ETHICAL CONSIDERATIONS

for partnering in patient-oriented research

Alberta
SPOR SUPPORT
Unit

Patient
Engagement
Platform

WHAT YOU WILL FIND IN THIS GUIDE

This document is part of a series of guides, which offer opportunities to reflect on aspects of patient engagement in health research. Other documents in the series will cover forming a patient advisory group, budgeting for patient engagement, community engagement approaches, and more.

In this document, we will cover some definitions helpful to understand ethics, and provide a series of ethical considerations for reflection to get you thinking about how to be ethically engaged in health research.

This guide was last updated in **October 2020**.

What are the differences between ethics, research ethics approval and ethical considerations?

Ethics are the moral principles that govern a person's behaviour or the conducting of an activity. Ethical research gives everyone the opportunity and space to communicate from their terms of reference. (Bagele Chilisa, 2011). Ethical engagement is an active, ongoing and consistently reflexive practice.

Research ethics board (REB) approval is required for any clinical or behavioural study that involves human participants. This helps to ensure the study protects the welfare of study participants. In Canada, this is governed by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2). Ethical review and approval of a study is given by the institution that holds the grant funding for a study, typically a university or other research organization.

Patient partners on the research team are not considered "human participants" in the project as defined in the TCPS 2. In most cases no unique Research Ethics Board (REB) approval is required for their involvement.

However, when partnering with patients in research, there are still **ethical considerations** that must be upheld to build the trust that is essential to ethical and productive partnerships. This document will explore ethical considerations of how patients and researchers can interact with each other in a respectful and socially beneficial way in a research partnership.

COMMON QUESTIONS:

Do I need specific ethics training to be a team member on a health research project?

The conduct of every research team member must be in accordance with the TCPS 2 (2010) and the Tri-Agency Framework: Responsible Conduct of Research (2016), and this includes patient research partners.

A certificate of completion of the TCPS 2 Tutorial is required for all team members working with study data, or directly with study participants or subjects.

Link to the training course can be found **here**.

Questions and tensions may arise when partnering in research.

- It is important for everyone to understand the different motivations and perspectives each team member brings to the project.

- When managed respectfully and responsibly, the resolution of conflicts can provide relationship and team building opportunities.

- Key points and questions for reflection are provided under each of the ethical consideration topics in the following sections. There are different consideration questions posed for each the patient partner and researcher perspectives. **We encourage you to read both.** Answers will vary for each person, and for each project.

