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Ethics Guidance for Developing Partnerships with Patients and Researchers

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Acknowledgements

In 2015, the CIHR Ethics Office initiated a project to develop ethics guidance for research partnerships involving patients. Patients include people with personal experience of living with an illness or other health condition, as well as informal caregivers such as family and friends. This initiative responded to a gap identified by the Patient Engagement Working Group of Canada's Strategy for Patient-Oriented Research (SPOR) SUPPORT Units, as well as by other stakeholders at conferences and workshops.

In 2016, after the CIHR Standing Committee on Ethics endorsed the project, CIHR formed a Working Group to lead development of the guidance. The Working Group was co-chaired by the Manager of the CIHR Ethics Office and a public member of the CIHR Standing Committee on Ethics. It was made up of equal numbers of patients and experts from relevant fields of research. These members brought diverse experience and expertise, including Indigenous perspectives.

Members of the Working Group were:

- Nicolas Fernandez (Co-chair), Patient partner, CIHR Standing Committee of Ethics public member, and Assistant Professor, Center for Applied Pedagogy, Faculty of Medicine, University of Montreal
- Genevieve Dubois-Flynn (Co-chair), Manager, Ethics Office, CIHR
- Alexandra King, Member of the Nipissing First Nation (Ontario), and the Cameco Chair in Indigenous Health, University of Saskatchewan
- Michael McDonald, Professor Emeritus of Applied Ethics, University of British Columbia
- Jean Miller, Patient partner, and Patient Researcher with the PaCER (Patient Community Engagement Research) Program, O'Brien Institute for Public Health, University of Calgary
- Ron Rosenes, Patient partner, community health advocate, and Chair of the Canadian HIV/AIDS Legal Network, Chair of the Community Advisory Boards for HPV-SAVE, CHANGE HIV and PROOV-IT research teams
- Donald Willison, Program Director and Associate Professor, Health Services Research, Institute of Health Policy Management and Evaluation, University of Toronto
- Cathy Woods, Patient partner, and co-lead of the Patient Council and Indigenous Peoples' Engagement and Research Council of the Can-SOLVE CKD initiative

The Working Group developed a first draft of the ethics guidance through a collaborative consensus-based process. After targeted consultations refined the draft, broad public consultations were held from November 2018 to February 2019. CIHR and the Working Group wishes to thank all the groups and individuals who provided input during this consultation process. This feedback has improved and enriched the guidance.

Purpose of the Guidance

This guidance was designed to help researchers and patients develop research partnerships in the design or conduct of research – a process known as patient-engaged research. This kind of research is similar to community-engaged participatory research. However, patient-engaged research also brings the living or lived experiences of patients to the research activity (see Box 1).

The guidance and accumulated wisdom in the document draw on the experiences of the authors, comments during consultations, and the academic and non-academic literature in this area. It intends to contribute to a conversation about the topic rather than to provide a final word on the issues. As well, this guidance seeks to move beyond simple "dos and don'ts" by suggesting ways to improve patient-engaged research.

Box 1. Patient engagement in research

What are patients?
In line with the SPOR definition, patients are people with personal experience of living with an illness or other health condition, as well as informal caregivers such as family and friends.

What is patient engagement?
As defined by SPOR, patient engagement occurs when patients meaningfully and actively collaborate in the governance, priority setting, and conduct of research. They also summarize, distribute, share, and apply its resulting knowledge, (i.e. the process known as knowledge translation and exchange). Patients who are involved in any of these roles are called "patient partners" in this document.

Why is patient engagement in research important from an ethical perspective?
From an ethical perspective, meaningful patient engagement:

- grounds research in a deep understanding of the health situations and the living or lived experiences of actual patients, including groups that are typically under-represented in research, to make research more relevant and usable by those patients;
- promotes research methods that are culturally safe, respectful, and appropriate;
- legitimizes research in the eyes of the community that the research is intended to benefit;
- strengthens capacity of patients to shape research that matters to them;
- builds relationships among patients and others involved in research that are mutually respectful; and
- creates an ethical space[1] for respectful dialogue and discussion wherein each person can speak in their own voice.

[1] See Ermine, W., "Ethical space in action," McMaster University, 2010, and "The ethical space of engagement," Indigenous Law Journal, Vol. 6, Issue 1, 2007.

This work builds on the SPOR Patient Engagement Framework and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition (TCPS 2). SPOR-funded research teams and other initiatives, organizations, and institutions are encouraged to adapt the guidance for use by anyone involved in partnerships between patients and researchers.

While the guidance was written primarily for patients and researchers who come together for research, they may well help a broad range of stakeholders. These could include institutions that foster or house patient-engaged research; research funders (including CIHR); those who play a role in reviewing and overseeing this type of research (including research ethics boards); and those who study this type of research. As such, the guidance has been written in a style that is meant to be broadly accessible. Footnotes and references have been kept to a minimum. However, the document includes a list of resources and references for further reading.

Consideration of Indigenous Perspectives

The Working Group, with its deliberate consideration of Indigenous peoples in Canada and their issues relevant to research, came together in reconciliation. With the support of CIHR, the Working Group intends this guidance to be one small step in contributing to implementation of reconciliation. It is also hoped that the various Indigenous-specific contributions found herein will resonate with other peoples. Further, in adopting and implementing guidance, it is hoped that patients, researchers, institutions, and funders will consider their respective roles and responsibilities with regard to our collective efforts to promote healing and reconciliation.

Box 2. Working with Indigenous communities

Our public consultations suggested it would be prudent to include an introduction to the Indigenous peoples in Canada – the Inuit, Métis, and First Nations peoples. This is a brief summary, and in no way intended to be comprehensive. It is our collective hope, as a Working Group, that everyone will read this for two reasons:

- We are all treaty people. In this era of reconciliation, we – both Indigenous and non-Indigenous people – need to work together, to reset our relationship so equity and respectful relations become overarching goals.
- While Indigenous peoples are uniquely positioned in Canada, much of what they desire – for example, self-determination, culturally safe and responsive research, and respect for their many different Ways of Knowing, Being and Doing – are also desired by the diverse peoples that now make Canada the wonderful country it is. We have much to learn from each other, and to do so, we need to create and maintain ethical spaces, approaching each other with respect, humility, and truly collaborative hearts, minds and spirits.

Indigenous peoples are tightly connected to the lands and waters from where they and their ancestors lived, survived and thrived. Our Ways of Knowing, Being and Doing are informed by our specific environments, which vary tremendously from coast to coast to coast. This results in incredible diversity amongst Indigenous peoples in Canada, who include over 650 First Nations, many Métis communities in Western Canada, and 53 Inuit communities spread across Inuit Nunangat (the lands, waters and ice of the four territories which comprise the Inuit homeland in the far north and northeast of Canada). Today, more than half the populations self-identifying as Indigenous now live in urban centres, where we see ourselves as multi-national peoples, guests on the traditional territories of our distal relatives. There is diversity amongst Indigenous people in almost every urban centre – pan-Indigenous or homogenizing concepts are not appropriate.

The diversity amongst Indigenous peoples has only been heightened by colonization and ongoing colonialism. This was not a single, moment-in-time event, experienced uniformly across the country. Rather, it has been a process unfolding for over 500 years in some regions. Colonialism differs based on Settler population (e.g., the French versus the British versus Canada as a new nation), the context and timing (e.g., the British and French recognized the necessity and generosity of First Nations for their survival during early contact whereas the new nation of Canada in the 1870s had an urgent need to acquire the right to colonize the new territories and saw the Indigenous peoples in a weakened position), and particular approaches to co-existence (e.g., treaty-based or not; and specific characteristics and terms of each treaty).

From time immemorial, First Nations and Inuit peoples had strong relationships between and within communities. These were governed by protocol – ways of interacting respectfully with each other. These are maintained in some form, even today. Non-Indigenous people also engage in protocol and even ceremony when working with Métis, First Nations and Inuit peoples – this is considered as respectful. This is not different from working internationally, which requires research, additional paperwork, compensation (for staff, resources, space) and, typically, gifts. Those who work well with Indigenous peoples in Canada do the same – they gain an understanding of the specific people with whom they want to work, learning about their history, culture, aspirations, strengths, and research needs/priorities. Some resources are listed in the Resources section and we would suggest that you learn about the specific community with whom you seek to work.

Genuine community engagement takes time, and is essential, in and of itself. Most successful research with Indigenous people begins with relationship building, which precedes any discussion related to research.

Written by Cathy Woods (Métis) and Alexandra King (Nipissing First Nation) on behalf of the Working Group.

