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# Draft CIHR Ethics Guidance for Developing Research Partnerships with Patients

For public consultation

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Canadian Institutes of Health Research    Instituts de recherche en santé du Canada

Canada

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# Preamble for the Consultation Draft

This project to develop ethics guidance for patient engagement in research was endorsed by the CIHR Standing Committee on Ethics in 2015, in support of Canada's Strategy for Patient-Oriented Research (SPOR). The project is a response to ethical issues that were initially identified by the SPOR SUPPORT Unit Patient Engagement Working Group, and reiterated at various conferences and workshops. The proposed ethics guidance builds on the SPOR Patient Engagement Framework and, once finalized, could be adapted in various formats by SPOR leads and other initiatives, organizations and institutions to serve as an education resource for all those involved in research partnerships with patients.

The CIHR Working Group on Ethics in Patient Engagement in Research was established in September 2016. The Working Group is co-chaired by the Manager of the CIHR Ethics Office and a public member on the CIHR Standing Committee on Ethics. Members consist of approximately equal numbers of patients and experts in relevant fields of research and ethics, and include Indigenous perspectives.

This working group, with its deliberate consideration of Indigenous peoples in Canada and their issues relevant to research, has come together in reconciliation. With the support of CIHR, we intend this to be one small step in contributing to Canada's complete implementation of reconciliation. We hope that the various Indigenous-specific contributions will resonate with others. Further, in adopting and implementing this guidance when finalized, we are sincerely hoping that patients, researchers, institutions and funders will consider their respective roles and responsibilities in collective efforts toward healing and reconciliation.

The Working Group welcomes your comments on this draft of the guidance.

Members of the Working Group are:

Nicolas Fernandez (Co-chair)  
Genevieve Dubois-Flynn (Co-chair)  
Alexandra King  
Michael McDonald  
Jean Miller  
Ron Rosenes  
Donald Willison  
Cathy Woods

Support for the Working Group is provided by the CIHR Ethics Office:

Sheila Chapman and Katelyn Landon.  
Jenna Coles provided support for the project as a summer intern in 2016.

# 1 A Word about this Document

2  
3 This is an ethics guidance document designed to assist those engaged or interested in a particular mode  
4 of health research called patient-engaged research, in which patients are amongst those conducting or  
5 facilitating the study. This guidance document had its origins in CIHR's Strategic Patient-Oriented  
6 Research (SPOR) initiative and in particular the SPOR Patient Engagement Framework.

7 This form of research has elements in common with other valuable modes of health research – such as  
8 public or citizen engagement in research and community participatory research – but is distinct in that it  
9 brings the lived experiences of patients to the research enterprise.

10 In this guidance, we begin from the assumption that patient engagement in research is a productive and  
11 important mode of health research. A good description of patient engagement in research and its  
12 advantages can be found in the SPOR *Patient Engagement Framework* ([http://www.cihr-](http://www.cihr-irsc.gc.ca/e/48413.html)  
13 [irsc.gc.ca/e/48413.html](http://www.cihr-irsc.gc.ca/e/48413.html)). Our primary purpose is to explore its ethical dimensions.

14 Our aim is to offer guidance or accumulated wisdom on ethical aspects of this type of research. That  
15 wisdom draws on the experiences of the document's authors, those who have generously offered  
16 comments on the document as well as academic and literature in this area. Our intention is to make a  
17 contribution to what we envision as an on-going conversation. It is not meant to be a final word on the  
18 issues discussed. We hope that this will encourage a productive on-going conversation. We have also  
19 tried to move beyond simple “do's” and “don'ts” to suggesting ways of improving the practice of patient-  
20 engaged health research.

21 While we take into account the *Tri-Council Policy Statement: Ethical Conduct for Research Involving*  
22 *Humans* (TCPS 2) and the *Tri-Council Framework: Responsible Conduct of Research*, we do not intend to  
23 add to, or modify, those documents. Nor do we intend this document to be regulatory or quasi-  
24 regulatory.

25 In this document we discuss the wide variety of roles that patients may play in the research ethics  
26 lifecycle. Many of these roles involve responsibilities beyond those considered in either the TCPS2 or the  
27 *Tri-Agency Framework: Responsible Conduct of Research*. For example, a patient may be involved in  
28 setting health research priorities for a community or research sponsor, serve as a member of a scientific  
29 review committee or play a leadership role in an Indigenous community commissioning a health research  
30 project. We note too that in the research under consideration there is a continuum of patient  
31 involvement from research that is driven and directed by researchers and research sponsors, to research  
32 that is based in or initiated by communities. Patients can be involved at any point in the continuum. Our  
33 advice is directed to those working at various points along this continuum.

34 The primary audiences we see for this guidance document are the patient and academic/clinical  
35 researchers who come together to conduct or contemplate conducting this type of research. Secondary  
36 audiences include institutions that foster or house this type of research, sponsors of the research

37 including particularly the Canadian Institutes of Health Research, those who play a role in regulating this  
38 type of research including research ethics boards, and those who study this type of research.  
39 Accordingly, we have written in a form that is meant to be broadly accessible rather than for specialist  
40 academic readers. We have also minimized the use of footnotes and references, preferring instead to  
41 include a bibliography of sources that we have found useful.

#### 42 **How is this guidance structured?**

43 This guidance is framed around the roles that patients take on when engaged in research across the  
44 research lifecycle<sup>1</sup>: in priority setting; development of the research proposal; scientific and ethics review  
45 of the proposal; oversight of a research project; recruitment of research participants; data collection,  
46 analysis and interpretation; knowledge translation of research results; and evaluation. These roles play  
47 out in a variety of settings: at the level of individual projects; at the level of institutions and communities  
48 within which the research occurs; and at the pan-institutional and societal level (for example, research  
49 funders).

50 We highlight overarching ethical considerations and ethical issues that are relevant to patient  
51 engagement across the research lifecycle, and offer guidance for specific roles.

#### 52 **What do we mean by *patients*?**

53 In line with how patients are defined in SPOR, we define *patients* as an overarching term that includes  
54 people with personal experience of living with an illness or other health condition, as well as informal  
55 caregivers, including family and friends.

#### 56 **What do we mean by *patient engagement*?**

57 As defined by SPOR, patient engagement occurs when patients meaningfully and actively collaborate in  
58 the governance, priority setting, and conduct of research, as well as in summarizing, distributing, sharing,  
59 and applying its resulting knowledge (i.e., the process referred to as *knowledge translation and*  
60 *exchange*). Patients who are involved in any of these roles are called *patient partners* in this document.

#### 62 **Why is patient engagement in research important?**

63 Patient engagement is a foundational concept of SPOR, and is becoming internationally more common as  
64 patients and the health research community become increasingly aware of the value of collaborating on  
65 research that is intended to benefit patients through improved health, more effective health services  
66 and products, or a strengthened Canadian health care system.

67 From an ethical perspective, meaningful patient engagement puts a high value on:

- 68 • Research that is grounded in a deep understanding of the health situations and lived experiences  
69 of actual patients -- including groups that are typically under-represented in research -- and  
70 therefore becomes more applicable to and usable by those patients;

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<sup>1</sup> 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.

- 71 • Research methods that are culturally safe, respectful and appropriate;
- 72 • Patients having the power and capacity to shape research that matters to them, and researchers
- 73 recognizing the importance of supporting patients for meaningful patient engagement;
- 74 • Research that is legitimate in the eyes of the community that the research is intended to benefit;
- 75 • Relationships among patients and others involved in research that are mutually respectful; and
- 76 • A relationship between academic researchers and patients that creates an *ethical space* for
- 77 respectful dialogue and discussion where each person can speak in their own voice.

78

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

80 The multiple contexts of patient engagement generate a variety of ethical issues across the research  
81 ethics lifecycle that need to be addressed, and so this document highlights questions -- and key points of  
82 reflection -- for patients, researchers, institutions, and funders, to help them think about how to do  
83 patient engagement in an ethical and meaningful way, and to turn these reflections into best practices.

84

85 **Do patient engagement plans require review by institutional research ethics boards?**

86 Research ethics boards are responsible for reviewing research protocols to ensure that the research  
87 involving humans will be conducted in compliance with TCPS 2, which includes appropriate protections  
88 for research participants. While ethics approval is not required for involving patients in the planning or  
89 design stages of research, at the point of ethics review it is within the purview of the research ethics  
90 board to consider how patient involvement has contributed or will contribute to the research, and that  
91 the patient partners have received sufficient training and support necessary for their roles on the  
92 research team.

93 Patient partners may appear in three distinct roles that research ethics boards need to consider:

94 1) As part of the research team. Here, research ethics boards are charged with scrutinizing their roles as  
95 members of the research team. For example, when patients are part of the research team, the  
96 research ethics board will consider their roles in such activities as:

- 97 a. Protocol development, including recruitment strategies, deliberating bio-ethical issues,
- 98 informed consent process and materials.
- 99 b. Field work, including assistance with recruitment and data collection.
- 100 c. Data analysis – adding insights from the patient’s perspective.
- 101 d. Knowledge Translation and Exchange (KTE), identifying target audiences and crafting
- 102 messages.