Ethical Considerations

FOR REFLECTION

Alberta SPOR SUPPORT Unit

PARTNERING MEANINGFULLY

BALANCING POWER DYNAMICS

PRESERVING CONFIDENTIALITY OF INFORMATION

RECOGNIZING BENEFITS AND HARMS

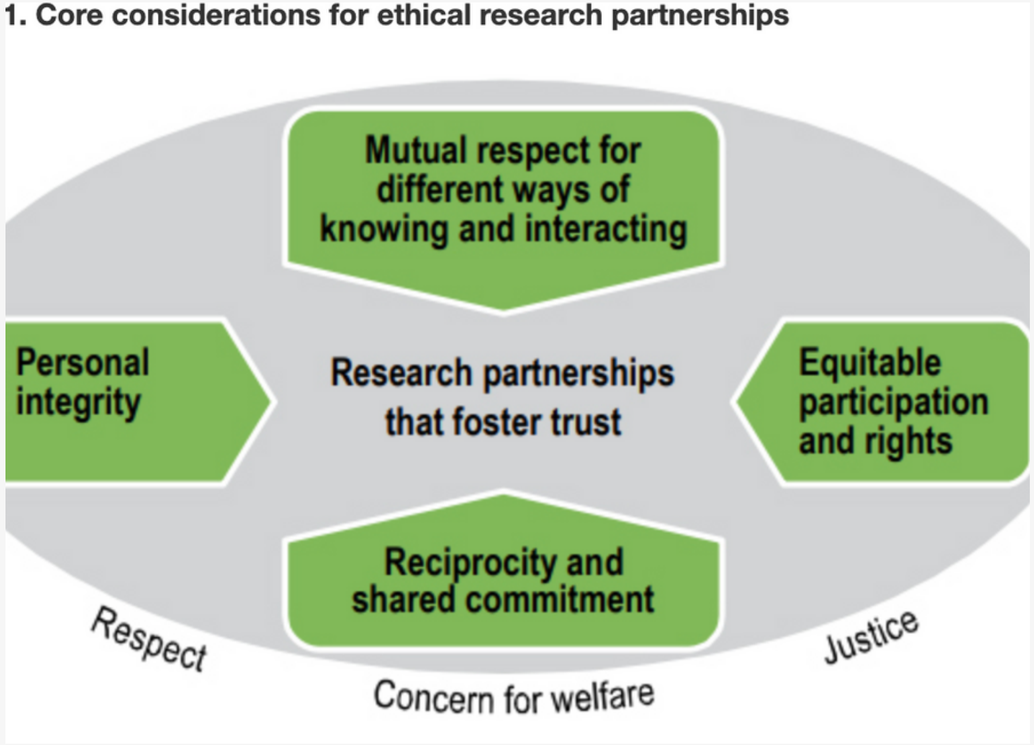
OVERCOMING BARRIERS

ACKNOWLEDGING CONFLICTS OF INTEREST

Partnering Meaningfully

Patient engagement fosters meaningful and active collaboration between patient partners and researchers at all stages of the research cycle. By including those whom research processes impact into the studies that are intended to benefit them, research can be more meaningful and relevant to all end-users and can be implemented sooner in language and formats that are more accessible to all.

CIHR identifies 4 core considerations for ethical research partnerships. [ref]



Questions for Reflection

Patient Partner

- Am I sharing my lived experience in a way that is helping others?
- Am I speaking as an individual with lived experience, or am I expected to represent a larger community of people impacted by a health condition?
- Do I represent the community, and does my community see me as acting on its behalf?

Researcher

- Are we willing to make the ongoing commitment and effort needed to fulfil a trusting relationship including following up after the project is ended?
- If we are asking patients to represent the views of others or their communities, do they have access to opportunities and resources to consult with others?
- Is there support such as training and administrative services to ensure patients can make greater contributions to research?

COMMON QUESTIONS:

What can I do if I feel my role on the project might be tokenistic, or that a research project would not benefit others?

If you feel that your role on a project might be tokenistic, or that a project does not reflect the priorities of the community it aims to benefit, there are some approaches you might take.

You can:

- propose ways to make your role or the project more meaningful
- share your concerns and problem-solve with the team
- decline to participate (you have the right to withdraw from a project at anytime)

COMMON QUESTIONS:

What can I do to make sure the partnership is meaningful?

You can support meaningful partnerships by:

- contributing to a welcoming and respectful research environment
- sharing personal experiences and insights to enhance deeper understanding
- listening carefully to others as they share their experiences and perspectives
- communicating in plain language, avoiding jargon and using terms that all team members are familiar with
- working collaboratively and democratically
- being interested in expanding your knowledge and skills

Balancing Power Dynamics

Power imbalances might be influenced by perceived status, control, access to information, economic disparities and unique cultural backgrounds. Each of these potentially affects the trust relationship that authentically engages patients as equal and active partners, and that grounds meaningful research.

It is important to check in regularly during the project to assure positive and collaborative engagement of all team members, and to confirm all team members are feeling respected and that their voices are heard.

It is also important that all team members are included in any feedback loops after the project is complete. This includes being regularly updated about dissemination and implementation of the results and how the project might have influenced and impacted change in healthcare policy and practice.

Questions for Reflection

Patient Partner

- Have the roles and responsibilities of each team member been explained?
- Have expectations been discussed and agreed upon within the research team?
- Has the training and support I need to fulfill my role on the research team been clearly identified and have arrangements been made to offer this?
- Do I understand how information will be shared?
- Do I understand the roles of other members of the research team and how I fit in? Do I feel that I am being treated equitably and with respect? Is my voice heard, and my contributions valued?

Researcher

- Am I considering the unique expectations of the patient partners and community?
- Have we included resources and support for patient partners at the project planning stage? Will these resources appropriately support patients to contribute meaningfully to research and dissemination?
- Are our processes authentically equitable and inclusive? Will they support all team members to understand what meaningful collaboration is and what their responsibilities are and to work together as such?

COMMON QUESTIONS:

What if researchers and patient partners have different motivations and skill-sets?

Patient partners have lived experiences of health condition(s) and can bring a range of relevant skills and expertise to the table.

