Ethical Guidelines for Engaging Patients as Partners in Health Research

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Final

Alberta Ethics Guidelines for Patient Engagement in Health Research

This document provides guidance on research ethics requirements where patients are meaningfully and actively engaged as partners in health research activities in roles other than as research participants.

What do we mean by patients, patient engagement, and patient-oriented research?
Defining key concepts and terms is critical to creating a common understanding of patient engagement in health research. Different language is used to describe the patient engagement enterprise globally. For example, the U.S. terminology focuses on 'patient-centered' while the UK uses the language of 'patient involvement', and in Australia the terminology is related to 'community participation'.

The following definitions establish the terminology used throughout this document[1]:

KEY TERM	DEFINITION
Patient	Individuals with personal experience of a health issue or situation and informal caregivers, including family and friends
Patient engagement	The inclusion of patients in research activities beyond the level of participation, such as in governance, priority setting, conduct of research, data analysis, knowledge translation, and evaluation
Patient-oriented research	A continuum of research by multidisciplinary teams that engage with patients as partners, focuses on patient-identified priorities, and improves patient outcomes

What does patient engagement in health research look like?

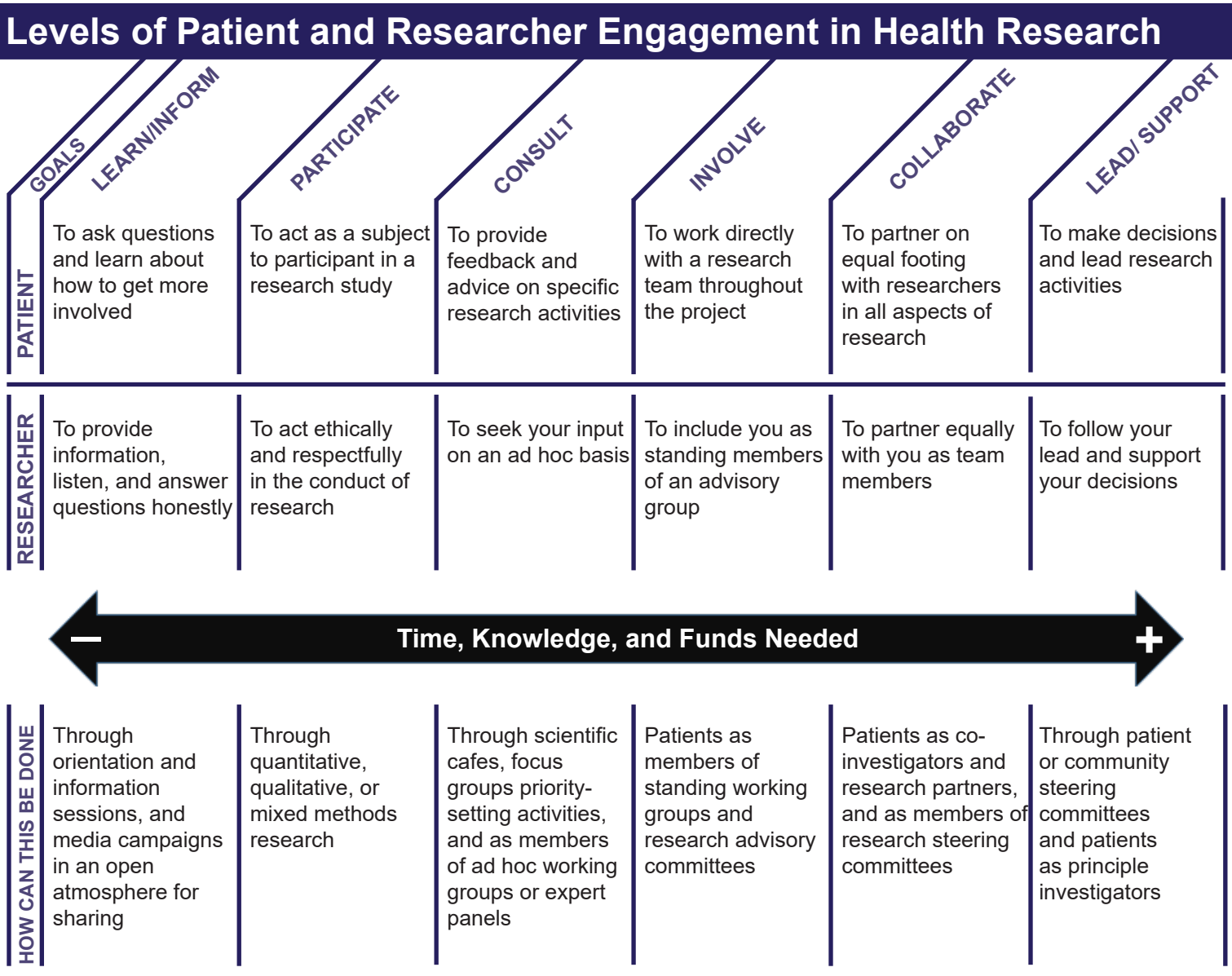
Patients can be engaged across the research cycle, from governance and planning to dissemination and evaluation. Some examples include[2]:

