Considering the Participant's Experience

Consent, Vulnerability and Safety

REB Info Session – June 27, 2024

Land Acknowledgement

I acknowledge with gratitude, that I am situated on the traditional, ancestral and unceded territories of the ***Coast Salish peoples – xʷməθkʷəy̓əm (Musqueam), sḵwx̱wú7mesh (Squamish), and səlilwətaɬ (Tsleil-Waututh) nations.***

Ahka-chu

Who we are

Research Ethics **Board**

- Chair & Vice-Chair
- Community members
- Scientific reviewers
- Ethicists
- Lawyers

Independent body that is **mandated to review** and **maintain** ongoing oversight of the **ethical acceptability of all proposed or ongoing research** involving human participants on behalf of the institution by applying the Tri-Council Core Ethical Principles.

Research Ethics **Office**

- Director
- Officers

Aim to **build capacity** in ethics, **integrity**, and **compliance** through **education, advising, research, policy/guidance development, and administration**. Also responsible for administration relating to the REB.

What we want to achieve today

- TCPS2 – Core Principles
- Consent – Good Practices
  - Voluntary
  - Vulnerability
  - Decision-Making Capacity
  - Therapeutic Misconception
  - Cultural Safety
  - Reimbursement
  - Re-Consent and Withdrawal
- Equitable Access
- Participant Confidentiality
- Discussion Questions/Takeaways

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TCPS 2 Core Principles – Back to Basics

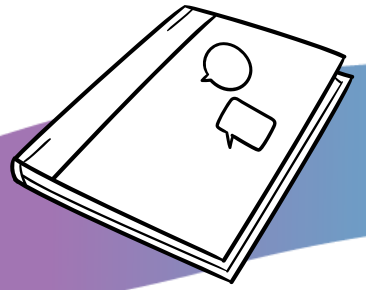
TCPS 2 Core Principles – Why they matter for the Participant

Respect for Persons – Autonomy

Concern for Welfare – Quality of the participants experience of life in all its aspects

Justice – Treating participants fairly and equitably including equitable recruitment

https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter1-chapitre1.html#b



Consider the Perspective of the Participant

Shelley is a Stage 2 Breast Cancer patient who has just finished her active treatment. She has a standard follow-up appointment with her oncologist who shares within her appointment that she is eligible for a clinical trial that would likely benefit her long-term survival. The study is closing to accrual in a matter of days and so Shelley is told that she is required to decide within this appointment if she would like to enroll. While trying to make her decision, the oncologist provides a very brief overview of the study and broadly states that there isn't enough time to go through the details. They ask Shelley "don't you want to improve your chances of living a long and healthy life? This might be your only option".

We will return to this example at the end of the presentation to discuss considerations.

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Consent

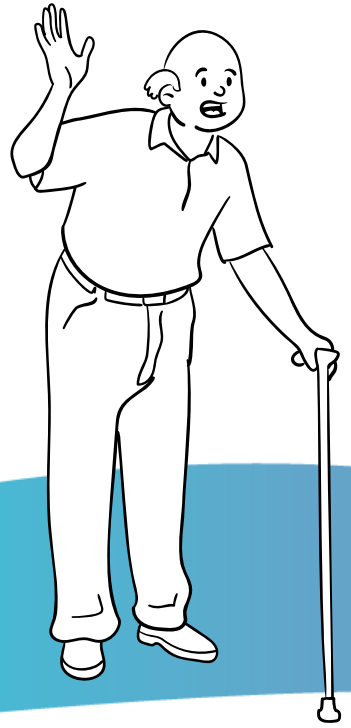
Voluntary 

- **Undue Influence**
  - Participants recruited by individuals in a position of authority
    - Physical, Psychological, Financial or Professional
    - Element of trust and dependency between patient and physician
- **Coercion** – more extreme form of undue influence
- **Incentives** - TCPS2 does not encourage or discourage incentives. Up to the researcher to justify to the REB the level of incentives. Appropriate reimbursement.

https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html

Vulnerable persons

- Individuals should not automatically be considered vulnerable simply because of assumptions made about the vulnerability of the group to which they belong. Their circumstances shall be considered in the context of the proposed research project.



Debunking Vulnerability!

The more information and support you give patients the more you remove vulnerability and the more you empower them

https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html

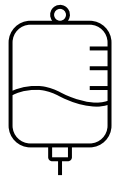
Decision-Making Capacity

Ability for a participant to understand relevant information presented about the research and to understand the risks to either participate or not.