Patients, researchers, institutions, and funders should consider what skills and experiences will be needed for working together in a research project. They should consider capacity building opportunities and resources, such as training, mentorship opportunities, education materials and systems that can support their POR work moving forward.

Researchers may have been drawn to a particular area of research based on personal or professional experiences. They may have their own preconceptions about the experiences of the patients with whom they work.

It is important for researchers to include patient partners as early as possible into the research cycle to gain insights and understandings that can identify unique recruitment, retention and dissemination approaches that are more culturally respectful and appropriate for the populations and communities the research is intended to benefit.

COMMON QUESTIONS:

How many patient partners should be on a research team?

Patient partners can be involved at any or all stages of the research lifecycle, though it is best practice to engage patient partners as early as possible and if possible more than one patient partner.

Multiple perspectives provide a sense of both the diversity and commonality of lived experience. They also help balance requirements of the research project with other aspects of life. In this way, patient partners are not over-burdened and can give each other mutual support.

Being the only person on a research team or committee without formal health or research-associated training can be intimidating.

Preserving Confidentiality of Information

Communities and individuals share personal experiences and insights that contribute to better research and care outcomes. Some information gathered throughout the research cycle will be confidential and protected by privacy policy; it cannot be shared. Researchers, institutions, and funders should ensure that all involved can uphold all expectations of confidentiality, and that appropriate policies and procedures are in place. All team members should respect expectations around individual and cultural confidentiality and privacy.

Questions for Reflection

Patient Partner

- Do I understand when and where information will be shared with me and do I have secure access to these services? (e.g., emails, library services).
- What are the expectations for confidentiality associated with the kinds of information I will be dealing with? What policies and procedures are there to guide me?
- Am I prepared to share responsibility in upholding protections for information provided in confidence? Am I able to ask for support or guidance about my responsibilities about confidentiality?

Researcher

- Have I thought about secure ways information will be shared and accessed? Are there policies, procedures, training, and supports in place for respecting expectations of confidentiality?
- Have I included training support for team members to understand the importance of confidentiality in the context of research and the value of building trusting relationships and safe spaces for sharing?
- Have I considered approaches that I can take if an unintentional confidentiality breach occurs?

COMMON QUESTIONS:

What do I do if I have concerns about confidentiality?

If you have concerns or questions about practices around confidentiality, it is best to talk about them with other team members first, if you are comfortable.

For example, if you have questions about how to best store data you have gathered (i.e. interview recordings), the research team will often have established practices for keep this data safe.

If confidentiality is breached, informing other team members to ensure mitigation strategies can be enacted is best practice.

If you have more serious concerns, the research institution you are working in will have its own process and department to hear inquiries.

The term “benefits” refers to any positive effects on an individual or group’s welfare; “harms” refers to any negative effects. Benefits and harms can be physical, financial, social or emotional. It's important to recognize that benefits and harms can be different depending on individual experiences and circumstances, and might change over time.
It is the goal of ethical research to avoid harms and promote benefits to all communities, both present and into the future.

Recognizing Benefits and Harms

Reflection Questions

Patient Partner

- What are the potential impacts of the research activities on my physical, mental, and spiritual health, and on my physical, economic, and social circumstances?
- Am I aware of possible unintended harms that might occur during this research project and am I comfortable sharing them?
- How can I safely contribute the lived experiences and insights of my community members and their health care providers to the research project?

Researcher

- Have opportunities been provided for patient partners to discuss potential benefits and harms of the research to themselves and research participants?
- Have we collaboratively discussed mechanisms, supports and resources and implemented them into the project plan and budget to pre-emptively address potential harms?
- When the research activity ends, how will we recognize and celebrate the contributions of patient partners, e.g. as co-authors? Can we help interested patients to find other opportunities for meaningful engagement?

COMMON QUESTIONS:

As a patient partner, how can I help to increase research benefits and reduce harms?

Reflecting on lived experiences, **patient partners** can help to increase research benefits and make researchers aware of potential harms:

- For research team members and participants, because of lived experiences patient partners are well positioned to advise other research team members about both potential harms and benefits for research partners and participants.
- For the general patient population, patient partners could identify potential harms in the ways that research results are communicated, shared and implemented; this can include an awareness of language and approaches that might be perceived as stigmatizing or discriminatory.
- For knowledge translation and exchange, patient partners could help inform health care providers and other patients of research results using language and information formats and venues that are accessible to all.