- Applying as joint grant holders or co-applicants on a research project
- Identifying research priorities
- Providing input into surveys, patient information sheets or other research materials
- Helping recruit participants
- Undertaking interviews with research participants
- Providing input related to analysis
- Identifying novel opportunities to share research findings

1 Weaver LC, B. Unpacking the participatory process. Journal of Multidisciplinary Evaluation. 2007:19-40
2 INVOLVE. <9938_INVOLVE_Briefing_Notes_WEB.pdf>. 2012.

It Is important to note that not all forms of engagement are considered equal, as reflected in the schematic of the Levels of Patient and Researcher Engagement. The deeper the level of engagement, the more influence the patient has in decision making, and the more time, knowledge and funds are required by both patients and researchers in order to execute each type of engagement (Figure 1).

Figure 1. Levels of Patient and Researcher Engagement in Health Research (Vandall-Walker, 2017, adapted with permission from IAP2 Spectrum)[3].



When patients are partners on the research team (Consult, Involve, Collaborate, Lead levels of engagement), they are not 'human participants' in the project as defined in the TCPS2. No unique REB approval is required for their involvement in this capacity, other than normal REB approval that may be required for the project itself.

3 Amirav I, Vandall-Walker V, Rasiah J, Saunders L. Patient and Researcher Engagement in Health Research: A Parent's Perspective. Pediatrics. 2017.

Engagement Ethics

No formal requirement exists for researchers to seek ethics approval to engage with patients as partners in their research. Nonetheless, there is an ethical imperative that exists and must be considered. From an ethical perspective, meaningful patient engagement puts a high value on:

- Research that is grounded in a deep understanding of the health situation and lived experience of actual patients – including patients from groups that are typically under-represented in research – so that it becomes more applicable to, and usable by, those patients;
- Patients having the power and capacity to shape research that matters to them, and researchers recognizing the importance of supporting patients for meaningful patient engagement;
- Research methods that are culturally safe, respectful, and appropriate;
- Research that is legitimate in the eyes of the community that the research is intended to benefit;
- Mutually respectful and beneficial relationships among patients, researchers, and others involved in research; and
- Relationships between academic researchers and patients that creates an ethical space for respectful dialogue and discussion where each person can speak in their own voice[4].

Key qualities and skills that support successful engagement of researchers and patients in health research include:

- Being respectful of others and their perspectives;
- Being a good listener;
- Seeking clarity to better understand insights that are expressed in lay, non-technical terms;
- Seeking clarity to better understand insights that are expressed technical terms;
- Being open and non-judgmental;
- Being able to use personal experiences constructively for deeper understanding;
- Being able to work collaboratively; and
- Being interested in expanding one's own knowledge and skills.

Research with First Nations Communities

The First Nations principles of Ownership, Control, Access and Possession (OCAP®) include a set of standards that establish how First Nations community data should be collected, protected, used, or shared. They are the de facto standard for how to conduct research with First Nations communities. For additional information on working with First Nations community partners, please refer to the First Nations Information Governance Centre (http://fnigc.ca/ocap.html).

4 For an elaboration of the concept of ethical space, see Professor Willie Ermine on 'Ethical space in action', McMaster University, 2010, in the context of creating dialogue between Indigenous and other ways of knowing: https://www.youtube.com/watch?v=85PPdUE8Mb0.

Research with First Nations Individuals

Individuals belonging to a First Nation, but engaging as individual patient partners in research that is not specific to a First Nations community, engage in the same manner as other non-First Nations patient partners.

Vulnerable Populations and People with Disabilities

Special consideration should also be given when working with vulnerable populations and people with disabilities.