Part I
Patient Engagement in Research – Reflections on Trust

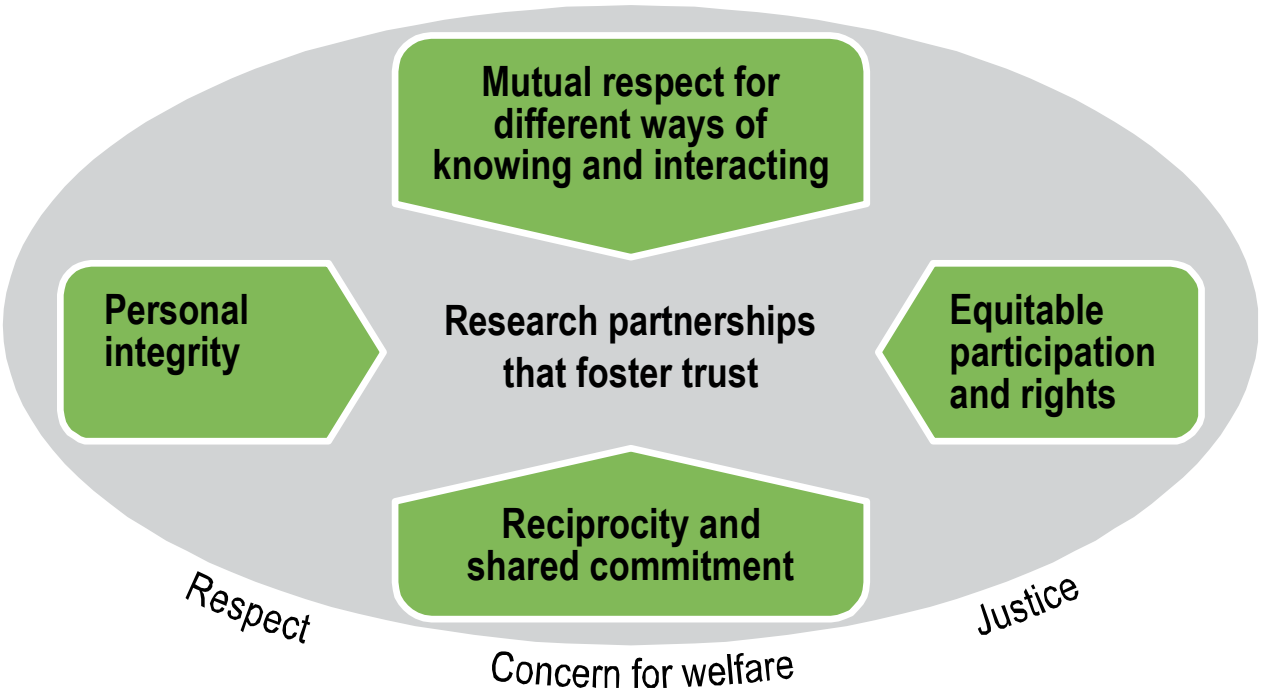
The first section of Part 1 reflects on how to build trust with patients engaged in research. It presents overarching ethical considerations, building on the core principles of respect, concern for welfare, and justice. The second section identifies six major ethical concerns that can arise during the research cycle. It then lists questions for both researchers and patients related to these concerns.

1. Overarching ethical considerations

There are four core considerations to build research partnerships that foster trust:

- mutual respect for different Ways of Knowing and interacting
- equitable participation and rights
- reciprocity and a shared commitment to producing relevant research results
- personal integrity

Figure 1. Core considerations for ethical research partnerships



The core principles of TCPS 2 – respect, concern for welfare, and justice – apply to all types of research involving humans, including patient-engaged research. This guidance focuses on ethical considerations that are relevant to patients as partners in health research, as opposed to patients acting as research participants. We recognize that patient-engaged research has much in common with community-based participatory research and has much to learn from principles used to guide research involving Indigenous peoples.

1.1 Mutual respect for different Ways of Knowing and interacting

There are many enriching paths to knowledge. These include knowledge gathered through research disciplines, knowledge gained through living or lived experience, and Indigenous Ways of Knowing. Patient engagement allows researchers to access these various paths to knowledge by bringing diverse perspectives to health research. It can also help reveal "blind spots" – conscious or unconscious biases – that may interfere with scientifically-rigorous health research and the delivery of effective health care. Due to their living or lived experiences, patients often have valuable insights to bring to research. Neglecting these potential contributions can cause researchers to miss important aspects of the health issues they are investigating. This, in turn, can make it harder to implement their research.

Some of the qualities that support successful partnerships in research include:

- respecting other perspectives
- listening carefully
- communicating in plain language (using non-technical terms that the average person can understand)
- being non-judgmental
- using personal experiences constructively for deeper understanding
- being able to work collaboratively
- being interested in expanding one's own knowledge and skills

These qualities help foster an environment of reflection and humility. This, in turn, allows exploration of various perspectives, strengths, and needs of researchers, patient partners, and research participants. Such an environment enables all members of the research team (including patient partners) to reflect on the direction of the research as it goes along.

1.2 Equitable participation and rights

Individual patients and their communities have every right to shape the research that is intended to benefit them, and to do so in meaningful ways throughout the process. Patient involvement in health research, for example, helps make the research activity more credible in several ways. First, it includes the diverse individual perspectives of patients who experience the health conditions being studied. Second, it includes community representatives who speak directly on behalf of others who live with those conditions.

1.3 Reciprocity and shared commitment to producing relevant research results

Reciprocity – exchanges based on mutual benefit and respect – is expressed in patient-engaged research in two ways. First, there is a shared commitment to developing research processes. Second, the processes produce results that are relevant to the health of patients. For this commitment to be honoured, patients must be treated as essential partners in this form of health research. They must be appropriately supported, recognized, and compensated[2] for their contributions to the research process.

1.4 Personal integrity

Personal integrity involves openness, honesty, and promise-keeping. It also includes the accurate analysis and reporting of research. Finally, it includes recognition and appropriate management of factors that may hinder research, such as conflict of interest and bias.

[2] See the SPOR *Considerations when paying patient partners in research*, May 2019. SPOR SUPPORT Units are another source of specific guidance on compensation – see Resources list.

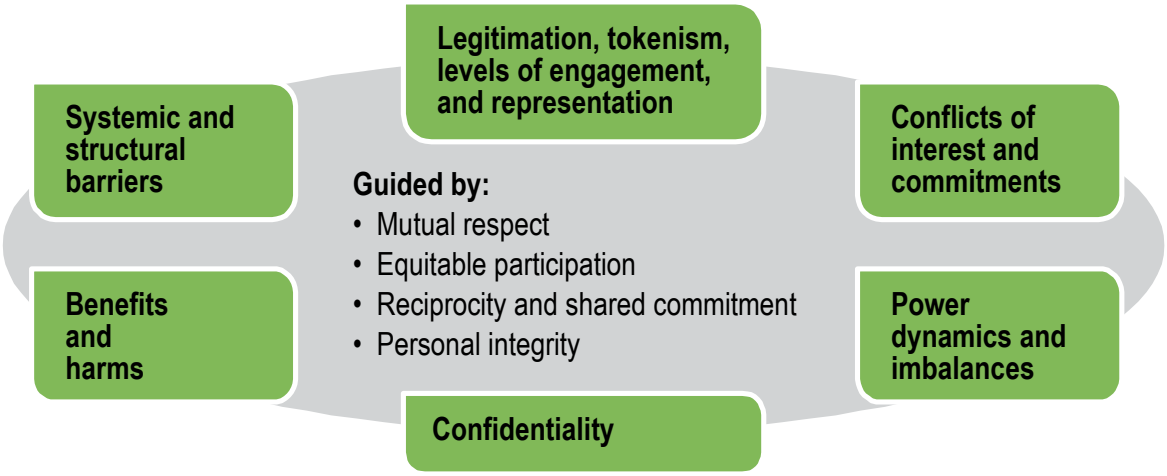
2. Ethical concerns across the research lifecycle

In this section, we identify major concerns that need to be addressed to maintain the trust relationships that are essential for successful patient engagement in research. These concerns are presented visually in Figure 2, and then discussed in the subsections that follow.

Questions and tensions may arise at various points in the research lifecycle[3] when patients are engaged as partners. Ethical concerns include:

- legitimation, tokenism, levels of engagement, and representation
- conflicts of interest and commitments
- power dynamics and imbalances
- systemic and structural barriers to patient engagement
- benefits and harms
- confidentiality of information

Figure 2. Reflecting on ethical concerns throughout the research process



Key points and questions for reflection are provided under each of these concerns. Somewhat different questions are posed for patients than for researchers, institutions, and funders. However, everyone is encouraged to find answers in light of the four overarching considerations described in the previous section: mutual respect for different Ways of Knowing and interacting; equitable participation and rights; reciprocity and shared commitment; and personal integrity. The underlying aim is to build the trust that is essential to ethical and productive patient engagement in research.

[3] We have taken the term "research lifecycle" from the paper by James A. Anderson, Brenda Swatzky-Girling, Michael McDonald, Daryl Pullman, Raphael Saginur, Heather A. Sampson, and Donald J. Willison, *Research Ethics, Broadly Writ*, *Health Law Review* 19, 3, 2011, 12-24

2.1 Legitimation, tokenism, levels of engagement[4], representation

This sub-section looks at legitimation, tokenism, levels of engagement, and representation. It presents general issues that can arise for both patients and researchers that could interfere with the research process, project, or team. It then lists specific questions for these two groups.

Legitimation. "Legitimate" engagement of patients in research requires a partnership relationship. Patient groups whose capacity has been strengthened may even kickstart a research project, and then draw in researchers for their technical expertise.

Tokenism. "Tokenism" occurs when researchers include a patient voice in their project, but mostly ignore it. Research must take the perspective of patients seriously and draw on them to shape the research.

Levels of engagement. Patients may take on specific tasks in the research process based on their skill levels. For example, on a research team, they can lead focus groups and do interviews. At the most engaged level on a research team, they can also be partners in design and implementation, or co-authors of the various outputs from the study.

Representation. The engagement of a respected and trusted member of a patient community in a research project adds credibility both to the project and the researchers in it. These patients may come to represent the project in the community. As a result, they legitimize it in the eyes of others and, by their presence, encourage other patients to take part. Therefore, patients have an obligation to ensure their role respects their trust relationships with both researchers and their communities.