Systemic barriers, also known as structural or institutional barriers, are those policies, practices, or procedures that result in some people receiving unequal access or being excluded from access to the research process as well as support and access to understand and benefit from research results. These barriers can be both real and perceived and can include language and literacy challenges, health and financial constraints, digital access and literacy and others. Barriers need to be identified early, addressed and overcome to achieve authentic inclusion of all individuals and communities.

Overcoming Barriers

Questions for Reflection

Patient Partner

- What potential barriers might exist to engaging in this project and am I comfortable sharing them?
- Is participation to the research process accessible to all potential partners such as scheduled breaks between meetings?
- Does the project budget include reimbursement for the direct financial costs of partnering in the project (including travel, parking, elder and child care) and compensation as recognition of time and valued lived-experience and expertise?

Researcher

- Have I taken the time to explain the objectives and processes of the research project and am I available and open to answer questions in a welcoming and a responsive manner?
- Have we explored and addressed potential systemic and/or structural barriers that may inhibit or prevent the collaboration of patient partners?
- Is our training inclusive of all literacy levels, learning styles and approaches?

Patient partners provide unique and valuable insights and perspectives essential to health research priorities and projects. [ref CIHR]

Reimbursement is out-of-pocket expenses incurred by patient partners as a direct result of engaging in a research activity. This includes travel, parking and can include child/elder care and other out-of-pocket expenses.

Compensation is fair recognition and appreciation for time, effort and valuable lived experience and expertise that is shared and contributed to a collaborative research project. Compensation must be offered and disbursed in ways that are considered, respectful and appropriate to research team members who choose to accept compensation.

Many SPOR jurisdictions and networks have developed their own appreciation guidelines for patient partner compensation.

COMMON QUESTIONS:

In addition to reimbursement for the expenses associated with partnering on a health research project, are there additional ways patient partner contributions can be recognized and appreciated?

Conflicts of interest can arise from diverse situations in which there is an incompatibility between two or more of the duties, responsibilities, or interests (personal or work-related) of an individual or institution as they relate to the research activity. Conflicts of interest can be potential, actual, or perceived. These incompatibilities are severe enough that one duty, responsibility, or interest cannot be fulfilled without compromising the others. They may break the trust that underlies the patient engagement relationship and can also distort a person's judgment without that person being consciously aware of it, therefore, conflicts of interest and commitments need to be assessed on a case by case basis. Following conflict of interest guidelines and checking with reliable third parties helps avoid or manage these problems.

Acknowledging Conflicts of Interest

Questions for Reflection

Patient Partner

- Do I have personal, business, or other relationships in my community that could conflict with my role in the research, and inhibit me from acting in the best interests?
- Have I disclosed these conflicts to others involved in the research and, where appropriate, to others in my patient group or community?
- Does the research team, institution, or funding organization have policies and processes for identifying and managing actual and potential conflicts?

Researcher

- Have fair and transparent policies and processes been established to declare, manage and minimize conflicts of interest, recognizing that patients are multi-dimensional and can have multiple roles (as research participants, research team members, community advisors, priority setters, etc.) and bring other interests, skills, and affiliations to their roles?
- Have we worked to the creation of safe spaces and identified processes for working through conflicts of interests that might arise?

Conflicts may arise because patients and researchers wear many hats.

Patients may have pre-existing or potential relationships or affiliations that could influence or interfere with how they carry out their role(s) in the research. These affiliations may be personal, political, commercial, or legal (for instance, duties of care such as legal guardianship).

Researchers may have other roles (such as a health service provider) that may be seen as a barrier to engaging certain patients in the research. For example, a clinician-researcher may not want to sit on the same committee as their own patients. However, this could mean that the patient, rather than the clinician-researcher, is kept off the committee. Patients with rare health conditions or who live in remote communities may have few other opportunities to be engaged in research that is important to them. In cases like this, patients and their clinicians may sit on the same committee, and try to separate the research from the patient's own health care. In this way, they can establish a productive working relationship as research partners.

Cultural differences. While conflicts will arise, the value of diversity and pre-existing relationships should be recognized. A conflict in one culture may not be seen as a conflict in another culture. Cultures may also have unique ways to manage conflict.