103 Research ethics boards should be aware that the involvement of patients in research has the  
104 potential to make research more relevant to the people it is trying to assist; and helps determine  
105 what is acceptable to research participants and improve the experience of research participation.

106 2) As research participants, if patient partners also have this role. Here, research ethics boards need to  
107 ensure proper protection for participants with the added complexity that these participants are also  
108 involved in the research effort as part of the research team.

109

110 3) As part of a community being researched or sponsoring research and perhaps as spokespersons for  
111 those communities. Here, norms of community participatory research and/or research involving First  
112 Nations, Inuit and Métis Peoples are relevant.  
113

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## 114 Glossary

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

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

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

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

125 **Cultural safety:** The concept of cultural safety was first proposed by a Maori nurse and educator, Irihapeti  
126 Ramsden. This concept is described by Simon Brascoupé and Catherine Waters as follows: “Cultural safety  
127 developed as a concept in nursing practice in New Zealand with respect to health care for Maori people [...]. It  
128 develops the idea that to provide quality care for people from different ethnicities and cultures, nurses must  
129 provide that care within the cultural values and norms of the patient [...] The outcome of the culturally safe  
130 practice is a two-way relationship built on respect and a bicultural exchange which aims for equality and  
131 shared responsibility. [...] a shift in the power positions needs to take place to build a strong relationship  
132 based on genuine respect, inclusive decision-making and joint effort”<sup>2</sup>. Different but related terms include  
133 *cultural humility* (focusing on self-reflection and humility in learning and understanding another’s  
134 experience<sup>3</sup>), and *cultural competence* (focusing on the knowledge and skills needed to work in cross-cultural  
135 contexts<sup>4</sup>). The concept of *cultural competence* has been criticized in the context of Indigenous health for  
136 assuming that knowledge and skills are sufficient, and for not recognizing that new relationships need to be  
137 established in which there is equality and shared responsibility to achieve a culturally safe outcome.

138 **Experiential knowledge:** Knowledge that is gained from lived experience. See definition of *Lived experience*.

139 **Knowledge translation and exchange:** A dynamic and iterative process that includes synthesis, dissemination,  
140 exchange and ethically-sound application of knowledge. This process takes place within a complex system of  
141 interactions between researchers and knowledge users which may vary in intensity, complexity and level of  
142 engagement depending on the nature of the research and the findings as well as the needs of the particular  
143 knowledge user<sup>5</sup>. An example of knowledge translation is the communication of scientific findings in plain

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<sup>2</sup> Brascoupé, S. and Waters, C., Cultural Safety – Exploring the Applicability of the Concept of Cultural Safety to Aboriginal Health and Community Wellness, Journal of Aboriginal Health, November 2009:

[http://www.naho.ca/documents/journal/jah05\\_02/05\\_02\\_01\\_Cultural.pdf](http://www.naho.ca/documents/journal/jah05_02/05_02_01_Cultural.pdf)

<sup>3</sup> For example, see the British Columbia First Nations Health Authority web site: <http://www.fnha.ca/wellness/cultural-humility#learn>

<sup>4</sup> For example, see the University of Ottawa web site: [https://www.med.uottawa.ca/sim/data/Serv\\_Culture\\_e.htm](https://www.med.uottawa.ca/sim/data/Serv_Culture_e.htm)

<sup>5</sup> See CIHR’s mandate in knowledge translation: <http://www.cihr-irsc.gc.ca/e/29418.html>



144 language for lay audiences, as well many other ways in which new knowledge can be communicated and  
145 applied.

146 **Lived experience of patients.** Personal experience (in the past or on an ongoing basis) of living with an illness  
147 or other health condition, or caring for someone with a health condition. The concept of the *expert patient*  
148 comes from the recognition that lived experience can be the basis of expertise in knowing how a health  
149 condition and treatment affect the patient’s own body and circumstances, and that patients should have “the  
150 confidence, skills, information and knowledge to play a central role in the management of life”<sup>6</sup> with their  
151 medical condition. Expertise from lived experience can also help to inform research related to a patient’s  
152 health condition as well as the ways in which the condition and treatment intersect with the social  
153 determinants of health (such as culture, social status, access to health services, etc.).

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

159 **Patient engagement in research:** Patient engagement occurs when patients meaningfully and actively  
160 collaborate in the governance, priority setting, and/or design and conduct of research, such as in the analysis  
161 and interpretations of findings, and summarizing, distributing, sharing and applying its resulting knowledge  
162 (based on SPOR).

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

164 **Patient partners:** Patients who collaborate in the governance, priority setting, and/or design and conduct of  
165 research, such as in the analysis and interpretations of findings, and summarizing, distributing, sharing and  
166 applying its resulting knowledge.

167 **Research participant:** An individual who is involved in a research study and whose data, or responses to  
168 interventions, stimuli or questions by a researcher, are relevant to answering a research question. In some  
169 forms of research, such as participatory research, research participants collaborate to define the research  
170 project, collect and analyze the data, produce a final product and act on the results. (TCPS 2, Glossary)

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

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<sup>6</sup> For example, see “The expert patient: a new approach to chronic disease management for the 21st century”, United Kingdom, Department of Health, 2001.  
[http://webarchive.nationalarchives.gov.uk/+/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4006801](http://webarchive.nationalarchives.gov.uk/+/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4006801)

176 provincial and territorial partners – all dedicated to the integration of research into care. Web site:  
177 <http://www.cihr-irsc.gc.ca/e/41204.html>

178 **Systemic and structural barriers to patient engagement:** Systemic barriers are policies, practices or  
179 procedures that result in some people receiving unequal access or being excluded. In terms of engagement  
180 on research teams, a systemic barrier may be tied to the long lag-times between the phases of the research,  
181 from protocol development through funding, ethics review, field work, analysis, and knowledge translation  
182 and exchange. Structural barriers are understood as a condition where one category of people is attributed  
183 an unequal status in relation to other categories of people. This relationship is perpetuated and reinforced by  
184 a confluence of unequal relations in roles, functions, decisions, rights, and opportunities. Poverty, race or lack  
185 of education are examples of potential structural barriers.

186 **TCPS 2:** *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans*, 2<sup>nd</sup> Edition 2014. This is a  
187 joint policy of the Canada's three federal research agencies—the Canadian Institutes of Health Research  
188 (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and  
189 Humanities Research Council of Canada (SSHRC). To be eligible to receive and administer funds from the  
190 Agencies, institutions must ensure that research conducted under their auspices adheres to this and other  
191 policies of the Agencies.

192 Other terms are defined contextually in this document.

# 193 Reflections on Trust in Patient Engagement in Health 194 Research 195

## 196 **1. Overarching Ethical Considerations** 197

198 In this section, we articulate the ethical considerations including four core principles and beliefs that we  
199 see as especially important to patient engagement in research:

- 200 1. Mutual respect for different ways of knowing and interacting
- 201 2. Democratic participation and rights
- 202 3. Solidarity, reciprocity and shared commitment
- 203 4. Personal integrity

204 In common with other forms of human endeavour, there are underlying ethical principles that apply to  
205 all types of research – in particular: *Concern for the welfare of others, Justice, and Respect.*

206 While these are foundational, our concern here is with articulating general ethical principles that are  
207 particularly relevant to patients engaged as partners in health research, as opposed to research  
208 participants. We recognize that this type of research has much in common with community-based  
209 participatory research and has much to learn from the principles used to guide research involving  
210 Indigenous Peoples. But we recognize too that not all patients are members of self-identifying  
211 communities. We also see an important source of values in the principles that ground research  
212 scholarship and integrity – such as critical enquiry, open dialogue, the articulation of and commitment to  
213 standards of good research, veracity and candour. However, patient partners in research are also  
214 patients as well as co-researchers.

### 215 **1.1 Mutual respect for different ways of knowing and interacting**

216 There are diverse enriching paths to knowledge, including empirically gathered knowledge, knowledge  
217 gained through lived experience (experiential knowledge), and Indigenous ways of knowing. Patient  
218 engagement is an important way of bringing different perspectives to the health research endeavour. It  
219 can help to reveal *blind spots* – conscious or unconscious biases – that may interfere with good health  
220 research and health care. Taking an inclusive and collaborative approach to research can strengthen the  
221 research. Due to their lived experiences, patients often have valuable insights to bring to research.  
222 Neglecting patients' potential contributions to health research may miss important aspects of the health  
223 issues involved and make the implementation of valuable research more difficult.

224 In addition, researchers and patients may come from different cultural backgrounds and have different  
225 expectations in regard to appropriate ways of interacting. This may be compounded by the patient's  
226 sense that they lack the vocabulary used by the rest of the research team.

227 Key qualities that support successful partnerships in research—for patients, researchers and others—  
228 include: being respectful of others’ perspectives; being a good listener; communicating in lay, non-  
229 technical terms; being non-judgmental; using personal experiences constructively for deeper  
230 understanding; being able to work collaboratively; and being interested in expanding one’s own  
231 knowledge and skills.

### 232 **1.2 Democratic participation and rights**

233 As key stakeholders in health research, patients and their communities have legitimate claims to be  
234 active in shaping the research that is intended to benefit them and to do so in meaningful ways  
235 throughout the research process. In a crucial sense, patient involvement in health research helps  
236 legitimize the research enterprise by including the often-diverse perspectives of those with the health  
237 conditions being studied and community representatives who speak on behalf of members of their  
238 community with those conditions.

