/communities
to establish good governance mechanisms



Canadian Institutes of Health Research



- Funding ▾
- Institutes ▾
- Strategies ▾
- Initiatives ▾
- Collaboration ▾
- Health research in action

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Ethics in Research: A Science Lifecycle Approach

- Introduction
- Four Themes
- Integrating Ethics and the Knowledge-To-Action Cycle
- Hypothetical Scenarios
- Biomedical Research
- Clinical Research
- Health Services Research
- Social, Cultural, Environmental, and Population Health Research

Ethics in research: A science lifecycle approach

[Introduction to this workbook](#)

[Four themes of CIHR funded health research](#)

[Integrating ethics and the knowledge-to-action cycle](#)

[Ethics resources](#)

[Hypothetical scenarios:](#)

[Biomedical research](#)

- [Publishing your research](#)
- [Modifying research questions](#)

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- [Who decides?](#)
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Other format

[PDF version \(1.19 MB\)](#)

[Social, cultural, environmental and population health research](#)

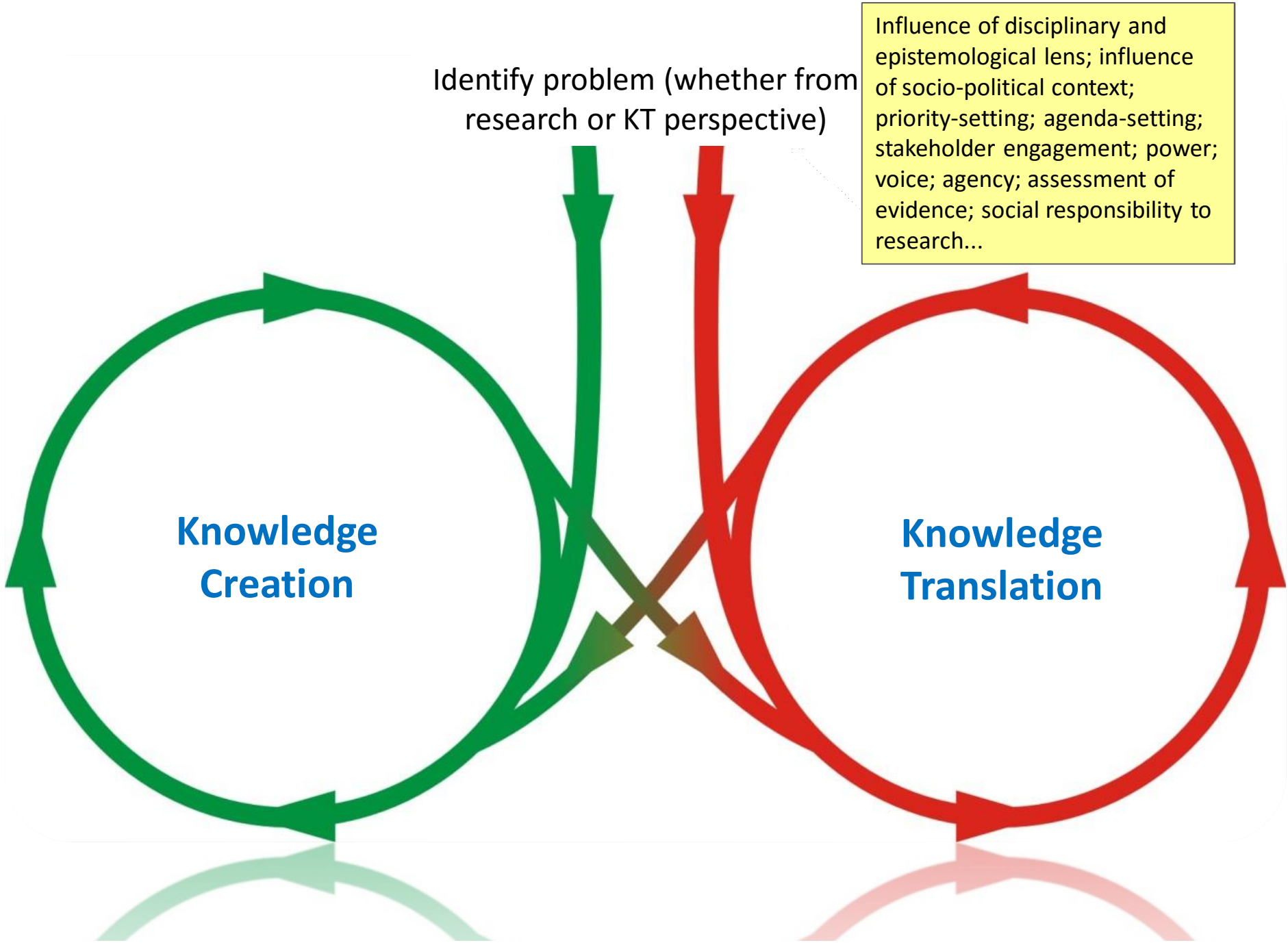
- [Research using social media](#)
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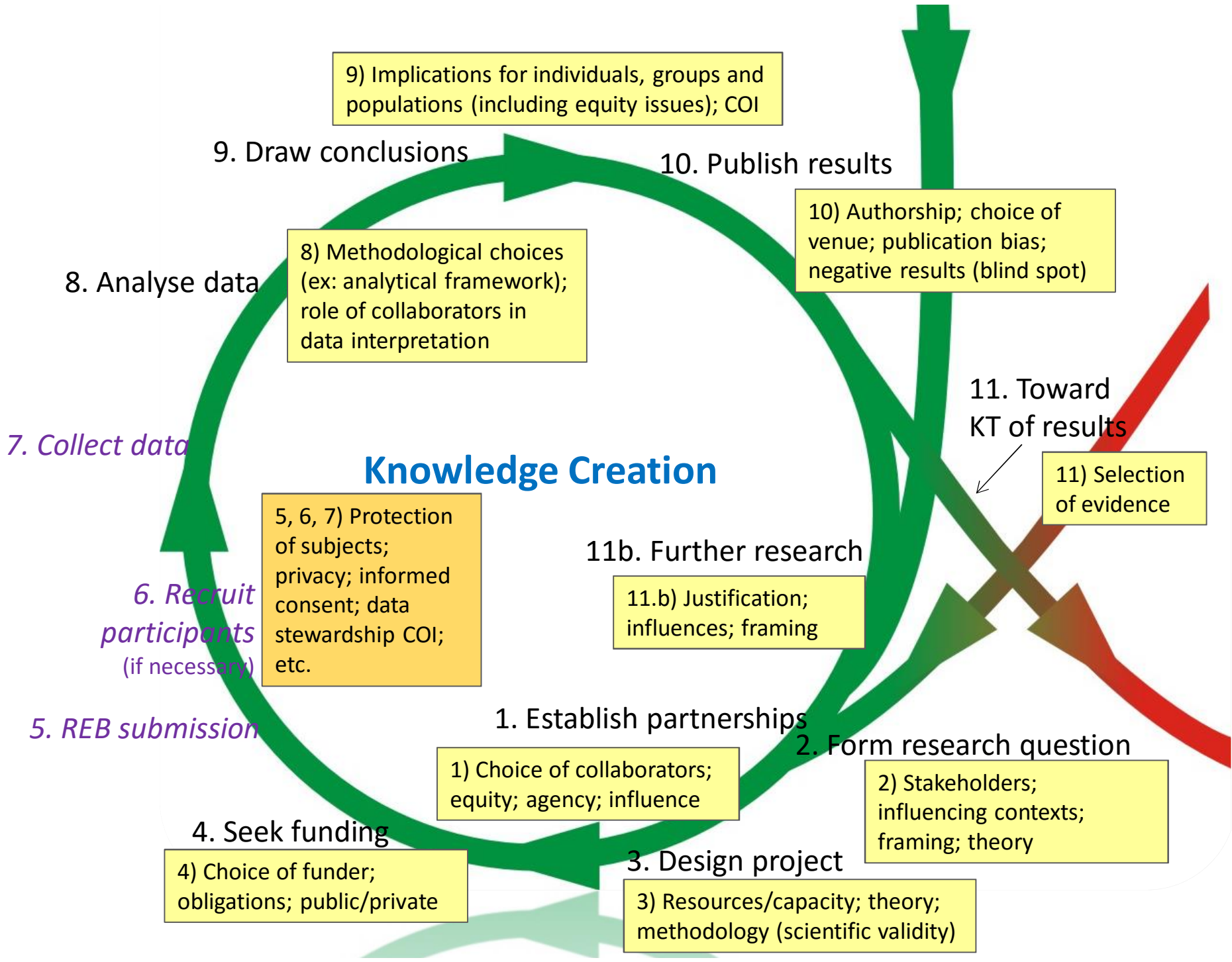
Contact Information