- Considerations:
  - Complexity of the choice being made
  - Circumstances surround the decision
  - Point in time at which consent is sought
- Assessing decision-making capacity is a question of determining, at a particular point in time

https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html

Therapeutic Misconception



- Therapeutic misconception occurs when trial participants do not understand that research is aimed primarily at producing knowledge and may not provide any therapeutic benefit to them. It also occurs when participants enter trials without understanding the ways in which elements of a clinical trial design may interfere with their own health care objectives.
- Clinicians who are also researchers on a CT must be careful not to create unrealistic expectations among participants with respect to the potential benefits of the research.
- **Consider Shelley's experience!**

https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html

Minimizing Therapeutic Misconception

1. **Primary clinicians** should have minimal involvement
   - Exceptions when primary clinician is needed for expertise
2. Providing clear information that is **not overly positive or persuasive** within the consenting process
3. Consider **power dynamics** and dual roles of clinician-researchers
4. Important to provide information on **risk vs. benefit** for the participant

https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html

Cultural Safety

"**Cultural Safety** means health care professionals adopt a humble, self-reflective clinical practice that positions them as respectful and curious partners when providing care, rather than as a future of higher knowledge and authority." – *FNHA's Policy Statement on Cultural Safety and Humility*

- Indigenous Cultural Safety – acknowledging historical and systemic traumas and racism
- Building relationships
- Integration of cultural practices and traditional medicines
- Oral Consent practices

https://www.fnha.ca/Documents/FNHA-Policy-Statement-Cultural-Safety-and-Humility.pdf

The First Nations principles of OCAP®

Ownership

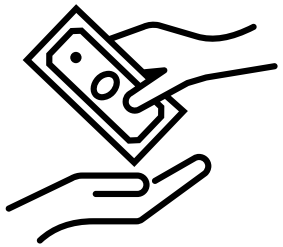
Control

Access

Possession

[The First Nations Principles of OCAP® - The First Nations Information Governance Centre (fnigc.ca)]

Appropriate Reimbursement



- **Direct expense**: parking, meals, travel, supportive care medications or other incidental costs over and above those needed for standard care
- **Indirect expense**: losses that arise from participation (for example unpaid leave from work)
- Consider reimbursement to **acknowledge their contributions**.
- Consider an **appropriate amount** – considering recent inflation in overall cost of living
- Participants should be **informed of the payments** they will receive (if any).

Re-consent

Consent is an **ongoing process**. It is the duty of the researcher to ensure that participants are provided with all information relevant to their ongoing consent to participate in the research.

	On treatment	Follow-Up
Additional safety risk	✓	Long Term Safety Risks
Change of PI / Sponsor / Funding	✓	As a notification
Updates to data privacy	✓	✓
Additional/Change in use of their samples	✓	✓
Change of treatment procedures/activities	✓	Only if it affects follow-up care
Change of study design	✓	As a notification
Study Closure	As a notification	As a notification

Please contact the REB if any uncertainty.

Withdrawal

- As per Article 3.1 of TCPS2: Consent can be withdrawn at any time and if a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials.

- In order to maintain voluntariness, participants are free to withdraw from a research project at any time and without providing a reason. They do not need to express their desire to withdraw in writing. If there are any circumstances where a participant's data cannot be withdrawn, these circumstances must be clearly disclosed in the consent form.

https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html

Participant's Options of Withdrawal – Clinical

- Treatment
  - Follow-Up
- Treatment + Follow-Up
  - Contact
  - Chart Review
- Treatment + Follow-Up + Contact
  - Access to Medical Records
  - Access to primary care physician
  - Caregiver contact
- Complete

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Equitable Access

Equitable Access 

- **Appropriate/Inappropriate Inclusion**

- **Inappropriate Inclusion:** vulnerable populations, convenient populations for research

- **Inappropriate Exclusion:**
  - Research Involving Women (e.g., due to reproductive risks)
  - Participants who lack decision-making capacity
  - Participants Vulnerability and Research

https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter4-chapitre4.html

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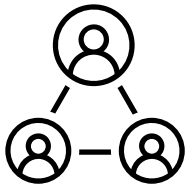
Confidentiality

Maintaining Confidentiality



- Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it. Institutions shall support their researchers in maintaining promises of confidentiality.
- Breaches of confidentiality may harm the participant, the trust relationship between the researcher and the participant, other individuals or groups, and/or the reputation of the research community.
- Participants should be aware of risks

https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html

Discussion Questions

Let’s go back to Shelley

Shelley is a Stage 2 Breast Cancer patient who has just finished her active treatment. She has a standard follow-up appointment with her oncologist who shares within her appointment that she is eligible for a clinical trial that would likely benefit her long-term survival. The study is closing to accrual in a matter of days and so Shelley is told that she is required to decide within this appointment if she would like to enroll. While trying to make her decision, the oncologist provides a very brief overview of the study and broadly states that there isn’t enough time to go through the details. They ask Shelley “don’t you want to improve your chances of living a long and healthy life? This might be your only option”.

What are the main considerations here?

Discussion Questions

1. How do you build trust with participants
2. Have you ever assumed about a participant's level of vulnerability or decision-making capacity? Did it affect the way in which you conducted the consent process?
3. Do you have any other ideas for improvement when thinking about the participant's experience.

How do you build trust with participants?