### 239 **1.3 Solidarity, reciprocity and shared commitment**

240 Solidarity and reciprocity based on mutual advantage are expressed in patient-engaged research through  
241 shared commitments, and a willingness to assist others in collective efforts toward common goals. The  
242 underlying idea is that patients are treated as essential partners in this form of health research, and are  
243 appropriately supported, recognized and compensated<sup>7</sup> for their contributions to the research process.

### 244 **1.4 Personal integrity**

245 This involves candour, honesty, and promise-keeping. It also includes accurate analysis and reporting of  
246 research as well as the recognition and appropriate management of factors that may hinder research,  
247 such as conflict of interest and bias.

---

<sup>7</sup> The Strategy for Patient-Oriented Research (SPOR) is presently developing a series of considerations to take into account when offering payment to patients involved in research. Once these considerations are finalized they will be posted on the [SPOR website](#).

248 **2. Establishing Trust for Patient Engagement in Research**

249  
250 The four elements described in the previous section can be seen as creating the conditions to establish a  
251 trust relationship. This relationship has three key aspects:

- 252
- First, there are important shared beliefs (a cognitive element) underlying the trust relationship.  
253 The researcher believes that the patient partner could bring to the table experiential knowledge  
254 and insights that are valuable to the research project or enterprise. Similarly, the patient partner  
255 believes that the researcher also has the technical knowledge and skills that are valuable to the  
256 research project and to those who would benefit from the research. In other words, there is the  
257 shared belief that together they could provide synergistic contributions to health research and  
258 practice.
  - Second, trust involves mutual recognition of each other’s integrity, veracity, and commitment to  
259 a shared research endeavour.  
260
  - Third, trust involves assuming a risk that the other could let you down and betray the trust.  
261 However, the parties proceed in good faith despite that risk. Indeed, in the absence of risk,  
262 there is no need for trust.  
263

264 Shared beliefs about the skill sets patients and researchers have creates the context for productively  
265 working together. These set the stage but, for collaboration to take place, there must be mutual  
266 commitment and the willingness to live up to it. In sum there is mutual trust in the other’s knowledge,  
267 skills, and commitment.

268 Beyond mutual trust, there is a further essential element for research to move forward: institutional  
269 support and resources.

270 Key questions to ask include:

- Would a common or shared research enterprise be potentially productive?  
271
- Is there sufficient trust there to warrant a shared effort?  
272
- Will there be enough resources including project and institutional support to warrant  
273 proceeding?  
274
- Have systemic and structural issues that may impede patient engagement been adequately  
275 addressed?  
276

### 277 **3. Key Cross-Cutting Ethical Concerns**

278  
279 In this section, we identify major concerns that need to be addressed to maintain the trust relationships  
280 essential for successful patient engagement in research.

281 Questions and tensions may arise at various points in the research lifecycle when patients are engaged  
282 as partners. Cross-cutting ethical concerns include:

- 283 • Legitimation, tokenism, levels of engagement, and representation;
- 284 • Conflicts of interest and commitments;
- 285 • Power dynamics and imbalances;
- 286 • Systemic and structural barriers to patient engagement;
- 287 • Benefits and harms; and
- 288 • Confidentiality of information.

289  
290 Key points for reflection for patients, researchers, institutions or funders are provided under each cross-  
291 cutting concern. Although somewhat different questions are posed for patients, researchers and others,  
292 all parties are encouraged to find answers in light of the four overarching considerations described in the  
293 previous section: *Mutual respect for different ways of knowing and interacting; Democratic participation*  
294 *and rights; Solidarity and shared commitment; and Personal integrity*. The underlying aim is to build the  
295 trust that is essential to ethical and productive patient engagement in research.

#### 296 297 **3.1 Legitimation, tokenism, levels of engagement, representation**

298 Meaningful engagement of patients in research involves a partnership relationship. Empowered patient  
299 groups may even be in the position of initiators of a research project, drawing in researchers for their  
300 technical expertise. Tokenism in researcher-initiated studies, where the patient voice is present but  
301 largely ignored, must be avoided. Patients' perspectives must be taken seriously and help to shape the  
302 research. For example, on a research team, patients may be responsible for predetermined tasks that  
303 require particular skills, such as focus groups and interviews, or, at the most engaged level, patients are  
304 significantly involved as partners in research design and implementation, and become co-authors of  
305 publications, reports, presentations, and other outputs from a research study.

306 When a respected and trusted member of a patient community is engaged in a research project, the  
307 patient by their presence adds credibility to the project and the researchers in it. Their presence in the  
308 research enterprise may encourage other patients and their communities to participate in the research.  
309 Since engaged patients can help to legitimize the project in the eyes of other patients and the  
310 community, these patients have an obligation to ensure that this role respects their trust relationships  
311 with both researchers and their communities.

312

313 3.1.1 For Patients

314 As a patient partner, you should understand and be comfortable with your role.

315 If you are bringing your personal lived experience of health issues to a research project, relevant  
316 questions to ask include the following:

- 317 • Do I have both the knowledge base and the commitment to make a meaningful contribution to  
318 the research project? If appropriate, can I secure any needed additional help or resources<sup>8</sup> from  
319 the research team or my community to make such a contribution?
- 320 • Am I lending my credibility as an individual and patient to projects that I think might make a  
321 positive contribution to health care for other patients?
- 322 • Is the scope of my role clear so that I am able to determine if I am being meaningfully engaged or  
323 not?
- 324 • Is my presence in the project meaningful or am I only being used as a token, for example to  
325 secure research funding or to just gain access to other patients? If my presence feels tokenistic,  
326 is there a mechanism for me to voice my concerns?
- 327 • How am I processing my experiential knowledge to guide the research process and enhance  
328 understanding?

329 As a patient, you should ask yourself about the basis of your representativeness:

- 330 • Am I speaking as an individual with lived experience or am I expected to represent a larger  
331 community of people impacted by a given health condition or disease?
- 332 • If I am speaking as an individual with a lived experience, what parts of that experience am I  
333 willing to share with others and what parts should I keep private because these involve  
334 confidential relationships with other patients and care-givers or because these are issues that I  
335 wish to remain private?
- 336 • If I am a member of a community with its own governing structures – has this community  
337 appointed me to represent them, or have I been elected by a membership to speak on their  
338 behalf? When am I just speaking for myself and when am I speaking for the community? In  
339 general, how do I fulfill my trust relationship with my community?
- 340 • Have I consulted sufficiently with my community (for example, other patients, patient groups,  
341 community leaders) to ensure that I represent the community, and my community sees me as  
342 acting on their behalf? These consultations should enable the patient to bring back valuable  
343 input to the project—ideally throughout the research lifecycle.

344 In situations where you feel that a proposed role in the project would be tokenistic, or that a research  
345 project would not benefit others, you have a number of options with increasing levels of seriousness and  
346 impact:

- 347 1) You may choose to decline to participate.
- 348 2) You may propose ways to make your role more meaningful.

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<sup>8</sup> A useful resource is the SPOR Foundational Curriculum for Patient-Oriented Research [link when available].

349 3) If you have concerns about the research going ahead and are not being listened to, you may wish  
350 to bring these concerns to the attention of those in positions of authority or influence, such as  
351 the research ethics board of the lead researcher’s institution; community leaders; a patient  
352 advocacy organization; or others who may have influence.

353

### 354 3.1.2 For Researchers, Research institutions, Funders

355 Researchers, research institutions and funders should reflect on the following questions:

- 356 • Does the involvement of patients in this research have a reasonable chance of increasing the  
357 usefulness of the research to the relevant patient community? In what areas of the research can  
358 patients most meaningfully contribute?
- 359 • Meaningfully involving patients in research requires building a trust relationship with them. Are  
360 we willing to make the commitment and effort that are essential for fulfilling that relationship?
- 361 • How can we provide the support needed (e.g., training, administrative services) to enable  
362 patients to make greater contributions to research? Sometimes, a patient may not want to learn  
363 the technicalities of, say, coding or data analysis. However, their thoughts, perspectives, and  
364 insights can easily be captured (if the researchers are adaptive and flexible).
- 365 • Is the role that we are asking patients to play meaningful or is it only tokenistic? Token  
366 engagement can lead to potential harms to the individual and to the collective relationships with  
367 patients and with communities in the future. There should be a mechanism in place for patients  
368 to voice their concerns if they feel that their engagement is tokenistic.
- 369 • If patients are asked to represent the views of others or their communities, are they given  
370 sufficient opportunities and resources to consult with others?

371

### 372 **3.2 Conflicts of interest and commitments**

373 The basic question that patients and researchers should ask themselves is: Are there any interests or  
374 commitments that could interfere with their ability to act in the best interests of the research process,  
375 project or team? Conflicts of interest and commitment arise when there is an incompatibility of two of  
376 more duties, responsibilities, or interests (personal or professional) of an individual or institution as they  
377 relate to the research activity, such that one cannot be fulfilled without compromising the other(s).  
378 Conflicts of interest and commitment can be potential, actual or perceived. Such conflicts may breach  
379 the trust that underlies the patient engagement relationship.