2.1.1 For patients

If you are bringing your personal living or lived experience of health issues to a research project, here are some relevant questions to ask yourself:

- Do I have both the knowledge and the commitment to make a meaningful contribution to the research project? If appropriate, can I get any needed additional help or resources[5] from the research team or my community to make such a contribution?
- Am I lending my credibility as an individual and patient to projects that I think might make a positive contribution to health care for other patients?

[4] Many guides describe the continuum of levels of engagement ("*Inform- Consult- Involve- Collaborate- Empower"*). These include the International Association for Public Participation (IAP[2]) Spectrum of Public Participation, and the Saskatchewan Centre for Patient-Oriented Research: *Patient-Oriented Research Level of Engagement Tool*. See the Resource list.

[5] A useful resource is the SPOR Foundations for Patient-Oriented Research Curriculum. For more information, contact the SPOR SUPPORT Unit in your region.

- Is the scope of my role clear so that I can decide if I am being meaningfully engaged or not?
- Is my presence in the project meaningful or am I only being used as a token, for example, to secure research funding or to just gain access to other patients? If my presence feels tokenistic, is there a way for me to voice my concerns?
- How am I processing my living or lived experience of my health condition to guide the research process and enhance understanding?

As a patient, you should ask yourself what it means to act as a representative:

- Am I speaking as an individual with living or lived experience, or am I expected to represent a larger community of people impacted by a health condition?
- If I am speaking as an individual with a living or lived experience, what parts of that experience am I willing to share? What parts should I keep private because these involve confidential relationships with other patients and caregivers? What parts do I simply want to keep private for my own reasons?
- If I am a member of a community with its own governing structures, has this community appointed me to represent them, or have I been elected by a membership to speak on their behalf? When am I speaking for just myself and when am I speaking for the community? In general, how do I fulfill my trust relationship with my community?
- Have I consulted enough with my community (for example, with other patients, patient groups, community leaders)? Do I represent the community, and does my community see me as acting on its behalf? Do I feel equipped to bring back valuable input to the project right through the research lifecycle?

You have three options if you feel that a proposed role in the project would be tokenistic, or that a research project would not benefit others. They are listed with increasing levels of seriousness and impact. You can:

1) decline to participate
2) propose ways to make your role more meaningful
3) bring your concerns to people in authority or influence such as the lead researcher's institution, community leaders, or a patient advocacy organization

2.1.2 For researchers, research institutions, and funders

Ask yourselves the following questions:

- Does the involvement of patients have a reasonable chance of increasing the usefulness of research to the relevant patient community? In what areas of the research can patients most meaningfully contribute?
- Are we willing to make the commitment and effort needed to fulfil a trusting relationship?
- How can we provide support such as training and administrative services to ensure patients can make greater contributions to research?
- Are we offering patients a meaningful role or is it only tokenistic?

- If we are asking patients to represent the views of others or their communities, are we giving them enough opportunities and resources to consult with others?

2.2 Conflicts of interest and commitments

This sub-section defines a conflict of interest and commitments. It presents general issues that can arise for both patients and researchers that could interfere with the research process, project, or team. It then lists specific questions for these two groups.

Definition. Conflicts of interest and commitment arise when two or more duties, responsibilities, or interests (personal or professional) are incompatible with the research activity. In other words, one cannot be fulfilled without compromising the other(s). Conflict can relate to an individual or institution.

Types. Conflicts can be potential, actual, or perceived. They may break the trust that underlies the patient engagement relationship. They may also distort a person's judgment without that person being consciously aware of it.

Examples. Conflicts may arise because patients and researchers wear many hats:

- **Patients** may be members of another non-patient community, or 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 relationships or 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). These may be seen as a barrier to engaging certain patients in the research. For example, clinician-researchers 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. Some patients may find this unfair. For example, patients with a rare health condition or who live in a remote community may have few other opportunities to be engaged in research that is important to them. Therefore, situations and relationships like these need to be assessed carefully. In some cases, clinicians and their patients will 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 by another culture. Different cultures may also have different ways to address a 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 a fair and 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 the person in charge of managing conflicts of interest to reach a solution. There may be times when disclosing interests or commitments is not enough to maintain the trust relationship. If this happens, additional actions are needed, such as vacating a conflicting role or leaving the research relationship. Conflicts of interest and commitment 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.

2.2.1 For patients

Consider the following:

- Do I have personal, business, or other relationships that could conflict with my role in the research, and prevent me from acting in its best interests? Have I disclosed these relationships to others involved in the research and, where appropriate, to others in my patient group or community? How can I rearrange my involvement in the research to avoid such conflicts?
- Does the research team, institution, funding organization, or my community have policies and processes to help me identify and manage actual and potential conflicts?

2.2.2 For researchers, institutions, and funders

Consider the following:

- Do we have fair and transparent policies and processes to manage and minimize conflicts of interest and commitments? Do these policies recognize that patients are multi-dimensional and wear many “hats” (as research team members, community advisors, priority setters, etc.) and bring other interests, skills, and affiliations to their role(s)?
- If we are considering friends, neighbours, and family members as “patient representatives”, will they be independent? Will their personal relationships present a conflict of interest that cannot be managed effectively or inhibit their participation in research?
- Have we consulted with our patient partners on how their commitments and interests are likely to be viewed by other patient partners in the research?

2.3 Power dynamics and imbalances

This sub-section looks at power dynamics that can affect the engagement of patients in research. It presents general issues that can arise for both patients and researchers that could interfere with the research process, project, or team. It then lists specific questions for these two groups.

Power imbalances can affect the engagement of patients in research. Factors include:

- *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.

Each of these factors potentially affects the trust relationship that grounds successful patient engagement in research. Misuses and manipulation of status, control, and information may diminish and even freeze out meaningful patient engagement in research. Trust-building measures include:

- respecting the status of patients as partners in research
- having open discussion and consultation about power issues
- providing relevant information in a timely manner

Patients and researchers bring many types of expertise and a range of skills and competencies to the research project. Mutual respect and valuing of alternate knowledge systems and ways of knowing can resolve tensions around power imbalances. For example:

- **Researchers** have devoted their professional lives to researching a subject. They may have been drawn to a particular area of research or clinical practice based on personal, family, or professional experiences. They may have their own preconceptions of the experiences of the patients with whom they work. These preconceptions may be based on personal experience or on generalizations drawn from interactions with patients, which may or may not map onto the experience of other patients. Bringing these preconceptions to light with the help of patient partners can help address potential impacts of misconceptions and power imbalances.
- **Patients with their living or lived experiences of a health condition** can bring a range of relevant skills and experience. Patients, researchers, institutions, and funders should consider what skills and experience will be needed for particular roles. They must

also consider what resources are needed to strengthen capacity (education, training, and support systems). Mentorship opportunities can also be part of capacity strengthening. For example, patient partners may provide training and development opportunities for other patients. The resource list includes examples of training tools and guides.

Information flows. Meaningful engagement of patient partners on research teams requires that information flows easily among team members. Patients must feel included in progress reporting and decision making. This may require efforts to develop a common language of communication between researchers and patients to bridge the gap between *researcher-speak* and *patient-speak*. The research team should agree on norms to ensure that information circulates correctly. This, in turn, will ensure that patients have access to the information they need to fulfill their role (for example, emails and library services). Meeting agendas should be set collectively and followed through in the meetings.

Cultural differences. Researchers and patients may come from different cultural backgrounds. As a result, they may have different, often unspoken, expectations about appropriate forms of social interaction. For example, many Indigenous communities expect food to be provided at meetings. In many academic communities, food is an optional extra at meetings. Also, different communities have different styles of conversation. At meetings where some people are outspoken, for example, patients may have a difficult time being heard.

2.3.1 For patients

Consider the following:

- Will I have access to the information, status, and power that I need to play a meaningful part in the research?
- Am I clear on the expectations that come with this role – my own, my community's, and those of others?
- Will I need resources to help me fulfill this role? Are these resources available to me? What influence or control do I have over these resources?
- Will I receive the training I need to fulfill my role on the research team?
- Could I have a role in training patients and researchers to help expose or improve power imbalances, and deal with them?
- 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 being heard, and my contributions acknowledged and valued?

2.3.2 For researchers, institutions, and funders

Consider the following:

- Have we included resources and support at the project planning stage? Will they allow patients to contribute meaningfully to research? Will they allow researchers and others to understand what meaningful collaboration is and what their responsibilities are?

- Have we established processes, support, and compensation? Will they allow patients to feel they are being treated equitably and with respect? Will they acknowledge and value the contributions of patients?
- Have we informed patients of the various roles on the research team? Have we told them about law or policy to which researchers, institutions, or funders may be held accountable?
- Is the project engaging more than one patient?
  Depending on the roles of patients, it is good practice to engage more than one patient. Multiple patient voices provide a sense of both the diversity and commonality of living or lived experience. They also help balance requirements of the research project with other aspects of life. In this way, patients are not over-burdened and can give each other mutual support. Peer-to-peer mentorship between those patients with more task-related skills and experience and those with less can also be effective. Being the only person on a research team or committee without formal health or research-associated training can be intimidating.
- Have we reflected on our cultural expectations as researchers and institutional representatives? Have we recognized the generally unspoken assumptions we bring to our interactions with patients? Have we considered that patients may have different expectations around how they interact with researchers?

2.4 Systemic and structural barriers to patient engagement

This sub-section looks at systemic and structural barriers to engaging patients. It presents general issues that can arise for both patients and researchers that could interfere with the research process, project, or team. It then lists specific questions for these two groups.

Certain aspects of research may present potential systemic and structural barriers to patient involvement on the research team.