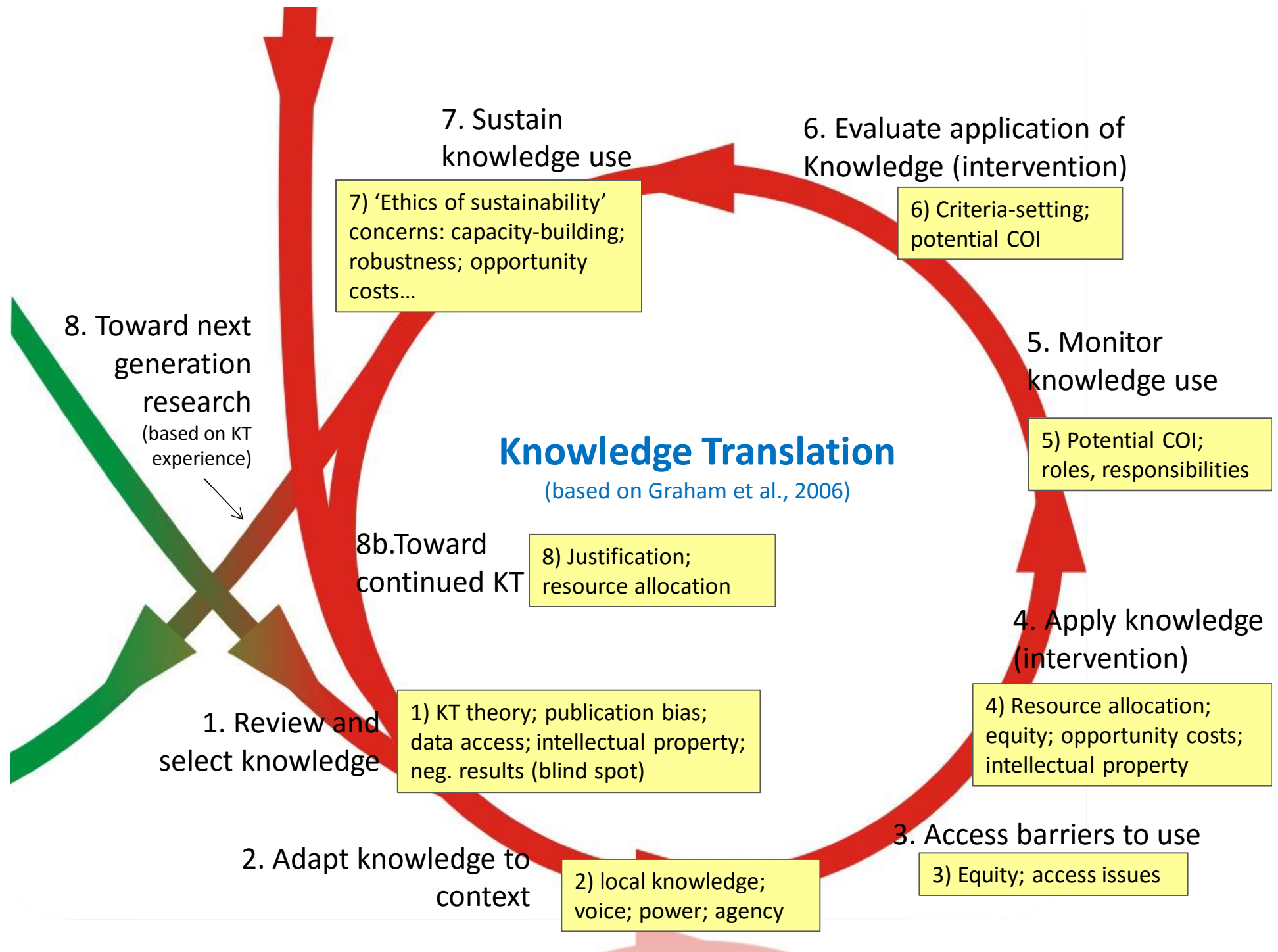
Ethics Office
 Email: ethics-ethique@cihr-irsc.gc.ca

Date modified: 2014-11-24









Ethics of Research Involving Gender Non-Conforming,
Genderqueer, and Transgendered People
(Inspiration for this case)

Ethics of Research Involving Gender Non-Conforming, Genderqueer, and Transgendered People

1. Participant perspective: Meaningful engagement in all aspects of the research lifecycle (including priority setting) similar to research with First Nations, Inuit, and Métis Peoples of Canada (as enshrined in *TCPS2 (2014)* Chapter 9)
2. Researcher perspective: Attract participants, pursue research objectives, produce results and benefits, protect participants
3. REB perspective: Protect participants, risk/benefit ratio, just distribution of resources

Case: Centering the human participant in REB review

Consider: An experienced researcher wants to conduct an interview study about the sexual habits of gender non-conforming, genderqueer, and transgendered youth between the ages of 16 and 18. The aim of this study is to identify effective methods of promoting sexual health with this population. Many of these individuals have not come out to their parents or are estranged from their parents.