380 It is important to note that such conflicts may distort a person’s judgement without that person’s being  
381 consciously aware of it. Following conflict of interest guidelines and checking with reliable third parties,  
382 helps avoid this.

383 Conflicts may arise because patients and researchers wear many hats:

- 384 • Patients may be members of another non-patient community, or may have pre-existing or  
385 potential relationships or affiliations that could influence or interfere with how they carry out



386 their role(s) in the research. These relationships or affiliations may be personal, political,  
387 commercial, or legal (for instance, duties of care such as legal guardianship).

388  
389 • Researchers may have other roles (such as a health service provider) that may be viewed as a  
390 barrier to the engagement of certain patients in the research. For example, clinician-  
391 researchers may prefer not to sit on the same committee as their own patients, because they  
392 may want to ensure that the clinician-patient relationship is not compromised by a peer-to-peer  
393 relationship created by being members of the same committee. However, some patients may  
394 feel that being excluded from the committee is unfair because, for example, there may be few  
395 other opportunities to be engaged in research that is important to them (such as when patients  
396 have a rare condition or live in a remote location). Thus, there needs to be judgment shown in  
397 regard to particular contexts and relationships. In some cases, clinicians and their patients  
398 endeavor to separate the research activity from the patient's own health care so that a  
399 productive working relationship as research partners can be established.

400 While recognizing that conflicts will arise, it is also important to recognize the value of diversity and  
401 pre-existing relationships. Conflicts of interest and commitment need to be assessed on a case by  
402 case basis. Furthermore, what is seen as a conflict in one culture may not be seen as a conflict by  
403 another culture, and the appropriate ways to address a conflict may vary in different cultures.

404 Interests and commitments that could have an impact on the research need to be disclosed to  
405 appropriate individuals and institutions; and conflicts of interest and roles managed and minimized  
406 in a fair and appropriate way. Generally, explicit or implicit conflicts should be disclosed. Disclosure  
407 may however be limited due to confidentiality or harm considerations, and these considerations  
408 should be discussed with whoever has the lead on the management of conflict of interest so that  
409 alternative steps can be taken to manage the conflict. As well there are situations in which disclosure  
410 is insufficient to maintain the trust relationship and other measures need to be taken, such as  
411 vacating a conflicting role or leaving the research relationship.

### 412 3.2.1 For Patients

413 Consider the following:

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

### 422 3.2.2 For Researchers, Institutions, Funders

423 Consider the following:

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- Have fair and transparent policies and processes been established to manage and minimize conflicts of interest and commitments, in recognition that patients are multi-dimensional and can have multiple roles (as research team members, community advisors, 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 representatives”, will these patient representatives be free to express an independent patient voice, or will their personal relationships present a conflict of interest that cannot be effectively managed, or 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.

### 435 **3.3 Power dynamics and imbalances**

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

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- *Status* -- due to differences in community or social status, expertise, compensation, and affiliations (for example, 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 for influence on its members.
  - *Information*-- due 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 in a satisfactory manner, patients may find it difficult or impossible to make effective contributions to the research without risking their own health and may therefore decide to withdraw as research partners.
  - *Economic Situation*– sometimes because of poverty there may be barriers to patients 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.

452

453 Each of these potentially affects the trust relationship that grounds successful patient engagement in

454 research. Misuses and manipulation of status, control and information may diminish and even freeze out

455 meaningful patient engagement in research. Trust building measures include respecting the status of

456 patients as partners in research, open discussion and consultation about control issues and the provision

457 of relevant information in a timely, communicative, and forthright manner.

458 Patients and researchers bring various types of expertise and a range of competencies to the research

459 project. Through mutual respect and valuing of alternate knowledge systems and ways of knowing,

460 tensions around power imbalances can be resolved.

461 Researchers have devoted their professional lives to researching a subject – they may have been drawn  
462 to a particular area of research or clinical practice based on personal, family or professional experiences.  
463 They may have their own preconceptions of the experiences of the patients with whom they work.  
464 These preconceptions may be based on personal experience or on generalizations drawn from  
465 interactions with patients which may or may not map on to the experience of other patients. Bringing  
466 these preconceptions to light with the help of patient partners can help address potential impacts of  
467 misconceptions and power imbalances.

468 Patients with their lived experiences of a health condition can bring a range of relevant skills and  
469 experience. Patients, researchers, institutions, and funders should consider what skills and experience  
470 will be needed for particular roles, and what capacity-strengthening resources (education, training, and  
471 support systems) need to be provided. Mentorship opportunities can also be part of capacity  
472 strengthening— for example where patient partners provide training and development opportunities for  
473 other patients.

474 Meaningful engagement of patients in research requires that information flows easily among team  
475 members, so patients feel included in progress reporting and decision making. This may require efforts  
476 to develop a common language of communication between researchers and patients to bridge the gap  
477 between *researcher-speak* and *patient-speak*. Norms should be discussed and agreed within the  
478 research team to ensure that information circulates correctly and that patients have access to  
479 information that they need to fulfill their roles (for example, emails, library services). Meeting agendas  
480 should be set collectively and followed through in the meetings.

481 Researchers and patients may come from different cultural backgrounds and thus have different, often  
482 unspoken, expectations about appropriate forms of social interaction. For example, in many Indigenous  
483 communities there is the expectation that food will be provided at meetings. In many academic  
484 communities, food is just an optional extra for research meetings. Also, there may be different style of  
485 conversational interaction in different communities so that, for example, patients may have a hard time  
486 getting a word in edgewise during meetings in which outspokenness is the norm.

### 487 3.3.1 For Patients

488 Relevant questions for patients to ask themselves include:

- 489 • Will I have the information access, status and power that I need to play a meaningful part in the  
490 research?
- 491 • Am I clear on the expectations that come with this role—my own, my community’s, others?
- 492 • Are there resources that I will need to help me fulfill this role? Are these resources available to  
493 me? What influence or control do I have over these resources?
- 494 • Will I receive the training I need to fulfill my role on the research team, such as CIHR’s training  
495 Modules 1, 2, 3, & 4 (Indigenous Learning Pathway)?
- 496 • Could I have a role in training patients and researchers to help expose or improve power  
497 imbalances, and deal with them?
- 498 • Do I understand the roles of other members of the research team and how I fit in?

- 499
- Do I feel that I am being treated equitably and with respect? Is my voice being heard, and my contributions acknowledged and valued?
- 500

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### 502 3.3.2 For Researchers, Institutions and Funders

503 Consider the following:

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- At the project planning stage, have you included resources and support so that:
    - patients can meaningfully contribute to research, and
    - researchers and others understand what meaningful collaboration is and what their responsibilities are?
  - Have you established processes, support and compensation so that patients feel they are being treated equitably and with respect, and their contributions are acknowledged and valued?
  - Have you informed patients of the various roles on the research team and any accountabilities by law and policy that researchers, institutions or funders are responsible for?
  - Depending on the roles patients will play, you are encouraged to engage more than one patient. Multiple patient voices provide a sense of the diversity and commonality of lived experience, and help to balance requirements of the research project with other aspects of life so that 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 you reflected on the generally unspoken but assumed cultural expectations embedded in being researchers and institutional representatives that you may bring to your interactions with patients? Have you taken into account that patients may have divergent expectations around how they interact with researchers?
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### 524 **3.4 Systemic and structural barriers to patient engagement**

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

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527 Systemic barriers are policies, practices or procedures that result in some people receiving unequal access or being excluded. In terms of participation on research teams, a systemic barrier may be tied to the long lag-times between the phases of the research, from protocol development through funding, ethics review, field work, analysis, and knowledge translation and exchange. Some of these may be addressed through managing patient partner expectations. In other cases, there may be very practical issues around cash flows and the ability to compensate patients for the time invested in the project. Budgeting honoraria for patients to participate in the research may be essential for some. In other cases, providing honoraria may disqualify patients from social benefits. It is also important to budget for food, food restrictions, travel and other expenses.

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536 Structural barriers are understood as a condition where one category of people is attributed an unequal  
537 status in relation to other categories of people. This relationship is perpetuated and reinforced by a  
538 confluence of unequal relations in roles, functions, decisions, rights, and opportunities. Poverty, race or  
539 lack of education are examples of potential structural barriers.

540 There may also be access barriers to meetings – for example, curbs or lack of elevators for individuals  
541 with mobility issues. There may also be the need to plan breaks to accommodate health needs of the  
542 patient partner.

#### 543 3.4.1 For Patients

544 Consider the following:

- 545 • How much time am I able to commit to the project and am I in a position to see the project  
546 through to completion? Although the latter may not be an expectation, it should be discussed  
547 up front.
- 548 • Will my research partners be able to support me? For example:
  - 549 ○ to accommodate any health conditions I have (for example, if needed at meetings,  
550 having a medical emergency plan in place, or scheduling breaks between meetings to  
551 allow time to rest)?
  - 552 ○ to help address the financial costs of participation such as lost wages or child care  
553 expenses?