Systemic barriers are those policies, practices, or procedures that result in some people receiving unequal access or being excluded. On research teams, a systemic barrier may be tied to the long lag-times between phases of the research, e.g. from proposal development through funding, ethics review, data collection and analysis, and knowledge translation and exchange. Some barriers may be addressed through managing the expectations of patient partners. There may be practical issues around cash flows and the ability to compensate patients for the time invested in the project. In some cases, it may be necessary to compensate patients financially for their participation in the research. In other cases, receiving money may disqualify patients from social benefits. It is also important to budget for food, food restrictions, travel, and other expenses.

Structural barriers occur when one category of people is considered unequal compared to others. This relationship is perpetuated and reinforced by unequal relations in roles, functions,

decisions, rights, and opportunities. Poverty, race, ethnicity, or lack of formal education are examples of potential structural barriers. There may also be access barriers to meetings, such as curbs or lack of elevators for individuals with mobility issues. Planned breaks may also be needed to accommodate the health needs of the patient partner.

2.4.1 For patients

Consider the following:

- How much time can I commit to the project? Can I commit to the project until it ends? Although the latter may not be an expectation, it should be discussed up front.
    - Can my research partners accommodate any health conditions I have? For example, do they have a medical emergency plan in place at meetings? Do they schedule breaks between meetings to allow time to rest?
    - Can my research partners help address the financial costs of participation such as compensating for lost wages or daycare expenses?

2.4.2 For researchers, institutions, and funders

Consider the following:

- Do all individuals understand processes and procedures about the research project? For example:
    - There will be considerable lag between proposal development and funding. This includes delays associated with the need to revise and re-submit a grant for the next grant cycle.
    - There may also be considerable lag between funding and research ethics review before being able to start the project.
- Have we addressed systemic and/or structural barriers that may inhibit or prevent the participation of patient partners due to their health condition, or their economic or social status? This includes:
    - physical access barriers
    - meeting times and duration – for example, the need for a break in a lengthy meeting
    - appropriate and sufficient support provided around teleconferences, videoconferences, and in-person meetings
- Have we provided enough training for individuals with lower literacy levels whose living or lived experience is of value to the project?
    - Are funds available to support patient partners for the time they have invested in the project during these periods when there are no project funds? For example, a funding agency might cover costs associated with proposal development. Funds might also come through the Vice President, Research at a university.
- If a patient partner cannot accept financial compensation for participation (e.g. if this would disqualify them for social assistance), what else could be offered? Non-financial compensation could include food at meetings, or the costs of transportation and accommodation for presenting to a conference.

2.5 Benefits and harms

This sub-section looks at benefits and harms from research. It presents general issues that can arise for both patients and researchers that could interfere with the research process, project, or team. It then lists specific questions for these two groups.

Through sharing their living or lived experiences of a health condition, patient partners can help to increase research benefits and reduce harms:

- **For themselves.** Patient partners can identify their own health needs so these needs can be accommodated in their roles in the research activity.
- **For research participants**. Through their living or lived experience of a health condition, patient partners are well positioned to advise other research team members. This advice could be about both potential harms and benefits for research participants.
- **For the general patient population.** Patient partners could identify potential harms to people affected by communication and use of the research results from, for example, stigmatization and discrimination.
- **For knowledge translation and exchange.** Patient partners could help inform health care providers and other patients of research results.

Patients and researchers should also be prepared to exit a partnership sooner than expected. For example, patient partners may feel too uncomfortable to continue. Their circumstances may also change, making it difficult to fulfill expectations. In addition, researchers may not be able to obtain funding for a project.

2.5.1 For patients

Consider the following:

- How might the research affect me personally? For example:
    - Do I have any health conditions that could affect my ability to participate?
    - Does my living or lived experience affect my feelings towards the topic?
    - What am I expected to do? Are these expectations reasonable?
- Does the project have mechanisms to support me? For example:
    - If the research activity triggers stressful memories associated with my living or lived experience of a health condition or circumstances, can an Elder help take care of the team for Indigenous research?
- What are the potential impacts of the research on other patients or my community?
- Could engaging in the research strengthen me?
  For example:
    - Will I add to my own skills and experience?
    - Can I make a positive contribution for the benefit of other patients, my community, and society?

- Does the research have potential benefits or harms that my colleagues may be unaware of?
- How can I best bring my living or lived experience of a health condition and what I learned in the research project to the awareness of community members and their health care providers?

2.5.2 For researchers, institutions, and funders

Consider the following:

- Are we giving patient partners opportunities to provide information about potential benefits and harms of the research for research participants?
- Do we have mechanisms to hear from patient partners about potential benefits and harms associated with their roles in the research process, and to support them when needed? Have we built the necessary resources, e.g. human, financial, and time, into the budget?
- 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?

2.6 Confidentiality of information

This sub-section looks at confidentiality issues. It presents general issues that can arise for both patients and researchers that could interfere with the research process, project, or team. It then lists specific questions for these two groups.

Some information gathered throughout the research lifecycle should be kept confidential. This includes, for example, applications submitted for scientific or ethics review, or information that would reveal the identities of research participants. Researchers, institutions, and funders should ensure that all involved can uphold all expectations of confidentiality, and that appropriate policies and procedures are in place. Patients may also be a source of expertise with respect to the expectations of particular communities around confidentiality and privacy. In some Indigenous communities, for example, only specific members of a family may be permitted to tell their family stories.

2.6.1 For patients

Consider the following:

- 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 responsibilities to uphold protections for information provided in confidence? Do I need more support or resources to fulfill my responsibilities?

2.6.2 For researchers, institutions, and funders

Consider the following:

- Are there appropriate policies, procedures, training, and supports in place for respecting expectations of confidentiality? Is there a mechanism to deal with breaches of confidentiality?
- Is everyone showing the same respect for confidentiality that is expected from patient partners?

Part II

Guidance for Specific Roles in the Research Lifecycle

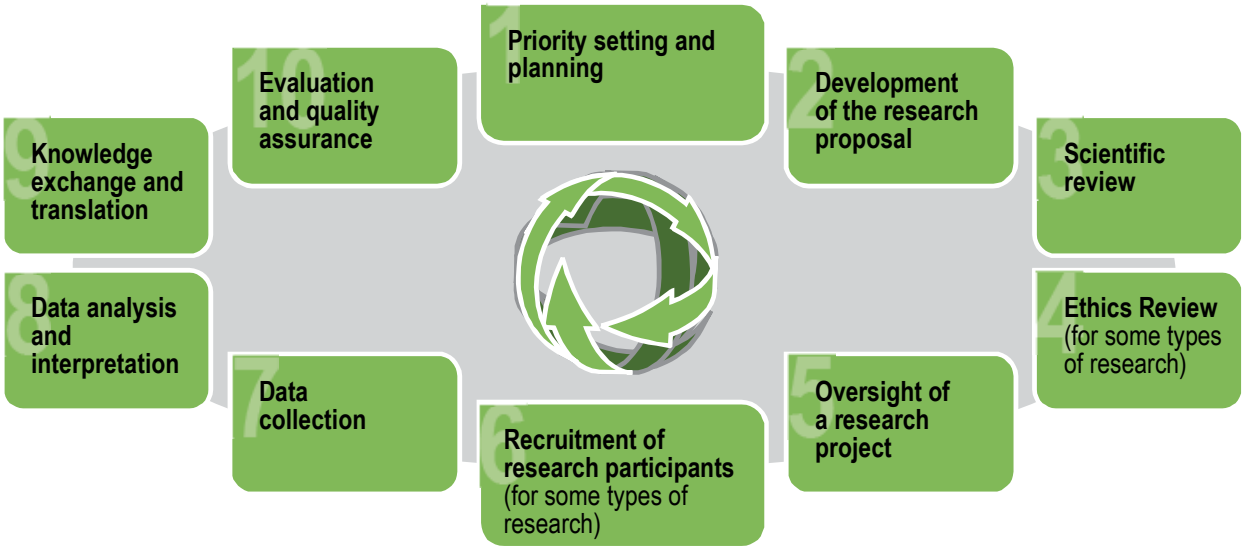
The ethical concerns and reflections described in Part I are relevant to all roles throughout the research lifecycle. Part II applies the ethics guidance to demonstrate good practices in 10 specific stages of the research lifecycle: priority setting and planning; development of the research proposal; scientific review; ethics review; oversight; recruitment of participants; data collection; data interpretation; knowledge transfer and translation; and evaluation.

Overview

We aim to promote broad engagement of patients across **all stages** of the research (see Figure 3). This ethics guidance is mainly focused on the engagement of patients in roles other than as participants. However, a patient can be a research participant, and also take on other relevant roles depending on the insights or skills they can offer. In a large-scale population health study, patients may be research participants and also have a formal voice on a committee to advise on the overall direction of the study. A patient can also be a research participant for a first phase of a study, and then take on an advisory role for a subsequent phase.

When institutions or funders engage patients to sit on independent scientific review committees or ethics review committees, those patients might also be partners on research teams. To avoid a conflict of interest, they would not review proposals from those teams.

Figure 3. Key stages in the research lifecycle



Stage 1: Priority setting and planning

Priority setting can take place in various contexts. For example, a funding agency could be developing its strategic plan or a research initiative on a specific emerging issue; a research centre dedicated to a particular health condition or population group could be determining how it should invest its funds; or a research team at the earliest stages of exploring knowledge gaps and stakeholders' interests is seeking a new research direction.