Ethical considerations in KC activities

STEP	KC activities	Some Potential Ethical Considerations
1	Establish partnerships	choice of collaborators; concern for equity; agency; influence; ...
2	Form research question	Stakeholders involvement; influencing context; framing; theory used; ...
3	Design project	resources/capacity available; theory used; methodology used (scientific validity); ...
4	Seek funding	choice of funder; obligations to funder; public/private funding; ...
5	REB submission	protection of participants; privacy; informed consent; data stewardship; Conflict of Interest (Col); ...
6	Recruit participants (if necessary)	protection of participants; privacy; informed consent; data stewardship; Col; ...
7	Collect data	protection of participants; privacy; informed consent; data stewardship; Col; ...
8	Analyse data	methodological choices; role of collaborators; ...
9	Draw conclusions	implications for individuals; groups and populations; Col; ...
10	Publish results	Authorship; choice of publication venue; publication bias; negative results; ...
11a	Towards KT of results	selection of evidence; ...
11b	Further research	Responsible stewardship of funds; ...

Ethical considerations in KT activities

STEP	KTA activity	Some Potential Ethical Considerations
1	Review and select knowledge	KT theory; publication bias; data access; intellectual property; negative results; ...
2	Adapt knowledge to context	Honouring local knowledge; voice; agency; ...
3	Assess, barriers to use	Concern for equity; access issues; ...
4	Apply knowledge (intervention)	Resource allocation; equity; opportunity costs; intellectual property; ...
5	Monitor knowledge use	Potential Col; roles; responsibilities; ...
6	Evaluate application of knowledge (intervention)	Criteria-setting; potential Col; ...
7	Sustain knowledge use	Sustainability concerns; capacity-building; robustness; opportunity costs; ...
8a	Towards next generation research	Selection of evidence; responsible stewardship of funds; ...
8b	Toward continued KT	Selection of evidence; responsible stewardship of funds; ...

Let's discuss!

- “How would your REB review this case?”
- “What are the main ethics issues?”

Research ethics procedural guidance and norms around consent, assent, and dissent

- “ There are cases when parental consent is ethically justified. Is this one of them? What norms do we draw on in other research domains?
 - “ Rule of Sevens
 - “ Mature minor threshold typically about 16 years in Canada
 - “ Direct benefit is a different story

Substantive research ethics issues

“ What moral obligations does the REB have to the research participants in this study?

Substantive research ethics issues around risks and benefits

- “ What are the risks to youth *pre*-participants when parental consent is required?
- “ What are the benefits of parental consent in this case and to whom?
- “ What happens to PIs who seek to conduct research in this area?
- “ What happens to the communities that are intended to benefit from this research?

Scenario (1)

- “ Suppose that your 10-year-old child is enrolled in a summer camp program for children at your local university.
- “ The camp instructor tells you that one of the boys in the program would now like to be called Andrea and has started to wear girls’ clothes. Andrea also wants to start using the girls’ bathroom.
- “ Andrea's classmates don’t seem to care much about the situation but a few of the parents are very upset.
- “ What are some of the ethics issues raised by this situation?

Let's discuss!

Scenario (2 a)

- “ Suppose further that you are now the organizer in charge of the school camp and not just a parent.
- “ Researchers from the university have asked you if it is okay to recruit children from your program into their study to discuss gender identity issues.
- “ What are some of the ethics issues raised by this situation? Should you allow them to recruit youth from your program?

Scenario (2 b)

- “ You decide to go ahead and allow the researchers to recruit youth from your program. A student from the research team attends your program the next day and presents the study to the youth from your program. They also hand out material for each youth to review at home before they decide to participate.
- “ Andrea is thrilled to participate but does not want her parents to know because they do not approve of her behaviour. They get annoyed when you have tried to talk with them about Andrea and they only refer to her by her male name.
- “ What are some of the ethics issues raised by this situation?

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Let's discuss!

Scenario (3)

- “ Andrea wants to enroll herself in a clinical research study that aims to test a new kind of hormone therapy to be used in sex change procedures without parental consent.
- “ What are some of the ethics issues raised by this situation?

Let's discuss!

Thank you!

Presenters

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