#### 555 3.4.2 For Researchers, Institutions and Funders

556 Consider the following:

- 557 • Have you ensured all individuals understand processes and procedures about the research  
558 project? For example:
  - 559 ○ That there will be considerable lag between protocol development and funding. This  
560 includes delays associated with the need to revise and re-submit a grant for the next  
561 grant cycle.
  - 562 ○ That there may also be considerable lag between funding and research ethics review  
563 before being able to start the project.
- 564 • Have you lessened or removed systemic and/or structural barriers that may inhibit or prevent  
565 the participation of patient partners due to their health condition, or their economic or social  
566 status? This includes:
  - 567 ○ Physical access barriers.
  - 568 ○ Meeting times and duration – for example, the need for a break in a lengthy meeting.
  - 569 ○ Appropriate and sufficient support provided around teleconferences, videoconferences  
570 and in-person meetings.
  - 571 ○ Is sufficient training provided for individuals with lower literacy levels whose lived  
572 experience is of value to the project?

- 573           ○ Are funds available to financially support patient partners for the time they have  
574           invested in the project during these periods when project funds are not forthcoming?  
575           This may include:  
576           ▪ Funds available from the funding agency for costs associated with protocol  
577           development.  
578           ▪ Funds available through the Vice President, Research at a university.
- 579       • In the event that your patient partner is unable to accept financial compensation for  
580       participation (e.g., if this would disqualify them for social assistance), what other non-financial  
581       compensation could you offer – such as providing food at meetings, and covering transportation  
582       and accommodation to a conference at which they may be a co-presenter?  
583

### 584 **3.5 Benefits and harms**

585 Through imparting their lived experiences of illness, patient partners can play a role in regard to  
586 increasing research benefits and reducing research harms for the following:

- 587       • Themselves as patient partners in the research, such as by identifying their own health needs so  
588       that they can be accommodated in the research.
- 589       • Research participants studied in the research. Through patient partners' lived experience of  
590       illness, they are well positioned to advise other research team members as to potential harms  
591       and benefits that the research participants may encounter.
- 592       • The general patient population to which the research will be generalized (such as by identifying  
593       potential harms from stigmatization and discrimination).
- 594       • Knowledge translation and exchange to health care providers and other patients.  
595

#### 596 3.5.1 For Patients

597 Ask yourselves:

- 598       • How might the research affect me personally, taking into consideration any health conditions I  
599       have that could affect my ability to participate; my lived experience and personal feeling of the  
600       research topic; and what I am expected to do (and whether these expectations are reasonable)?
- 601       • Does the project have mechanisms to support me? For example:  
602           ○ to help me if the research activity triggers stressful memories associated with my lived  
603           experience of a health condition or circumstances (for example, arranging to have an  
604           Elder help to take care of the team for Indigenous research)?  
605           You may wish to propose that support mechanisms be put in place for you and others in your  
606           situation. If supports cannot be made available, you may decide not to participate.
- 607       • What are the potential impacts of the research on other patients or my community?
- 608       • Is there potential for me to feel strengthened by being engaged in research?

609 For example:

- 610       ○ Will I add to my own skills and experience?

- 611                   ○ Can I make a positive contribution for the benefit of other patients, my community and  
612                   society?
- 613                   • Are their potential benefits or harms of the research that my research colleagues may be  
614                   unaware of?
  - 615                   • In knowledge transfer, how can I best bring my lived experience of illness and what I learned in  
616                   the research project to the awareness of community members and their health care providers?

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### 619 3.5.2 For Researchers, Institutions and Funders

620 Consider the following:

- 621                   • Are you making good use of patient partners as sources of information about benefits and harms  
622                   of the research that we are conducting or funding?
- 623                   • Are there mechanisms to hear from patient partners about potential benefits and harms  
624                   associated with their roles in the research process, and to support them when needed? Have  
625                   the necessary resources (for example, human, financial and time) been built into the budget?
- 626                   • When the research activity comes to an end, how will the contributions of patient partners be  
627                   recognized and celebrated? Can interested patients be assisted to find other opportunities for  
628                   meaningful engagement?

629

## 630 **3.6 Confidentiality of information**

631 Some information gathered throughout the research lifecycle should be kept confidential—for example,  
632 applications submitted for scientific or ethics review or information that would reveal the identities of  
633 research participants. Patients, researchers, institutions and funders should ensure that all involved are  
634 aware of and have the capacity to uphold all expectations of confidentiality, and that appropriate  
635 policies and procedures are in place. Patients may also be a source of expertise with respect to the  
636 expectations of particular communities around confidentiality and privacy – for example, in some  
637 Indigenous communities, only specific members of a family may be allowed to tell their family stories.

### 638 3.6.1 For Patients

639 Questions for patients to ask themselves include:

- 640                   • What are the expectations for confidentiality associated with the kinds of information I will be  
641                   dealing with, and what policies and procedures are there?
- 642                   • Am I prepared to share responsibilities to uphold protections for information provided in  
643                   confidence? Do I need more support or resources to fulfill my responsibilities?

644

### 645 3.6.2 For Researchers, Institutions and Funders

646 Consider:

- 647                   • Are there appropriate policies, procedures, training and supports in place for respecting  
648                   expectations of confidentiality, and is there a mechanism to deal with breaches of  
649                   confidentiality?

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- 651
- Does your behaviour manifest the respect for confidentiality that you expect from patient partners?

DRAFT



652 **Ethics Guidance for Specific Roles in the Research**  
653 **Lifecycle**

654  
655 The cross-cutting ethical concerns and reflections described in the previous sections are relevant to all  
656 roles. This section applies the ethics guidance in the previous section to demonstrate good practices in  
657 the context of specific roles throughout the research lifecycle (see key stages of the research lifecycle in  
658 the figure below).

659 We aim to promote broad engagement of patients across **all stages** of the research. For example, an  
660 individual patient may be engaged throughout a research project and therefore take on a succession of  
661 roles; or different patients may be engaged at different points in the research cycle, depending on the  
662 insights or skills they can contribute.

663 This ethics guidance is principally focused on the engagement of patients in research in roles other than  
664 as research participants. However, there may be situations where a patient is also a research  
665 participant, and takes on other roles that may be relevant (for example, in a large-scale population  
666 health study where patients may be research participants and also have a formal voice on a committee  
667 to advise on the overall direction of the study; or where a patient was a research participant for a first  
668 phase of a study, and now has an advisory role for a subsequent phase).

669  
670 *Key stages in the research lifecycle: From priority setting to evaluation, and back to*



674 **Stage 1: Priority Setting and Planning**

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 676 Priority setting can take place in various contexts: for example, when a funding agency is developing its  
 677 strategic plan or a research initiative on a specific emerging issue; when a research centre that is  
 678 dedicated to a particular health condition or population group is determining how it should invest its  
 679 funds; or when a research team is at the earliest stages of exploring knowledge gaps and stakeholders’  
 680 interests to determine a new research direction.

681

Examples of Patient Roles:	Guidance:
<ul style="list-style-type: none"> <li>✓ Advise on a priority-setting panel</li> <li>✓ Contribute to a priority-setting workshop</li> <li>✓ Contribute to interpretations of research outcomes to inform priorities for new research</li> <li>✓ Brainstorm with other members of the research team to identify research questions, study aims, and potential research impacts.</li> </ul>	<p><u>For Patients:</u></p> <ul style="list-style-type: none"> <li>• 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 to identify the ways in which the research can be more useful for patients like you and others. Based on an understanding of your lived experiences and/or those of others in your community, you can contribute insights for research priorities that may influence the emphasis of the projects being considered and benefit a broader group of patients.</li> </ul> <hr/> <p><u>For Researchers, Institutions, and Funders:</u></p> <ul style="list-style-type: none"> <li>• Engagement of patients can start at the early research stages with building relationships with individual patients and with members of the community of interest, and continue throughout the life of a project. At the initial planning stages of a research activity, build into your budget the resources 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), and to strengthen the capacities of both patients and researchers for meaningful collaboration.</li> <li>• Introducing patient voices into priority setting can open the research to new perspectives and reveal where important needs and knowledge gaps are. Find ways – for example with the help of relevant communities-- to reach patient groups that are under-served in society and under-represented in research so that their perspectives are taken into account.</li> <li>• Patient priorities should be translated collectively into feasible and realistic research goals through open and sustained discussion.</li> </ul>

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## Stage 2: Development of the Research Proposal

Examples of Patient Roles:	Guidance:
<ul style="list-style-type: none"> <li>✓ Provide expertise to inform Methods and Knowledge Translation (KT) sections of the proposal</li> <li>✓ Contribute to the development of informed consent materials, and an understanding of potential impacts of the proposal on patient groups</li> <li>✓ Build community engagement plans and appropriate Indigenous cultural norms and ways of knowing into the research design</li> <li>✓ Inform the inclusion criteria for a representative sample of the whole population to be recruited as research participants (known as a sampling strategy)</li> </ul>	<p><u>For Patients:</u></p> <ul style="list-style-type: none"> <li>• You can shape the design of the research to maximize its usefulness to patients like yourself and others in your community. This implies learning how research unfolds and what is required to maximize the possibility that the knowledge that is created is accurate and incorporates the experiential knowledge of patients, and contributes to improvement.</li> <li>• You can make a substantial contribution by suggesting opportunities for different ways of knowing to be included in the research design, such as the lived experience of patients, and the circumstances and traditional knowledge of particular Indigenous communities.</li> <li>• You can contribute knowledge about the diversity of patients who are affected by the research topic and this could shape decisions around whose patient experiences will be gathered as part of proposed research.</li> <li>• You can inform the development of strategies to recruit patients to participate in the research to minimize barriers to participation.</li> <li>• As a patient you should strive to understand and appreciate researchers' perspectives and suggestions with regard to shaping the research application.</li> </ul> <p><u>For Researchers:</u></p> <ul style="list-style-type: none"> <li>• You should appropriately recognize the contributions of patients to the development of a research proposal, which might go through many versions and different groups of people working on each version, before the application is accepted for funding. It is important to recognize patients who were part of the journey in the development of the proposal.</li> <li>• As part of an application for a long-term project, you will need to consider what would be an appropriate governance structure for oversight of the project. Consider where patients' voices are most needed, and will be most effectively heard in this governance structure. For example: a large research project may have a Steering Committee; an Ethical, Legal and Social Issues (ELSI) Advisory Committee; a Community Advisory Committee; and various other technical committees and working groups. Patients could become members on one or more of these bodies, or fully integrated into every governance body.</li> </ul>