Priority setting and planning: Examples of patient roles	Guidance:
✓ Advise on a priority-setting committee. ✓ Contribute to a priority-setting workshop. ✓ Contribute to interpretations of research outcomes to inform priorities for new research. ✓ Brainstorm with other members of the research team to identify research questions, study aims, and potential research impacts.	<u>For patients</u>: • Recognize the value of your experience as a patient and actively work to make that knowledge available to the research team. Your perspective can help identify how the research can be more useful for patients like you and others. • Contribute insights for research priorities based on an understanding of your living or lived experiences and/or those of others in your community. Your insights may influence the shape of projects being considered and benefit a broader group of patients. <u>For researchers, institutions, and funders</u>: • Engage patients at the early research stages by building relationships with individual patients and with members of the community of interest. Continue this process throughout the life of a project. In the planning stages, build resources into your budget to meaningfully compensate patients throughout the activity. You may also need to budget for processes to overcome barriers to participation (particularly for those groups of patients that are under-represented in research). Also, consider setting aside funds to strengthen the capacities of both patients and researchers for meaningful collaboration. • Introduce patient voices into priority setting to open the research to new perspectives and reveal important needs and knowledge gaps. Engage with relevant communities, for example, to reach patient groups that are under-served in society and under-represented in research to consider their perspectives. • Translate patient priorities collectively into feasible and realistic research goals through open and sustained discussion.

Stage 2: Development of the research proposal

Development of the research proposal: Examples of patient roles	Guidance:
✓ Provide expertise to inform "Methods and Knowledge Translation" sections of the proposal. ✓ Contribute to the development of informed consent materials, and an understanding of potential impacts of the proposal on patient groups. ✓ Build community engagement plans and appropriate Indigenous cultural norms and Ways of Knowing into the research design. ✓ Inform the inclusion criteria for a representative sample of the whole population to be recruited as research participants (known as a sampling strategy).	<u>For patients</u>: • Shape the design of the research to maximize its usefulness to patients like you and others in your community. This implies two things. First, it means learning how research unfolds. Second, it means learning how to maximize the possibility of creating knowledge that is accurate and that incorporates the living or lived experience of patients, and then helps improve it. • Suggest opportunities for different Ways of Knowing to be included in the research design. This could include the living or lived experience of patients, and the circumstances and traditional knowledge of particular Indigenous communities. This could make a substantial contribution to the research. • Contribute knowledge about the diversity of patients who are affected by the research topic. This could shape how researchers choose which patient experiences will be part of proposed research. • Recruit patients to participate in the research to minimize barriers to participation. This could help develop strategies. • Strive to understand and appreciate researchers' perspectives and suggestions with regard to shaping the research application. <u>For researchers</u>: • Discuss possibilities of authorship at the start of the project, including sharing credit with patient partners. • Give appropriate recognition to patients who helped develop a research proposal. The proposal may go through many versions and involve different groups of people at various stages before being accepted for funding. It is important to recognize patients who were part of the journey in the development of the proposal. • Consider an appropriate governance structure for oversight of a long-term project. Where are patients' voices most needed? Where will they be most effective in this governance structure? For example, a large research project may have a steering committee; an ethical, legal, and social issues advisory committee; a community advisory committee; and

Development of the research proposal: Examples of patient roles	Guidance:
	various other technical committees and working groups. Patients could join one or more of these bodies, or be fully integrated into every governance body. • Manage expectations of patient partners by explaining the application process. If you don't receive funding, be open and honest about the decision and what this means for the research partnership. If possible, suggest other avenues for the patient partners to be engaged in research.

Stage 3: Internal and external scientific review of the research proposal

Scientific review: Examples of patient roles	Guidance:
✓ Review research proposals of other teams. ✓ Review drafts of their own team's research proposal. ✓ Prepare summaries of research proposals that are easy to understand by the average person. ✓ Provide feedback on potential impacts on patients of a research proposal. ✓ Assess the extent of meaningful patient engagement in the proposal.	<u>For patients</u>*:* • Help ensure the review of the research proposal integrates and uses the patient's perspective and needs. This includes ensuring the research leads to outcomes that are relevant to patients. If you also have academic or professional expertise in the area under review, you will need to focus on bringing your perspective as a patient. • If you are bringing the patient perspective on a funder's scientific peer review committee, ensure that you know how to preserve confidentiality of the information and the review committee discussions. Be clear to others outside the committee that you cannot speak about applications under review. • If you are on a funder's independent scientific review committee, do not review proposals from a research team that you are partnering with. Doing so would be a conflict of interest.
	<u>For researchers</u>*:* • Recommend that people with living or lived experience of the health condition or context under study be members of funders' scientific review committees.
	<u>For research institutions, communities, and funders sponsoring scientific review committees:</u> • Include people with living or lived experience of a health condition on funders' scientific review committees. This is

Scientific review: Examples of patient roles	Guidance:
	particularly important for funding opportunities for which patient engagement is explicitly encouraged or required in applications. However, it is a good practice for all types of applications. • Consider what power dynamics will likely occur on a committee that includes both scientific experts and patients because of such things as the subject matter. Reflect on the guidance in the Ethics Concerns section under *Power Imbalances*. • Be clear about expectations and the extent of the patient's influence on the committee's rating of an application. Where appropriate, the quality of the patient engagement plan and the scientific elements should have equal weight in the application. • Explain to patients and other committee members what would constitute a conflict of interest or commitment. Establish a fair and transparent process to manage and minimize conflicts. • Ensure appropriate policies, procedures, training, and support are in place for respecting expectations of confidentiality, and dealing with breaches.

Stage 4: Ethics review of the research proposal

Under TCPS 2, institutions must establish or appoint research ethics boards to review the ethical acceptability of all research involving humans. These research ethics boards are expected to have at least one community member with no affiliation to the institution. A community research ethics board may also review proposals involving Indigenous peoples.

<table>
<tr><th>Ethics review: Examples of patient roles</th><th>Guidance:</th></tr>
<tr><td rowspan="2">✓ Identify and raise ethics concerns during the review of research proposals by an institutional or community research ethics board.
✓ Review informed consent materials, and potential impacts of the proposals on patient groups.</td><td><u>For patients</u>:
Consider playing an important role on an institution’s research ethics board as a community member. If you are also a partner on a research team, you would not review submissions from your team. Doing so would be a conflict of interest.
Provide major input into reviewing the proposed consent form and process to be used with research participants. Some things to consider:
People should participate in research voluntarily. They should understand its purpose, and its risks and potential benefits, as much as they reasonably can.
Prospective research participants should have enough time and opportunity to understand and ask questions about information in the informed consent process.
Information for prospective research participants should be understandable. For example, this could mean preparing the consent process in the preferred format and language of potential participants.
Recognize that community members on research ethics boards are often seen as having special insights into particular groups. They can be seen as speaking for these groups. If you have this role, be willing to indicate the limits of your knowledge and awareness of groups with which you are identified.</td></tr>
<tr><td><u>For institutions and communities:</u>
Recognize that a patient on the research ethics board will bring a personal voice, and living or lived experience. This may be different from the views and experience of others. If patients are asked to represent the views of other persons or of the community, there are several possible approaches. First, ensure patients have enough opportunities to consult with others. Second, select patients who are members of</td></tr>
</table>

Ethics review: Examples of patient roles	Guidance:
	patient organizations and communities that are organized to provide a collective voice. Third, choose both option one and two together.

Stage 5: Oversight of a research project

A long-term project might have decision making or advisory boards as part of its internal governance structure. A data and safety monitoring board may be established for some studies to help monitor the safety of research participants.

Oversight: Examples of patient roles	Guidance:
✓ Contribute to oversight of research activities (such as community engagement, recruitment of research participants, and data collection and analysis) during a project. ✓ Raise concerns about the safety of research participants.	<u>For patients</u>: • Ensure you understand how your committee makes decisions. In some cases, the patient is the expert and should have greater say in the process. In other cases, scientific, methodological, and technical issues may be the focus. Wherever possible, decisions should be made by consensus or by majority vote. Be aware of the process of decision making. Speak up if you feel uncomfortable with the process or decisions. • Be aware of any other interests, expertise, experience, and affiliations that could influence or interfere with your role on the committee. Tell the appropriate staff or chair of the committee about them to manage and minimize conflicts of interest. Data and safety monitoring boards and governance committees need to formulate advice and decisions through a fair and transparent process.
	<u>For institutions and communities:</u> • Consider how to help patients become effective members of an advisory or decision-making committee. This can include providing information in plain language, and avoiding jargon and acronyms. It can also mean providing space at meetings to ask questions if something is not clear. • Ensure the participation of patients makes a difference to them. Ensure their voices are meaningfully considered among all other voices on the committee. Develop a transparent process for communicating why some advice or input is not put into action.

Oversight: Examples of patient roles	Guidance:
	• Establish a fair and transparent process for disclosure of interests and management of conflicts of interest. • Negotiate assignment of roles in a respectful, fair, and transparent way, and manage conflicts of interest and roles. Consider any pre-existing relationships when making up a committee if researchers are part of the community they study. For example, are clinician-researchers and their own patients comfortable being on the same committee?