Patient Partners as Participants/Subjects

If a patient will fill the two roles of research participant or subject and as a patient partner, strong rationale for both roles is needed (e.g., in the case of rare diseases). Special attention must be paid to the informed consent process and to who has access to the data for analysis.

Tri-Agency Framework and Policy Statement

When patients are engaged as members of a research team, their conduct must be in accordance with the Tri-Council Policy Statement 2 (TCPS 2, 2010) and the Tri-Agency Framework: Responsible Conduct of Research (RCR, 2016)[5] , as is the case for any other research team member. A certificate of completion of the TCPS2 Tutorial is required for all team members. Further resources can be found at: http://pre.ethics.gc.ca/eng/education/participation/.

Conflicts of Interest and Commitments

The basic question that patients and researchers should ask themselves is:

> *Are there any interests or commitments that could interfere with my ability to act in the best interests of the research process, project, or team?*

Conflicts of interest and commitment arise when there is an 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). Conflicts of interest and commitment can be potential, actual, or perceived.

For Patients

Consider the following:

- Do I, as a patient, have personal, business, or other relationships in my community that could conflict with my role in the research, and inhibit me from acting in the best interests of the research.

5 See the 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/

- Have I disclosed these conflicts 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, or funding organization have policies and processes for identifying and managing actual and potential conflicts?

For Researchers, Institutions, Funders

Consider the following:

- Have fair and transparent policies and processes been established to manage and minimize conflicts of interest and commitment, in recognition that patients are multi-dimensional and can have multiple roles (as research participants, research team members, community advisors, or priority setters, etc.) and bring other interests, skills, and affiliations to their role(s)?
- If considering inviting friends, neighbours, and family members to be 'patient members' on the research team, consider whether or not these patient members are free to express an independent patient voice; or will their personal relationships with the researcher present a conflict of interest that cannot be effectively managed, or that could inhibit their participation in research?
- Researchers should consult with patients on how their commitments and interests are likely to be viewed by other patient partners in the research.

Power Dynamics and Imbalances

Engagement of patients in research can be affected by power imbalances with respect to such things as:

- **Status** — due to differences in community or social status, expertise, compensation, and affiliations (e.g., among members of a committee or research team)
- **Control** — due to responsibilities for the funding for the research, and other accountabilities (by law and policy) at the level of the funder, institution, or research project; as well as possible community expectations of influence on its members
- **Information** — due to differences in expertise, experience, and access (e.g., to academic journals) to help with understanding the research

Patients and researchers bring a range of competencies – skills, knowledge, behaviours, and beliefs – to the research project. Through mutual respect and valuing of alternate knowledge systems and ways of knowing, tensions around power imbalances can be resolved.

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 about 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 can help address potential impacts of misconception and power imbalances.

Patients have lived experiences of a health condition, and can bring a range of relevant skills and experience to the table. Patients, researchers, institutions, and funders should consider what skills and experiences will be needed for enacting particular roles, and what capacity-strengthening resources (education, training, and support systems) need to be provided. Mentorship opportunities can also be part of capacity strengthening, e.g., where patient-researchers provide training and development opportunities for other patients.

Meaningful engagement of patients in research requires that information flows easily among team members so that patients 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*. Norms should be discussed and agreed upon within the research team to ensure that information circulates correctly and that patients have access to information that they need to fulfill their roles (e.g., emails, library services).

Benefits and Harms

The term *benefits* refers to any positive effect on an individual's or group's welfare, and harms refers to any negative effects. Alongside the consideration of potential benefits of the research itself, the potential impact of the research activity on the physical, mental, and spiritual health of patient partners, as well as their physical, economic and social circumstances should be taken into account by the patient partners in their decision whether or not to become engaged and at what level. Patients, researchers, institutions, and funders may have diverse conceptions about potential benefits and harms of the research activity. Patients can play a very valuable role by alerting researchers, institutions, and funders to potential unexpected benefits and harms of research that may be experienced by patients and their communities.

Confidentiality of Information

Some information gathered throughout the research lifecycle may be provided with the expectation that it will be kept confidential, e.g., applications submitted for scientific or ethics review, and information that could reveal the identities of research participants. Patients, researchers, institutions, and funders need to ensure that all of those involved have the capacity to uphold all expectations of confidentiality, and that appropriate policies and procedures are in place to support this.

Consider completing a research agreement that outlines the roles and responsibilities of each member of the team.

For more information:

Please contact the Alberta SPOR SUPPORT Unit (AbSPORU) at www.absporu.ca/Patientengagement.

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