### Stage 3: Internal and External Scientific Review of the Research Proposal

Examples of Patient Roles:	Guidance:
<ul style="list-style-type: none"> <li>✓ Review research proposals of other teams</li> <li>✓ Review drafts of their own team's research proposal</li> <li>✓ Prepare lay summaries of research proposals</li> <li>✓ Provide feedback on potential impacts on patients of a research proposal</li> <li>✓ Assess the extent of meaningful patient engagement in the proposal</li> </ul>	<p><u>For Patients:</u></p> <ul style="list-style-type: none"> <li>• You have an important role in ensuring that the patient’s perspective and needs are integrated and used in the review of the research proposal, including leading to relevant outcomes from a patient’s perspective. If you do have academic or professional expertise in the area under the review, you will need to focus primarily on bringing the patient perspective.</li> <li>• If you are bringing the patient perspective on a funder’s scientific peer review committee, ensure that you are informed of appropriate procedures related to confidentiality of the information and the review committee discussions. You will need to be clear to others outside the committee that you are not able to speak about applications under review.</li> </ul>
	<p><u>For Researchers:</u></p> <ul style="list-style-type: none"> <li>• Recommend that people with lived experience of the health condition or context under study be members of funders’ scientific review committees.</li> </ul>
	<p><u>For Research Institutions, Communities, and Funders sponsoring scientific review committees:</u></p> <ul style="list-style-type: none"> <li>• Include people with lived experience of a health condition on funders’ scientific review committees, particularly (but not necessarily only) for funding opportunities for which patient engagement is explicitly encouraged or required in applications.</li> <li>• 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, and reflect on the guidance in the Cross-Cutting Ethics Concerns section under <i>Power Imbalances</i>.</li> <li>• 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 in an application should have equal weighting with all other components that comprise scientific excellence.</li> <li>• Explain to patients and other members of the committee what would constitute a conflict of interest or commitment, and establish a fair and transparent process to manage and minimize conflicts.</li> <li>• Ensure there are appropriate policies, procedures, training and support in place for respecting expectations of confidentiality, and a mechanism to deal with breaches.</li> </ul>

689 **Stage 4: Ethics Review of the Research Proposal**

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 691 Institutions that administer funding from the three main federal granting councils, and their researchers, are  
 692 required to comply with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Human*  
 693 (TCPS). TCPS includes a chapter on research involving the First Nations, Inuit or Métis Peoples. Under TCPS,  
 694 institutions must establish or appoint research ethics boards to review the ethical acceptability of all research  
 695 involving humans, and these research ethics boards are expected to have at least one community member  
 696 who has no affiliation with the institution. In addition, for research involving Indigenous Peoples, review by a  
 697 community research ethics board or the leadership of an Indigenous community may be appropriate.  
 698

Examples of Patient Roles:	Guidance:
<ul style="list-style-type: none"> <li>✓ Identify and raise ethics concerns during the review of research proposals by an institutional or community research ethics board</li> <li>✓ Review informed consent materials, and potential impacts of the proposals on patient groups</li> </ul>	<p><u>For Patients:</u></p> <ul style="list-style-type: none"> <li>• You can have an important role to play on research ethics boards. You will have a major input in reviewing the proposed consent form and process. Some things to consider are that:               <ul style="list-style-type: none"> <li>• There should be evidence that persons who participate in research will do so voluntarily, understanding the purpose of the research, and its risks and potential benefits, as fully as reasonably possible.</li> <li>• There should be evidence that prospective participants will be given adequate time and opportunity to understand and ask questions about the information provided in the informed consent process.</li> <li>• There should be evidence that the information given to prospective research participants will be presented in a way that facilitates understanding—for example, this could mean having the consent process in the preferred format and language of prospective research participants.</li> </ul> </li> <li>• On institutional research ethics boards, community members are often seen as having special insights into particular groups and can be seen as speaking for these groups. As a patient in a community member role on an institutional research ethics board, you should be willing to indicate the limits of your knowledge and awareness of groups with which you are identified.</li> </ul>
	<p><u>For Institutions and Communities</u></p> <ul style="list-style-type: none"> <li>• The patient on the research ethics board will bring a personal voice and lived experience, which may be different from the views and experience of others. If the patient is being asked to represent the views of other persons or of the community, they will need to be given sufficient opportunities to consult with others, and/or patients can be selected who are members of patient organizations and communities that are organized to provide a collective voice.</li> </ul>

699 **Stage 5: Oversight of a Research Project**  
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701 A long-term project might have decision-making or advisory boards as part of the project’s internal  
 702 governance structure. A Data and Safety Monitoring Board may be established for some studies as part of the  
 703 plan to monitor of the safety of research participants.

Examples of Patient Roles:	Guidance:
<ul style="list-style-type: none"> <li>✓ Contribute to oversight of research activities (such as community engagement, recruitment of research participants, and data collection and analysis) during the course of a project</li> <li>✓ Raise concerns about the safety of research participants</li> </ul>	<p><u>For Patients:</u></p> <ul style="list-style-type: none"> <li>• Ensure that you understand how decisions are being made in the committee of which you are a member. There are some decisions in which the patient is the expert and thus should have bigger sway in the process; in other cases, scientific, methodological and technical issues may prevail. Wherever possible, decisions should be made by consensus, or by majority vote. Be aware of the process of decision making and speak up if you feel uncomfortable with the process or the decisions.</li> <li>• Data and Safety Monitoring Boards and governance committees need to formulate advice and decisions through a fair and transparent process. Be aware of any other interests, expertise, experience and affiliations that could influence or interfere with your role on the committee and disclose these to the appropriate staff of the committee or the Chair of the committee, so that conflicts of interest can be managed and minimized appropriately.</li> </ul> <hr/> <p><u>For Institutions and Communities:</u></p> <ul style="list-style-type: none"> <li>• Consider how to support patients so that they can be effective members of an advisory or decision-making committee. This can include providing information in lay language, avoiding jargon and acronyms, and providing opportunities at meetings to ask questions and seek clarification.</li> <li>• You should ensure that patients are going to see that their participation makes a difference, and that 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 being actioned.</li> <li>• Establish a fair and transparent process for disclosure of interests, and management of conflicts of interest.</li> <li>• When researchers are part of the community they study, there can be pre-existing relationships that need to be considered when determining membership of a committee (for example, whether clinician-researchers and their own patients are comfortable being on the same committee). Decisions on the assignment of roles will need to be negotiated in a respectful, fair and transparent way, and conflicts of interest and roles managed.</li> </ul>

705 **Stage 6: Recruitment of Research Participants**

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Examples of Patient Roles:	Guidance:
<ul style="list-style-type: none"> <li>✓ Help with coordinating representatives of the community, clinics, individual clinicians, and others, for the recruitment of persons to become research participants</li> <li>✓ Help with recruiting patients to participate in the research process (for example, by presenting the research project)</li> <li>✓ Design, write or provide feedback to letters of information and recruitment strategies</li> </ul>	<p><u>For Patients</u></p> <ul style="list-style-type: none"> <li>• As a patient in a research team you may take the lead in recruitment efforts to find appropriate patients, some of whom may rarely participate in research projects. You could have an important role in:               <ul style="list-style-type: none"> <li>○ commenting on the inclusion criteria (sampling frame) for recruiting potential research participants,</li> <li>○ adapting a consent form and information, to ensure that it is clear and appropriate for the community (for example, some Indigenous health researchers are implementing a tobacco protocol as a culturally appropriate alternative to a written or verbal informed consent process),</li> <li>○ helping contact patients, and/or</li> <li>○ being directly involved in asking people to consent to the research. However, there may be particular kinds of research, such as high risk clinical trials, for which there may be specific requirements about who should be directly involved in asking people to consent to the research.</li> </ul> </li> <li>• As a patient involved at some level in recruiting other members of the community into the research project, your contribution will lend credibility and legitimacy to the project. Consider the reflections described in the Cross-Cutting Ethical Concerns section under <i>Legitimation</i> to determine your degree of comfort in this role.</li> <li>• You should speak up within the research team if you feel that there are conflicts of interests (between your role as a recruiter for research, your role in the community, and any personal relationships with people being recruited) that could interfere with obtaining a truly voluntary consent to the research from others or if you feel your safety might be at risk. Depending upon your role in the community, your mere endorsement or participation in recruitment may constitute undue influence on potential research participants.</li> <li>• If this research is on a topic that is sensitive or controversial (for example, because of events in your or your community’s past, or because of current unresolved issues), consider what personal benefits or harms could arise for you in being directly involved in the consent process. You may feel strengthened by helping recruit community members into research on this important topic, or you may feel that negative feelings and memories will be stirred up. Find out if there are support systems in place for patient partners.</li> </ul>