Stage 6: Recruitment of research participants

Recruitment: Examples of patient roles	Guidance:

✓ Help coordinate representatives of the community, clinics, individual clinicians, and others, for the recruitment of research participants.
✓ Help recruit patients to participate in the research process (for example, by presenting the research project).
✓ Design, write, or provide feedback to letters of information and recruitment strategies.
	<u>For patients:</u>
	• Consider taking the lead to recruit appropriate patients, some of whom may rarely participate in research projects. You could have an important role in:
	  • commenting on the inclusion criteria (sampling frame) for recruiting potential research participants;
	  • adapting a consent form and information so it is clear and appropriate for the community, e.g. some Indigenous health researchers are implementing a tobacco protocol as a culturally appropriate alternative to a written or verbal informed consent process;
	  • helping contact patients; and
	  • asking people to consent to the research. However, there may be particular kinds of research with specific requirements for who should be directly involved in asking people to consent to the research. This could include, for example, high-risk clinical trials.
	• Recognize that, as a patient involved in recruiting other community members, your contribution will lend credibility and legitimacy to the research project. Consider the reflections in the ethical concerns section under *Legitimation* to determine your degree of comfort in this role.
	• Speak up within the research team if you are not comfortable. You may feel there are conflicts of interests between your role as a recruiter for research, your role in the community, and personal relationships with people being

Recruitment: Examples of patient roles	Guidance:
	recruited. Perhaps you feel they could interfere with obtaining a truly voluntary consent to the research from others. Or maybe you feel they could put your safety at risk. Depending upon your role in the community, your mere endorsement or participation in recruitment may convince potential participants to take part in the research (or to reject the idea). If you think this could happen, you should not take part in recruiting community members. • Consider the personal benefits or harms in being directly involved in the consent process. Is the topic sensitive or controversial? Does it relate to events in your or your community's past? Does it touch on unresolved issues? You may feel strengthened by helping recruit community members into research on this important topic. But you may feel the project will stir up negative feelings and memories. Find out if there are support systems in place for patient partners. • Safeguard any personal information collected as part of the consent process. This could include, for example, who consented and who did not.

	<u>For researchers</u>:
	• Ensure you can demonstrate to the satisfaction of a research ethics board that the consent process will be voluntary and informed. If you are considering using a patient partner in the recruitment process, ensure the person has adequate training and self-awareness for the role so they do not exercise undue influence.
	• Consider asking patients (and other community members) to help recruit people. This may be an effective approach, especially with populations that have traditionally not been involved in research. Patients can provide valuable assistance by:
	  • ensuring the consent process is appropriate to this community, e.g. that the form of consent and any information materials reflect the community's language and values;
	  • commenting on the inclusion criteria for the research;
	  • helping reach prospective participants; and/or
	  • being directly involved in obtaining consent.

Recruitment: Examples of patient roles	Guidance:

	• If selecting patients to help with recruitment, consider if they represent the community, if they have credibility with the community, and if they have living or lived experience of the issue under study. All of these factors could be important for successful recruitment.
	• If you are asking patients to be directly involved in the consent process, ensure that you:
	  • inform patients of the research goals, and any potential benefits and harms to individuals and to the community as a whole. In this way, they can communicate this information to prospective research participants in a balanced way.
	  • keep in mind that the status of the patient in the community. Any pre-existing relationships with people being recruited can influence the voluntariness of consent. Consider if a patient's potential conflicts of interests and roles can be appropriately managed if a patient wants to be directly involved in obtaining consents from prospective research participants. Would it be better for a member of the research team or a neutral third party to handle the consent process?

Stage 7: Data collection

Data collection: Examples of patient roles	Guidance:
✓ Conduct individual and group interviews. ✓ Collate and prepare data for analysis.	<u>For patients:</u> • Consider the ethical concerns section under *Legitimation* to determine your degree of comfort in collecting data. As a member of the research team, your contribution will lend credibility and legitimacy to the project for the community and the funders of the research. • Recognize that research participants may be more comfortable sharing their experiences with you as a peer than with researchers. They may find researchers seem far removed from what they, as patients, experience. • Negotiate your role in data collection at the beginning of the research project. This will help ensure you are comfortable with what the research team expects of you. You may need some training in the type of data collection involved in the research. • Recognize that, as a research team member, participants may tell you confidential information. Respect these confidences and do not discuss them with friends and neighbours from your community. • Explore the supports available to you as a patient researcher. You may need to fully consider the impact of the experiences of others on your own well-being. Ask for the supports that you need to fulfill this role.
	<u>For researchers:</u> • Be comfortable that the patients on your team have, or can acquire, the necessary skills and experience to collect data. These include understanding different data collection methods, avoiding bias in data collection, documenting accurately, and storing data securely. Provide appropriate support as needed. • Consider the possibility that some research participants would prefer not to be interviewed by a peer. Provide another option where feasible. • Acknowledge appropriately the role of patient partners in presentations and publications. • Take steps to ensure the safety of all members of the research team involved in data collection. Put safeguards in

Data collection: Examples of patient roles	Guidance:
	place to protect patients during the research, e.g. during the interview process.

Stage 8: Data analysis and interpretation

Data analysis and interpretation: Examples of patient roles	Guidance:
✓ Contribute to analysis and interpretation of quantitative and qualitative data. ✓ Discuss findings with researchers and other partners. ✓ Contribute to the interpretation of research results, bringing a patient voice of living or lived experience to the study findings. ✓ Write analysis reports as appropriate.	<u>For patients:</u> • Negotiate your role in data analysis and interpretation at the beginning of the research project. This will help ensure you are comfortable with what the research team expects of you. Remember as well that your role may evolve over time. You may need some training in the type of analysis involved in the research. • Learn how to analyze data, which could be quantitative, qualitative, or both. • Contribute your interpretations based on living or lived realities. Provide real-world examples and other information to help research team members understand the findings. • Explore the supports available to you as a patient researcher. Depending on the research topic, analysis and interpretation of data can be stressful for all researchers. This is especially true for those with similar living or lived experience.
	<u>For researchers:</u> • Consider presenting preliminary statistical results to a group of patients. This group will then "story" the data. In other words, they add their interpretations based on living or lived realities, and provide real-world examples to better illustrate and give meaning to a number. Be ready to answer requests for further analysis. • Be comfortable that the patients on your team have or can acquire the skills and experience needed to collaborate on data analysis. Provide appropriate support or training as needed. • Acknowledge patient partners appropriately in presentations and publications.
	<u>For institutions:</u>

	• Consider what services might be provided at an institutional level to help engage patients in analysis. Typically, data analysis workshops, e.g. for coding and NVivo, are available for researchers and students. In addition, consider offering analytic workshops geared towards patient and community researchers.

Stage 9: Translation and exchange of research knowledge

Knowledge translation and exchange: Examples of patient roles	Guidance:
✓ Write articles for a variety of media that share knowledge to different audiences in lay terms, and help identify potentially offensive language and propose alternatives. ✓ Prepare and deliver presentations to share knowledge with different audiences. ✓ Assist with the development of alternative or innovative forms of knowledge translation and exchange, e.g. performance art installations, social media). ✓ Discuss implications of new knowledge with health care providers and relevant communities to	<u>For patients:</u> • Negotiate your role in translation and exchange of research knowledge at the beginning of your relationship with the research team. Recognize this role may evolve over time. • Be clear about the resources you need to engage in these activities. This could include, for example, access to online library searches, and costs of meeting and conference attendance. This will allow them to be covered in the research budget. • Be aware it can take years for study results to appear in an academic journal. This reality may conflict with your motivation for taking part in the study, i.e. making a difference in people's lives as soon as possible. Of note, there are many other ways of sharing findings and legitimizing patient-engaged research beyond publications. • Consider the timelines in producing a publishable manuscript in relation to your availability and resources. • Negotiate (co)authorship with the research team. If you have been an integral member of the research team and helped write an article, you should be listed as an author rather than just acknowledged in the article. • Become familiar with journals that publish articles about patient engagement in research. <u>For researchers:</u> • Acknowledge patients as authors or co-authors of publications if they contribute to the research design, data collection, data interpretation, or knowledge translation activities. At the very least, they should be acknowledged in presentations and publications. For example, you could

Knowledge translation and exchange: Examples of patient roles	Guidance:
identify possible applications. ✓ Gather feedback from patient groups on research findings. ✓ Work alongside researchers with policy makers when advocacy at the level of the system (for example, to change health policy) is required. ✓ Author or co-author reports and scientific articles.	acknowledge an Elder or Knowledge Holder of Indigenous ancestry for setting the overall tone of meetings and taking care of a research team. They may also have provided guidance and insight on particular aspects of the research. • Build in resources for patients who make this level of commitment to your study to co-present at conferences. • Remember that knowledge translation and exchange is contextual. Doing it well with communities often takes consideration, resources, and time. Patients can be valuable partners in this activity. • Work alongside patients to translate your study findings directly to patients. This will help ensure they can use the information to improve their health. • Co-author and present with patients engaged in your research. This will contribute to the credibility of your work in the research community. • Discuss your publication plans with patients engaged in your research to understand how they want to be involved. If need be, choose appropriate places for publishing e.g. scientific journals and professional journals, according to your needs and those of patients. • Consider journals that publish patient engagement articles. <u>For institutions:</u> • Play an enabling role by providing resources, facilities, and training for researchers and patients new to patient-engaged research. This should strengthen their capacity to collaborate throughout the research process, including in knowledge exchange and translation activities.