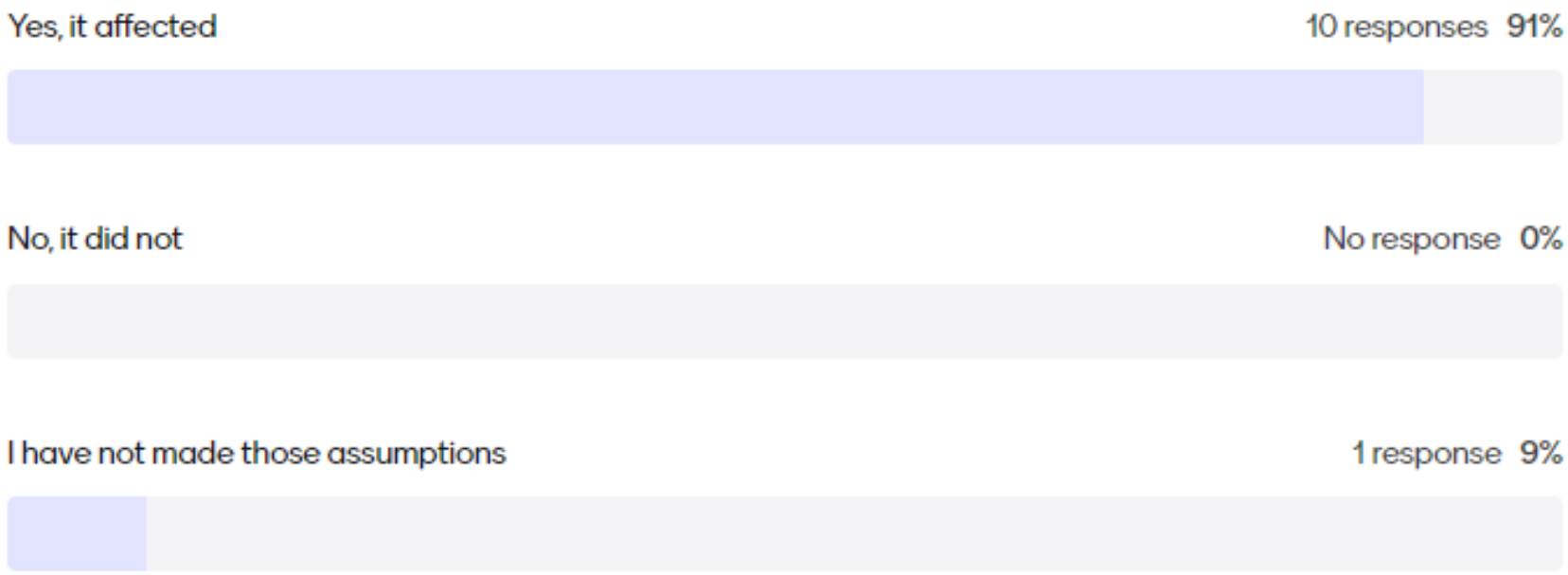
Breakdown

16 of 19 responded • 16 responses

- Listening
- Explain all treatment options
- Clear communication
- Respecting their boundaries
- No push
- Discussing risks / benefits
- Giving them ample time to ask questions
- Face-to-face instead of an email invitation
- Be patient and give them as much time to ask questions
- Provide non biased information to patient
- Personal Conversations
- Transparency
- Providing contact information to keep an open line of communication between coordinators and the participant
- Planning for multiple meetings/discussions
- Actively listen and be patient
- Allowing time for questions and concerns to be discussed

Have you ever assumed about a participant's level of vulnerability? Did it affect the way in which you conducted the consent process?

11 of 19 responded



Do you have any other ideas for improvement when thinking about the participant's experience.

Breakdown

12 of 19 responded • 12 responses

- Patient partner engagement to evaluate systems
- Take time do not rush through and reaffirm they can change their mind at any time
- Undestanding patients diversity and cultural beliefs
- Consent environment, ie, not standing over the participant
- Newsletters for updates on the study not only locally but globally
- Active listening Including them in the process
- Ensure that participant has face to face appointments if that is better for them.
- Quiet environment when talking to pt
- Somehow making consent form shorter if possible to not overwhelm them
- Put yourself in the participant's shoes when considering the consent
- More time set aside to follow up with patients (nurses are very busy already)
- ask patient questions to ensure understanding of procedures and such

Key Takeaways

- Do not assume vulnerability
- Provide time and information to decide to enhance decision-making capacity
- How someone responds depends on where they are in their journey
- Ensuring recruitment does not feel transactional – show gratitude
- Consider power and knowledge differences within the room
- Consider the knowledge the participant may already have
- Consider Cultural Safety

Thank you!

Contact us at: REB@bccancer.bc.ca

Thank you to collaborators!

Gayle Gorrill – Patient Partner

Pat Evans – REB Community Member

Joann Isaacson – REB Community Member