Management. Current or potential interests and commitments that could have an impact on the research need to be disclosed to appropriate individuals and institutions. However, conflicts of interest and roles must also be managed and minimized in an appropriate way. For example, someone may not be able to make a full disclosure of interests and commitments related to the research because of confidentiality or harm considerations. In this case, the person should discuss these reasons with those in charge of managing conflicts of interest to reach a solution. There may be times when disclosing interests is not enough to maintain the trust relationship and additional actions may be needed, such as vacating a conflicting role or leaving the research relationship.

COMMON QUESTIONS:

Are there different types of conflicts of interest?

Resources for ethical considerations when engaging Indigenous communities

The Group for Research with Indigenous Peoples (GRIP) at the University of Calgary has some excellent resources that we encourage you to review.

As of October 2020, you can access information about:

- OCAP (Ownership, Control, Access, and Possession), a research practice that reflects on the handling of principles of ethical research.
- Scholarly articles, research protocols and important documents in the history of Indigenous populations in Canada (including the Truth and Reconciliation Commission of Canada and the Royal Commission on Aboriginal Peoples).

KEY WORDS/TERMS

Patients	Individuals with personal experience of a health issue or situation, and informal caregivers, including family and friends. [CIHR ref] Who is a patient? (video) https://www.youtube.com/channel/UCrLgpRV0t4CeOp69XYzPffQ
Patient engagement (PE)	The inclusion of patients in research activities beyond the level of participation, such as in governance, priority setting, conduct of research, data analysis, knowledge translation, and evaluation [CIHR ref]
Patient-oriented research (POR)	A continuum of research by multidisciplinary teams, POR engages with patients as partners, focuses on patient-identified priorities, and seeks to improve patient outcomes [CIHR ref]
Status	This refers to differences in community or social status, expertise, compensation, and affiliations (for example, among members of a committee or research team).
Control	This refers to different responsibilities for the funding of the research, and other accountabilities (by law and policy) at the level of the funder, institution, or research project. It also refers to possible community expectations for influence on its members. In particular, institutions and funders have a key role in addressing systemic and structural barriers to patient engagement.

Information	This refers to differences in expertise, experience, and access (for example, to academic journals) to help with understanding the research.
Health condition	Patients may have to attend to their health needs on a continuing or intermittent basis. If these needs are not accommodated, patients may find it difficult or impossible to contribute effectively to the research without risking their own health. As a result, they may decide to withdraw as research partners.
Economic situation	Barriers may arise due to economic hardship, and prevent patients from acting as full-fledged partners in research.
Divergent cultural protocols	Researchers and patients may come from different cultural backgrounds and have different expectations in regard to appropriate ways of interacting.
Legitimation	The process where something (an act or belief) becomes legitimate in the eyes of society.
Tokenism	The practice of making only a symbolic effort to do something. In the context of patient engagement in health research, this can include recruiting a patient research partner to give the appearance of inclusion, without making their role meaningful or valuable.

Ethics	The moral principles that govern a person's behaviour or the conducting of an activity.
Research Ethics Board (REB) approval	A university or institutional process whereby a study undergoes review by an ethics board to ensure that a research project is being done ethically.
CIHR	Canadian Institutes of Health Research (CIHR) is the major funding body for health research in Canada.
Jargon	Terminology often used by experts that can be confusing or alienating to non-experts.
Cultural Safety	An approach that considers how contextual factors (such as culture or history), as well as power imbalances, shape one's experience.

Briefing notes for researchers: Public involvement in NHS, public health and social care research.

Tri-Council Policy Statement: Ethical conduct for research involving humans.

What is ethical space?

Ethical space in action

CIHR Ethics Guidance for Developing Partnerships with Patients and Researchers

CIHR Considerations for Paying Patient Partners in Research

Patient Partner Appreciation Policy and Protocol, SPOR Evidence Alliance

How are PCORI-funded researchers engaging patients in research and what are the ethical implications?

additional resources (external links)

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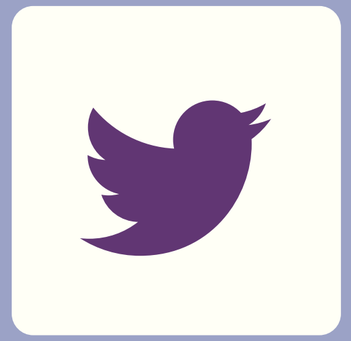

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