Stage 10: Evaluation and quality assurance[6]

Evaluation and quality assurance: Examples of patient roles	Guidance
✓ Take an active role in evaluation and quality assurance of the research project as a member of the research team or as a member of an oversight body, bringing a living or lived experience lens or specific focus. ✓ Take part in an evaluation process to explore the effectiveness and efficiency of patients being involved in research. ✓ Contribute to the identification of information needs or gaps in existing materials and tools. ✓ Identify language or materials that are confusing or unhelpful, as well as identify materials that are particularly well formatted and helpful. ✓ Assist with testing and adjusting the materials. ✓ Serve on improvement teams with patient safety goals, e.g. engaging patients and staff in identifying safety risks; reducing preventable readmissions, medication incidents, falls, and infections. ✓ Review materials related to improvement initiatives.	<u>For patients:</u> • Familiarize yourself with the evaluation or quality assurance function in which you are involved. Identify the terms of reference, who is receiving your advice, and your role in this process. • Consider how well the research engaged people with living or lived experience throughout the lifecycle in evaluations of projects that have ended. • Pay attention to concerns around confidentiality in terms of accessing information from the project and advising those receiving any reports. <u>For researchers, institutions, and funders:</u> • Draw methods and tools from different domains, e.g. patient engagement, quality improvement, project planning, and communications. This will help you clarify the purpose, and choose the right people and right methods. It will also help you recruit and orient patient partners into their roles, and support everyone towards equal partnership and effective collaboration. • Consider how the impact of patient engagement will be evaluated and reported so that others may benefit.

[6] Quality assurance is aimed at ensuring that required standards of an activity will be met. Examples of relevant tools include: the Canadian Patient Safety Institute: *Engaging Patients in Patient Safety – a Canadian Guide* (2017); the University of Montreal's Centre of Excellence on Partnership with Patients and the Public: *Patient and Public Evaluation Toolkit*; and the Ontario SPOR SUPPORT Unit: *Patient Engagement Evaluation Tools*.

Evaluation and quality assurance: Examples of patient roles	Guidance
✓ Help test and adjust new quality and safety processes. ✓ Discuss findings of the quality assurance and improvement exercises. ✓ Identify improvements to be made to the way research was conducted. ✓ Monitor that quality improvements are implemented.	

Real Life Examples of Patient Engagement

(Disclaimer: CIHR is not responsible for the content of external web links)

Institution:	Patient partner roles include:	Internet links
Can-SOLVE CKD (Chronic Kidney Disease) Network	✓ Priority setting ✓ Oversight of a research initiative, e.g. see the Patient Council and the Indigenous Peoples' Engagement and Research Council	https://cansolveckd.ca/
Children's Hospital of Eastern Ontario (CHEO) Research Institute: Research Family Leaders Program	✓ Development of the research proposal ✓ Member of the research team throughout the life of the project	http://www.cheori.org/en/researchfamilyleadersprogram
James Lind Alliance: Priority Setting Partnerships	✓ Priority setting	http://www.jla.nihr.ac.uk/jla-guidebook/
Canadian HIV Cure Enterprise (CanCURE)	✓ Priority setting	https://www.cancurehiv.org/community-engagement
Living with HIV (LHIV) Innovation Team Grant-Community Scholar Program	✓ Development of the research proposal	http://www.cihr-irsc.gc.ca/e/49628.html#a2
Strategy for Patient-Oriented Research (SPOR) Networks in Chronic Disease – Selection Panel Review Guide	✓ Participation on scientific peer review committees for applications for funding	http://www.cihr-irsc.gc.ca/e/49642.html
American Cancer Society	✓ Participation on scientific peer review committees for applications for funding	https://www.cancer.org/research/we-fund-cancer-research/apply-research-grant/stakeholder-participation-grant-peer-review-committees.html
Manitoulin Anishinaabek Research Review Committee	✓ Participation on community review committee	https://www.noojmowin-teg.ca/programs-services/manitoulin-

Institution:	Patient partner roles include:	Internet links
		anishinabek-research-review-committee
Walmsley program of research into HIV and Healthy Aging (CHANGE-HIV)	✓ Oversight of a research initiative, e.g. see the Community Advisory Committees	https://academic.oup.com/ije/article/42/2/402/732813/Cohort-Profile-The-Ontario-HIV-Treatment-Network
Patient and Community Engagement Research (PaCER) Unit, O'Brien Institute for Public Health, University of Calgary	✓ Priority setting and planning ✓ Development of the research proposal ✓ Recruitment of research participants ✓ Data collection ✓ Data analysis and interpretation ✓ Translation and exchange of research knowledge (Engagement researchers in the PaCER program have published research that was embedded in larger research projects. They have also co-authored articles with their research teams).	https://pacerinnovates.ca

Glossary

Capacity strengthening: This involves giving people the tools to strengthen their existing capacities. This term is preferred over related terms such as *capacity building* or *empowerment* because this term recognizes that people bring their existing abilities, skills, and exercise of power to their engagement in research.

Community: A group of people with a shared identity or interest that has the capacity to act or express itself as a collective. A community may be territorial, organizational, or a community of interest. See TCPS 2.

Community member: Someone who self-identifies, and is recognized by the community, as belonging to a specific community. See definition of *Community*.

Conflict of interest or commitment: The perceived, actual, or potential incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the research activity, such that one cannot be fulfilled without compromising the other(s). This is adapted from TCPS 2.

Cultural safety: Respectful relationships can be established when the research environment is socially, spiritually, emotionally, and physically safe. Cultural safety is a participant-centred approach that encourages self-reflexivity among health researchers and practitioners. It requires an examination of how systemic and personal biases, authority, privilege, and territorial history can influence these relationships. Cultural safety requires building trust with Indigenous peoples and communities in the conduct of research. Realizing cultural safety in health and well-being research entails understanding the social, political, and historical contexts that have resulted in power imbalances. It requires an individual to have cultural humility, competence, sensitivity, and awareness in determining relevant health research policies, programs, models, and projects with Indigenous peoples. Meaningful and culturally safe practices refer to equity in health research and delivery. In a meaningful and culturally safe research environment, each person's identity, beliefs, needs, and reality are acknowledged. Participants feel safe based on mutual respect, meanings, learning experiences, and shared knowledge. Cultural safety ensures that the participating community, group, or individual is a partner in decision making. See CIHR Institute of Indigenous Peoples' Health web site.

Ethical dimensions of research partnerships: In this document, we explore how patients and researchers can interact with each other in a respectful and socially beneficial way.

Experiential knowledge: Knowledge that is gained from living or lived experience. See definition of *Living or lived experience*.

Knowledge translation and exchange: A dynamic and iterative process that includes synthesis, dissemination, exchange, and ethically-sound application of knowledge. This process takes place within a complex system of interactions between researchers and knowledge users. It may vary in

intensity, complexity, and level of engagement depending on the nature of the research and the findings, as well as the needs of the particular knowledge user. An example of knowledge translation is the communication of scientific findings in plain language for lay audiences, as well as many other ways in which new knowledge can be communicated and applied. See CIHR's mandate in knowledge translation.

Living or lived experience of patients: Personal experience (in the past or on an ongoing basis) of living with a health condition, or caring for someone with a health condition. The concept of the *expert patient* comes from the recognition that living or lived experience can be the basis of expertise in knowing how a health condition and treatment affect the patient's own body and circumstances. It recognizes that patients should have "the confidence, skills, information, and knowledge to play a central role in the management of life" [7] with their medical condition. Expertise from living or lived experience can also help inform research related to a patient's health condition, as well as the ways in which the condition and treatment intersect with the social determinants of health (such as culture, social status, access to health services, etc.).

Participatory research: "A systematic inquiry that includes the active involvement of those who are the subject of the research. Participatory research is usually action-oriented, where those involved in the research process collaborate to define the research project, collect, and analyze the data, produce a final product and act on the results. It is based on respect, relevance, reciprocity, and mutual responsibility." (TCPS 2, Chapter 9, Research Involving First Nations, Inuit and Métis Peoples of Canada, Article 9.12, Application).

Patients: An overarching term inclusive of individuals with personal experience of living with an illness or other health condition, and informal caregivers, including family and friends (based on the SPOR definition). This guidance was developed in support of SPOR and therefore uses SPOR's broad definition of patients to encompass the range of people who may be engaged as partners in research. Other related terms are *knowledge users*, *citizens, community members, etc.*

Patient engagement in research: Patient engagement occurs when patients meaningfully and actively collaborate in the governance, priority setting, and/or design and conduct of research. This includes engagement in the analysis and interpretations of findings, and summarizing, distributing, sharing, and applying its resulting knowledge. This is based on the SPOR definition.

Patient-engaged research: Research in which patients contribute as patient partners.

Patient partners: Patients who are engaged in any of the roles in the research lifecycle.

Reciprocity: Reciprocity involves relationships that are based on mutual benefit and exchange, including, for example, the obligation to give something back in return for gifts received. This is adapted from TCPS 2, Chapter 9, Research Involving the First Nations, Inuit and Métis Peoples of Canada.

[7] For example, see "The expert patient: A new approach to chronic disease management for the 21st century", United Kingdom, Department of Health, 2001.

Research: An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation. See TCPS 2, Glossary.

Research participant: An individual who is involved in a research study and whose data, or responses to interventions, stimuli, or questions by a researcher, are relevant to answering a research question. See TCPS 2, Glossary.

SPOR: Canada's Strategy for Patient-Oriented Research (SPOR) is about ensuring that the right patient receives the right intervention at the right time. Patient-oriented research refers to a continuum of research that engages patients as partners, focuses on patient-identified priorities, and improves patient outcomes. This research, conducted by multidisciplinary teams in partnership with relevant stakeholders, aims to apply the knowledge generated to improve health care systems and practices. SPOR is a coalition of federal, provincial, and territorial partners.

Systemic and structural barriers to patient engagement: Systemic barriers are those policies, practices, or procedures that result in some people receiving unequal access or being excluded. On research teams, a systemic barrier may be tied to the long lag-times between the phases of the research (from proposal development through funding, scientific and ethics review, data collection and analysis, and knowledge translation). Structural barriers are circumstances where one category of people is attributed an unequal status in relation to other categories of people because of unequal relations in roles, functions, decisions, rights, and opportunities. Poverty, race, ethnicity, or lack of formal education are examples of potential structural barriers.