Examples of Patient Roles:	Guidance:
	<ul style="list-style-type: none"> <li>• Any personal information collected as part of the consent process (for example, who consented and who did not) must be properly safeguarded.</li> </ul> <p><u>For Researchers:</u></p> <ul style="list-style-type: none"> <li>○ You will be expected to 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 that the person has adequate training and self-awareness for the role so that they do not exercise undue influence.</li> <li>• Asking patients (and other community members) to help recruit people may be effective, especially with populations which have traditionally not been involved in research. Patients can provide valuable assistance by: <ul style="list-style-type: none"> <li>○ ensuring that the consent process is appropriate to this community (for example, do the form of consent and any information materials reflect the community’s language and values?);</li> <li>○ commenting on the inclusion criteria for the research;</li> <li>○ helping reach prospective participants; and/or</li> <li>○ being directly involved in obtaining consent.</li> </ul> </li> <li>○ In selecting patients to help with recruitment, consider if they represent the community, if they have credibility with the community, and if they have lived experience of the issue under study. All of these factors could be important for successful recruitment.</li> <li>○ If you are asking patients to be directly involved in the consent process: <ul style="list-style-type: none"> <li>○ Patients should be informed of the research goals, and any potential benefits and harms to individuals and to the community as a whole, so that they can communicate this information to prospective research participants in a balanced way.</li> <li>○ keep in mind that the status of the patient in the community and any pre-existing relationships with the 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, or if it would be better to have a member of the research team or a neutral third party conduct the consent process.</li> </ul> </li> </ul>



708 **Stage 7: Data Collection**  
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Examples of patient roles:	Guidance:
<ul style="list-style-type: none"> <li>✓ Conduct individual and group interviews</li> <li>✓ Collate and prepare data for analysis</li> </ul>	<p><u>For Patients</u></p> <ul style="list-style-type: none"> <li>• 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. Consider the reflections described in the Cross-Cutting Ethical Concerns section under <i>Legitimation</i> to determine your degree of comfort in this role.</li> <li>• Research participants may be more comfortable sharing their experiences with you as a peer, than to researchers who may seem far removed from what they, as patients, experience.</li> <li>• You will want to negotiate your role in data collection at the beginning of the research project to 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.</li> <li>• As a research team member, you may be privy to confidential information given by research participants. You must respect these confidences and not discuss them with friends and neighbours from your community.</li> <li>• You will want to 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.</li> </ul>
	<p><u>For Researchers</u></p> <ul style="list-style-type: none"> <li>• You will need to be comfortable that the patients on your team have, or acquire, the necessary skills and experience to be involved in data collection (such as an understanding of different data collection methods, avoidance of bias in data collection, accurate documentation, and secure storage of data). Provide appropriate support as needed.</li> <li>• Consider the possibility that some research participants would prefer not to be interviewed by a peer. Provide another option where feasible.</li> <li>• Patient partners should be appropriately acknowledged in presentations and publications.</li> <li>• Steps should be taken to ensure the safety of all members of the research team involved in data collection. Safeguards should be in place for situations in which patients may be put at risk through their involvement in research, for example in conducting interviews.</li> </ul>

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711 **Stage 8: Data Analysis and Interpretation**  
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Examples of patient roles:	Guidance:
<ul style="list-style-type: none"> <li>✓ Contribute to analysis and interpretation of quantitative and qualitative data</li> <li>✓ Discuss findings with researchers and other partners</li> <li>✓ Contribute to the interpretation of research results, bringing a patient voice of lived experience to the study findings</li> <li>✓ Write analysis reports as appropriate</li> </ul>	<p><u>For Patients</u></p> <ul style="list-style-type: none"> <li>• You will want to negotiate your role in data analysis and interpretations at the beginning of the research project to ensure you are comfortable with what the research team expects of you, recognizing that this role may evolve over time. You may need some training in the type of analysis and interpretation involved in the research.</li> <li>• This is an opportunity to learn how to analyze data, which could be quantitative or qualitative or both.</li> <li>• You will want to explore the supports available to you as a patient researcher. Depending on the research topic, analysis and interpretation of data can be traumatic for all researchers, but especially for those with similar lived experience.</li> </ul>
	<p><u>For Researchers</u></p> <ul style="list-style-type: none"> <li>• Consider presenting preliminary statistical results to a group of patients who then “story” the data – add in their interpretations based on lived realities, provide real-world examples to better illustrate and give meaning to a number-- and may request further analysis.</li> <li>• You will need to be comfortable that the patients on your team have or acquire the necessary skills and experience to collaborate on data analysis, and provide appropriate support or training as needed.</li> <li>• Patient partners should be appropriately acknowledged in presentations and publications.</li> </ul>
	<p><u>For Institutions</u></p> <ul style="list-style-type: none"> <li>• Consider what services might be provided at an institutional level to enable patient engagement in analysis. For example, in addition to the usual data analysis workshops (for example, coding, NVivo) available for researchers and students, offer workshops geared towards patient and community researchers.</li> </ul>

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## Stage 9: Translation and Exchange of Research Knowledge

Examples of patient roles:	Guidance:
<ul style="list-style-type: none"> <li>✓ Write articles for a variety of media that disseminates knowledge to different audiences in lay terms, and help identify potentially offensive language and propose alternatives.</li> <li>✓ Prepare and deliver presentations to disseminate knowledge to different audiences</li> <li>✓ Assist with the development of alternative or innovative forms of knowledge translation and exchange (for example, performance art, installations, social media)</li> <li>✓ Discuss implications of new knowledge with health care providers and relevant communities to identify possible applications</li> <li>✓ Gather feedback from patient groups on research findings</li> <li>✓ Work alongside researchers with policy makers when advocacy at the level of the system (for example, to change health policy) is required</li> <li>✓ Author or co-author reports and scientific articles</li> </ul>	<p><u>For Patients</u></p> <ul style="list-style-type: none"> <li>• You need to be aware that it can take years for study results to appear in an academic journal. This reality can be in conflict with your motivation for taking part in the study: making a difference in people’s lives as soon as possible. While the published article lends important legitimacy to engaging patients in research, you are encouraged to work with the research team to develop other means of getting the message out.</li> <li>• Negotiate your role in translation and exchange of research knowledge at the beginning of your relationship with the research team, and recognize that this role may evolve over time.</li> <li>• Clarify that the resources you need to engage in these activities (for example, access to online library searches; costs of meeting and conference attendance) are covered in the research budget.</li> <li>• Negotiate (co)authorship with the research team. If you have been an integral member of the research team and involved in writing an article, you should be listed as an author rather than just acknowledged in the article.</li> <li>• Consider the timelines in producing a publishable manuscript in relation to your availability and resources.</li> <li>• Become familiar with journals that publish patient engagement articles.</li> </ul>
	<p><u>For Researchers:</u></p> <ul style="list-style-type: none"> <li>• Patients may be authors or co-authors of publications if they contribute to the research design, data collection, data interpretation or knowledge translation activities and at a minimum should be acknowledged in presentations and publications. For example, an Elder or Knowledge Holder of Indigenous ancestry could be acknowledged for setting the overall tone of meetings and taking care of a research team, and sometimes providing guidance and insight on particular aspects of the research.</li> <li>• Build in resources for patients who make this level of commitment to your study to co-present at conferences.</li> <li>• Knowledge translation and exchange is contextual and doing it well with communities often takes consideration, resources and time. Patients can be valuable partners in this endeavor.</li> </ul>

Examples of patient roles:	Guidance:
	<ul style="list-style-type: none"> <li>• Work alongside patients to translate your study findings directly to patients so that they can use this information to improve their health.</li> <li>• Co-authoring and presenting with patients engaged in your research will contribute to the credibility of your work in the research community.</li> <li>• Discuss your publication plans with patients engaged in your research and how they want to be involved. If need be, choose appropriate venues for publishing according to your needs (for example, scientific journals and professional journals) and to the needs of patients.</li> <li>• Consider journals that publish patient engagement articles.</li> </ul> <p><u>For Institutions</u></p> <ul style="list-style-type: none"> <li>• Institutions can play an enabling role by providing resources, facilities and training for researchers and patients new to patient-oriented research to collaborate throughout the research process, including in knowledge exchange and translation activities.</li> </ul>

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717 **Stage 10: Evaluation and Quality Assurance**

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Examples of Patient Roles:	Guidance
<ul style="list-style-type: none"> <li>✓ 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 lived experience lens or specific focus.</li> <li>✓ Be involved in an evaluation process to explore the effectiveness and efficiency of patients being involved in research.</li> <li>✓ Contribute to the identification of information needs or gaps in existing materials and tools.</li> <li>✓ Identify language or materials that are confusing or unhelpful, as well as identify materials that are particularly well formatted and helpful.</li> <li>✓ Assist with testing and adjusting the materials.</li> <li>✓ Serve on improvement teams with patient safety goals (for example, engaging patients and staff in identifying safety risks, reducing preventable readmissions, medication incidents, falls and infections).</li> <li>✓ Review materials related to improvement initiatives.</li> <li>✓ Help test and adjust new quality and safety processes.</li> <li>✓ Discuss findings of the quality assurance and improvement exercises.</li> <li>✓ Identify improvements to be made to the way research was conducted.</li> <li>✓ Monitor that quality improvements are implemented.</li> </ul>	<p><u>For Patients</u></p> <ul style="list-style-type: none"> <li>• Familiarize yourself with the particular evaluation or quality assurance function in which you are involved: identify the terms of reference, who is receiving the advice you will be providing, and your role in this process.</li> <li>• If evaluating a project that has reached completion, consider how well the research engaged people with lived experience throughout the lifecycle of the project.</li> <li>• Pay attention to concerns around confidentiality in terms of accessing information from the project and providing advice to those receiving any reports.</li> </ul>
	<p><u>For Researchers, Institutions, Funders</u></p> <ul style="list-style-type: none"> <li>• Partnering in quality and safety processes involves drawing methods and tools from different domains (for example, patient engagement, quality improvement, project planning, and communications) to clarify purpose, choose the right people and right methods, recruit and orient patient partners into their roles, and support everyone towards equal partnership and effective collaboration.</li> </ul>

719 Real Life Examples of Patient Engagement across the  
 720 Research Lifecycle  
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Patient engaged in the:	Patient partner roles include:	Internet links
Can-SOLVE CKD (Chronic Kidney Disease) Network	<ul style="list-style-type: none"> <li>✓ Priority setting</li> <li>✓ Oversight of a research initiative (e.g., see the Patient Council and the Indigenous Peoples' Engagement and Research Council)</li> </ul>	<a href="https://cansolveckd.ca/">https://cansolveckd.ca/</a>
James Lind Alliance: Priority Setting Partnerships	<ul style="list-style-type: none"> <li>✓ Priority setting</li> </ul>	<a href="http://www.jla.nihr.ac.uk/jla-guidebook/chapter-3/the-features-of-a-jla-priority-setting.htm">http://www.jla.nihr.ac.uk/jla-guidebook/chapter-3/the-features-of-a-jla-priority-setting.htm</a> (Note that the James Lind Alliance brings together clinicians, patients and caregivers to identify research priorities, and does not include engaging patients in the conduct of the research.)
Canadian HIV Cure Enterprise (CanCURE)	<ul style="list-style-type: none"> <li>✓ Priority setting</li> </ul>	<a href="https://www.cancurehiv.org/community-liaison">https://www.cancurehiv.org/community-liaison</a>
Living with HIV (LHIV) Innovation Team Grant-Community Scholar Program	<ul style="list-style-type: none"> <li>✓ Development of the research proposal</li> </ul>	<a href="http://www.cihr-irsc.gc.ca/e/49628.html#a2">http://www.cihr-irsc.gc.ca/e/49628.html#a2</a>
Strategy for Patient-Oriented Research (SPOR) Networks in Chronic Disease	<ul style="list-style-type: none"> <li>✓ Participation on scientific peer review committees for applications for funding</li> </ul>	<a href="http://www.cihr-irsc.gc.ca/e/49643">http://www.cihr-irsc.gc.ca/e/49643</a>
American Cancer Society	<ul style="list-style-type: none"> <li>✓ Participation on scientific peer review committees for applications for funding</li> </ul>	<a href="https://www.cancer.org/research/we-fund-cancer-research/apply-research-grant/stakeholder-participation-grant-peer-review-committees.html">https://www.cancer.org/research/we-fund-cancer-research/apply-research-grant/stakeholder-participation-grant-peer-review-committees.html</a>

Patient engaged in the:	Patient partner roles include:	Internet links
Manitoulin Anishinaabek Research Review Committee	<ul style="list-style-type: none"> <li>✓ Participation on community review committee</li> </ul>	<a href="http://www.noojmowinteg.ca/SitePages/MARRC.aspx">http://www.noojmowinteg.ca/SitePages/MARRC.aspx</a>
Walmsley program of research into HIV and Healthy Aging	<ul style="list-style-type: none"> <li>✓ Oversight of a research initiative (e.g., see the Community Advisory Committees)</li> </ul>	<a href="https://academic.oup.com/ije/article/42/2/402/732813/Cohort-Profile-The-Ontario-HIV-Treatment-Network">https://academic.oup.com/ije/article/42/2/402/732813/Cohort-Profile-The-Ontario-HIV-Treatment-Network</a>
Patient and Community Engagement Research (PaCER) unit, O'Brien Institute for Public Health, University of Calgary	<ul style="list-style-type: none"> <li>✓ Priority setting and planning</li> <li>✓ Development of the research proposal</li> <li>✓ Recruitment of research participants</li> <li>✓ Data collection</li> <li>✓ Data analysis and interpretation</li> <li>✓ Translation an exchange of research knowledge (Engagement Researchers in the PaCER program have published PaCER research that was embedded in larger research projects in peer reviewed journals such as The Patient-Patient Centered Outcomes Research; PLoS ONE; Health Expectations; BMJ Open; and Critical Care Medicine. They have also co-authored articles with their research teams).</li> </ul>	<a href="https://pacerinnovates.ca">https://pacerinnovates.ca</a>

## 723 Additional Resources

- 724
- 725 Canadian Institutes of Health Research (CIHR) CIHR Peer Review Manual for Grant Applications, Section  
726 6.2.3 [http://www.cihr-irsc.gc.ca/e/4656.html#s3\\_6\\_2\\_3](http://www.cihr-irsc.gc.ca/e/4656.html#s3_6_2_3)
- 727 HIV Community-Based Research (CBR) Fact Sheet #3- Managing Multiple Roles and Boundaries (2014)  
728 [http://www.hivethicscbr.com/documents/HIVCBREthics\\_FactSheet03.pdf](http://www.hivethicscbr.com/documents/HIVCBREthics_FactSheet03.pdf)
- 729 HIV Community-Based Research (CBR) Fact Sheet #2- Recruiting Hard to Reach Individuals and  
730 Communities in CBR [http://www.hivethicscbr.com/documents/HIVCBREthics\\_FactSheet02.pdf](http://www.hivethicscbr.com/documents/HIVCBREthics_FactSheet02.pdf)  
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- 732 National Health Service (NHS) Handbook for Researchers: Patient and public involvement in health and  
733 social care research.  
734 [www.sheffieldclinicalresearch.org/download/.../RDS\\_PPI%20Handbook\\_web.pdf](http://www.sheffieldclinicalresearch.org/download/.../RDS_PPI%20Handbook_web.pdf)
- 735 The Patient – Patient Centered Outcomes Research <https://link.springer.com/journal/40271>
- 736 Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2<sup>nd</sup> Edition (TCPS 2):
- 737 • Policy statement: [http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-  
eptc2/Default/](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-<br/>738 eptc2/Default/)
- 739 • CORE Education module: <http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/>  
740 Wellesley Peer Research- Peer Research in Action III: Ethical Issues,  
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747 participation-grant-peer-review-committees.html](https://www.cancer.org/research/we-fund-cancer-research/apply-research-grant/stakeholder-<br/>746 participation-grant-peer-review-committees.html)
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756 <http://www.fnha.ca/wellness/cultural-humility#learn>  
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- 758 Canadian Institutes of Health Research (CIHR) Peer Review Manual for Grant Applications, Section 6.2.3  
759 [http://www.cihr-irsc.gc.ca/e/4656.html#s3\\_6\\_2\\_3](http://www.cihr-irsc.gc.ca/e/4656.html#s3_6_2_3)  
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763 irsc.gc.ca/e/29418.html](http://www.cihr-<br/>762 irsc.gc.ca/e/29418.html)
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765 <https://www.youtube.com/watch?v=85PPdUE8Mb0>  
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- 767 Health Canada and the Public Health Agency of Canada Guidelines on Public Engagement.  
768 [http://www.healthycanadians.gc.ca/publications/health-system-systeme-sante/guidelines-  
770 public-engagement-publique-lignes-directrice/index-eng.php](http://www.healthycanadians.gc.ca/publications/health-system-systeme-sante/guidelines-<br/>769 public-engagement-publique-lignes-directrice/index-eng.php)
- 771 HIV Community-Based Research (CBR) Fact Sheet #2- Recruiting Hard to Reach Individuals and  
772 Communities in CBR [http://www.hivethicscbr.com/documents/HIVCBREthics\\_FactSheet02.pdf](http://www.hivethicscbr.com/documents/HIVCBREthics_FactSheet02.pdf)  
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- 774 HIV Community-Based Research (CBR) Fact Sheet #3- Managing Multiple Roles and Boundaries (2014)  
775 [http://www.hivethicscbr.com/documents/HIVCBREthics\\_FactSheet03.pdf](http://www.hivethicscbr.com/documents/HIVCBREthics_FactSheet03.pdf)  
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788 <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>  
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