TCPS 2 – Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, 2nd Edition. This is a joint policy of Canada's three federal research agencies: CIHR, the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). To be eligible to receive and administer funds from the Agencies, institutions must ensure that research conducted under their auspices adheres to this and other policies of the Agencies.

Tri-Agency Framework: Responsible Conduct of Research, 2016 (RCR Framework): The RCR Framework sets out the responsibilities and corresponding policies for researchers, institutions, and the Agencies, that together help support and promote a positive research environment. The RCR Framework contains the Tri-Agency Research Integrity Policy.

Frequently Asked Questions

Is there other relevant guidance that patients and researchers should be aware of?

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2) and the *Tri-Agency Framework: Responsible Conduct of Research* (RCR Framework) are relevant to the ethical conduct of research, whether or not patient partners are involved. The core principles of TCPS 2 (respect, concern for welfare, and justice) are demonstrated in soundly conducted patient-engaged health research. Similarly, the principle of research integrity found in the RCR Framework is essential to patient-engaged research.

Researchers funded by the three federal research councils (including CIHR) must comply with TCPS 2 and the RCR Framework. Patient partners on research teams may be in roles where they interact with research participants and therefore have responsibilities under TCPS 2. In some cases, patient partners may also be research participants. Similarly, the RCR Framework is relevant to patient partners who are members of a research team. For example, researchers should ensure proper acknowledgement of contributions to the research, and management of conflicts of interest.

While we consider TCPS 2 and the RCR Framework, we do not intend to add to, or modify, those policies. This document is intended as an educational resource, and not as a policy with compliance requirements. In addition, we have compiled examples of additional tools and guides developed by other organizations, in the Resources list at the end of this document.

Does patient engagement in research raise specific ethical questions and issues?

Patient engagement can generate a variety of ethical issues across the research lifecycle that need to be addressed. This document highlights questions – and key points of reflection – for patients, researchers, institutions, and funders, to help them think about how to do patient engagement in an ethical and meaningful way, and to turn these reflections into good practices.

Do patient engagement plans require review by research ethics boards?

Research ethics boards review research proposals to ensure that research involving humans will be conducted in compliance with TCPS 2. Such compliance includes appropriately respecting and protecting research participants.

Ethics approval is not required for involving patients in the planning or design stages of research. At the point of ethics review, patient partners may appear in three distinct roles that are relevant for research ethics boards to consider:

- **As part of the research team.** Research ethics boards assess the roles of members of the research team, particularly their interactions with research participants. For example, when patient partners are involved in participant recruitment and data collection and analysis, the research ethics board will want assurances from the lead researcher that patient partners will conduct these activities according to the core ethical principles of TCPS 2: respect, concern for welfare, and justice.
- **As research participants, if patient partners also have this role.** Here, research ethics boards need to ensure that participants will be respected and protected, with the added complexity that these participants are also involved in the research effort as part of the research team.
- **As members of a community being researched or funding research, or as spokespersons for those communities.** TCPS 2 addresses community participatory research, particularly in research involving First Nations, Inuit, and Métis peoples (see Chapter 9 in TCPS 2). We also provide some reflections on working with Indigenous communities in the *Consideration of Indigenous Perspectives* section.

Research ethics boards should be aware that partnerships with patients in research have the potential to:

- make research more relevant to the people the research is trying to assist;
- help determine what is acceptable to research participants; and
- improve the experience of research participation.

Thoughtful engagement of patients in research should apply the core principles of TCPS 2: respect, concern for welfare, and justice.

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Additional Resources

(*Disclaimer: CIHR is not responsible for the content of external web links*)

CIHR:

Canada's Strategy for Patient-Oriented Research (SPOR)

- SPOR home page: http://www.cihr-irsc.gc.ca/e/51036.html
- SPOR Patient Engagement Framework: http://www.cihr-irsc.gc.ca/e/48413.html
- SPOR considerations when paying patient partners in research (May 2019): http://cihr-irsc.gc.ca/e/51466.html
- CIHR Jargon Buster: http://www.cihr-irsc.gc.ca/e/48952.html#q
- SPOR Networks: http://www.cihr-irsc.gc.ca/e/45854.html
- SPOR SUPPORT Units (in every region, with contact information): http://www.cihr-irsc.gc.ca/e/45859.html

Institute of Indigenous Peoples' Health: http://www.cihr-irsc.gc.ca/e/8668.html

Tri-Agency (CIHR, SSHRC, NSERC):

Tri-Council Policy Statement: *Ethical Conduct for Research Involving Humans,* 2nd Edition (TCPS 2):

- TCPS 2 Policy statement: http://www.pre.ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html
- CORE Education module: http://www.pre.ethics.gc.ca/eng/education_tutorial-didacticiel.html
- TCPS 2, Chapter 9, Research Involving the First Nations, Inuit, and Métis Peoples of Canada: http://www.pre.ethics.gc.ca/eng/tcps2-eptc2_2018_chapter9-chapitre9.html

Tri-Agency Framework: *Responsible Conduct of Research,* Section 2.1 Tri-Agency Research Integrity Policy: http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/

External:

Research 101: *A Manifesto for Ethical Research in the Downtown Eastside*, 2018: http://bit.ly/R101Manifesto

Alzheimer Society:

- *Supporting Research Recruitment: A Guide to Get Started*: https://ars.els-cdn.com/content/image/1-s2.0-S2352873717300550-mmc1.pdf
- Person-centered language: https://alzheimer.ca/sites/default/files/2017-11/Person_Centred_Language_Guidelines-e.pdf
- *The Canadian Charter of Rights for People Living with Dementia*: www.alzheimer.ca/charter
- *Meaningful Engagement of People with Dementia*: *A Resource Guide:* https://alzheimer.ca/sites/default/files/files/national/meaningful-engagement/meaningful_engagement_e.pdf

Arthritis Research Canada:

Workbook to guide the development of a Patient Engagement in Research (PEIR) Plan. May 2018: http://www.arthritisresearch.ca/wp-content/uploads/2018/06/PEIR-Plan-Guide.pdf

Canadian Patient Safety Institute:
Engaging Patients in Patient Safety – a Canadian Guide (2017): https://www.patientsafetyinstitute.ca/en/toolsResources/Patient-Engagement-in-Patient-Safety-Guide/Pages/default.aspx

Centre of Excellence on Partnership with the Patients and the Public, University of Montreal
Patient and Public Engagement Evaluation Toolkit: https://ceppp.ca/en/our-projects/evaluation-toolkit/

Children's Hospital of Eastern Ontario (CHEO) Research Centre – Research Family Leader program: http://www.cheori.org/en/researchfamilyleadersprogram

HIV Community-Based Research (CBR): *Fact Sheet #2 – Recruiting hard to reach individuals and communities in CBR*:
http://www.hivethicscbr.com/documents/HIVCBREthics_FactSheet02.pdf

HIV Community-Based Research (CBR): *Fact Sheet #3 – Managing Multiple Roles and Boundaries*:
http://www.hivethicscbr.com/documents/HIVCBREthics_FactSheet03.pdf

Indigenous peoples:

- Framework for Research Engagement with First Nation, Métis, and Inuit Peoples: http://umanitoba.ca/faculties/health_sciences/medicine/media/UofM_Framework_Report_web.pdf
- First Nations Health Authority. Cultural humility webinars: http://www.fnha.ca/wellness/cultural-humility#learn

First Nations:

- Assembly of First Nations: https://www.afn.ca/policy-sectors/health/,
- British Columbia First Nations Health Authority: http://www.fnha.ca/what-we-do/research-knowledge-exchange-and-evaluation, especially http://www.fnha.ca/what-we-do/research-knowledge-exchange-and-evaluation/research-related-resources
- Kahnawake Schools Diabetes Prevention Project: http://ksdpp.org/scholar/articles.php, especially articles about how to do research

Inuit:

- Inuit Tapiriit Kanatami: https://www.itk.ca/about-canadian-inuit/
- Pauktuutit Inuit Women of Canada: https://www.relations-inuit.chaire.ulaval.ca/sites/relations-inuit.chaire.ulaval.ca/files/InuitWay_e.pdf

Métis:

- Five provincial Métis nations: http://www.metisnation.ca/

International Association for Public Participation (IAP^2) Spectrum of Public Participation: https://www.iap2.org/page/pillars

National Institute for Health Research (NIHR) - INVOLVE: https://www.invo.org.uk/

- Resource centre: https://www.invo.org.uk/resource-centre/
- National Health Service (NHS): *Handbook for researchers: Patient and public involvement in health and social care research:* https://www.rds-yh.nihr.ac.uk/wp-content/uploads/2015/01/RDS_PPI-Handbook_2014-v8-FINAL-11.pdf

Nuffield Council on Bioethics:

- Nuffield Council on Bioethics (2015): *Children and clinical research: Ethical issues:* www.nuffieldbioethics.org/project/children-research
- Nuffield Council on Bioethics (2015): *The collection, linking and use of biomedical research and health care: Ethical issues:* https://nuffieldbioethics.org/publications/biological-and-health-data
- Participatory Evaluation approach: https://www.betterevaluation.org/en/plan/approach/participatory_evaluation

Patient Advisors Network: https://www.patientadvisors.ca/

The Patient – Patient-Centered Outcomes Research: https://link.springer.com/journal/40271