BC SUPPORT Unit
Advancing Patient-Oriented Research
British Columbia Academic Health Science Network

Ensuring the Ethical Conduct of Patient-Oriented Research: A Guide for Researchers

October 2018

Contents

SECTION 1: PURPOSE AND APPROACH

The Canadian Institutes of Health Research (CIHR)-led Strategy for Patient-Oriented Research (SPOR) supports evidence-informed health care as a method to improve patient experience and health care outcomes[1]. Patient Oriented Research (POR) is a widespread movement with initiatives such as INVOLVE in the United Kingdom and the Patient-Centered Outcomes Research Institute (PCORI) in the United States[2,3]. Despite progress in the implementation of POR frameworks and methodologies, there remains a lack of clarity among researchers regarding what POR entails and how to navigate it ethically[4]. To contribute to the growing body of literature on ethical engagement in POR, this document has been developed to provide researchers, trainees, and post-doctoral fellows with an overview of the current areas of ethical consideration discussed in the research literature on ethical engagement in POR.

This document is the result of a summer student project funded by the BC SUPPORT UNIT. As a graduate student, the author is not an expert in the field of POR, however, concepts and recommendations included are the result of a literature review in research ethics in POR and community-based participatory research (CBPR) as these methods include the fundamental underpinning of conducting research in collaboration with, for lack of a better term, lay researchers. The information included is presented in a manner that is intended to be informative and useful for researchers when considering ethical engagement with patient partners in health research. Every effort has been made to include the most recent scientific publications in the rapidly expanding discourse on research ethics within the context of POR.

SECTION 2: WHAT IS PATIENT-ORIENTED RESEARCH (POR)?

POR is health research conducted in meaningful and collaborative partnership with patients that engages patient partners in the governance, development, and conduct of health research, as well as in summarizing, distributing, sharing, and applying its resulting knowledge[5]. POR aims to answer research questions that matter to the population it is intended to serve with the goal of improving health care and health outcomes[6].

Many health researchers confuse POR with patient involvement as research participants/ subjects or through community engagement activities[4]. Terms vary between regions, for example, researchers in the UK use the term “involvement” in the same way that Canadian researchers use “engagement” to denote research conducted collaboratively with patient partners[6,1]. Furthermore, research teams may elect to use an alternate term, such as “community member” when referring to patient partners in an effort to remove the “patient label”[7]. Confusion over terminology is compounded for researchers interested in POR in instances where methods used to collect research data can also be applied to engaging patients as research partners[8].

The BC SUPPORT Unit uses the term ***patients*** to denote *“individuals with personal experience of a health issue or their informal caregivers, including family and friends”* [6]. For the purposes of this document, terms such as ***participation, participant, and/or subject*** refer to the traditional concept of patients as research participants/subjects. Conversely, terms such as ***patient/community/public engagement, involvement, and/or partnership*** will be used when referring to a range of research activities conducted in partnership with patients and communities as members of the research team in POR. To view the spectrum of public engagement in research, see Appendix Tables A1 and A2.

SECTION 3: RESEARCH ETHICS IN CANADA – THE CURRENT ETHICAL FRAMEWORK

Institutions administering Canadian Federal research grants awarded by the Tri-Councils (Canadian Institutes of Health Research, the Social Sciences and Humanities Research Council, and the Natural Sciences and Engineering Research Council) are required to have a Research Ethics Board (REB) in place to provide oversight of the ethical acceptability of all human research conduced under their institutional auspices to ensure research is compliant with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2 (TCPS 2) [9]. Research must be ethically sound, protect the dignity of research participants, and protect them from harm.

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans defines ethical research in the following way:

> *Respect for human dignity requires that research involving humans be conducted in a manner that is sensitive to the inherent worth of all human beings and the respect and consideration that they are due. In this Policy, respect for human dignity is expressed through three core principles – Respect for Persons, Concern for Welfare, and Justice*[9] (p.6).

Traditionally the core principles of Respect for Persons, Concern for Welfare, and Justice have been upheld by REBs through the ethical requirements of informed consent, considerations of potential research harms and benefits, and the equitable inclusion of eligible individuals as research participants[10]. These considerations are still the cornerstone of research ethics, however, the movement towards community and patient partnerships in research expands ethical considerations outside of the arena of REB scrutiny to encompass the way in which researchers and patient partners engage with one another collaboratively.

SECTION 4: IS RESEARCH ETHICS BOARD (REB) APPROVAL REQUIRED FOR PATIENT PARTNERSHIPS IN RESEARCH?

REB approval is not required for patient-researcher partnerships in general, however, there are some exceptions. REB ethical review is necessary under the following circumstances:

Patient Engagement Activities Requiring REB review and approval:

a) Research on patient engagement methodologies and processes as the subject of research requires REB review and approval for patient partner participation[8].
b) Research proposals directly impacting the welfare of Indigenous communities require community engagement as an ethical obligation under TCPS Chapter 9[11]. Researchers wishing to conduct studies in the following areas are mandated to describe how their TCPS 2 requirements for community input and engagement have been met in their REB applications:
    a. research conducted on First Nations, Inuit or Métis lands;
    b. recruitment criteria that include Aboriginal identity as a factor for the entire study or for a subgroup in the study;
    c. research that seeks input from participants regarding a community's cultural heritage, artefacts, traditional knowledge or unique characteristics;
    d. research in which Aboriginal identity or membership in an Aboriginal community is used as a variable for the purpose of analysis of the research data; and

e. interpretation of research results that will refer to Aboriginal communities, peoples, language, history or culture.

Researchers should ensure they are familiar with culturally appropriate customs as well as *First Nations Principles of Ownership, Control, Access and Possession* (OCAP) **prior** to engaging in research-related activities. OCAP principles "…are the *de facto* standard for how to conduct research with First Nations" [12]. Researchers need to understand their roles and responsibilities, within the context of Indigenous controlled data collection, use, and dissemination.

Regardless of the formal requirement for ethical review of patient engagement activities, patient partners acting as members of research teams are obligated to conduct research-related activities in accordance with ethical policies and standards as is the case with all individuals engaging in the conduct of research. It is recommended that patient partners, especially those interacting with research participants, complete the *TCPS 2 Tutorial Course on Research Ethics (CORE)* [7,13]. Some institutions may require completion of TCPS 2 CORE for all research team members. Whether it is mandatory or optional, TCPS 2 CORE provides research team members with a framework to better understand the ethical issues in research, equipping them to better inform their research team partners on how to serve their community in an ethically acceptable manner.

SECTION 5: PATIENT-ORIENTED RESEARCH AND ETHICAL CONSIDERATIONS OUTSIDE THE PURVIEW OF TRADITIONAL REB PROCESSES

Once a decision has been made to engage in POR, ethical issues that may arise should be considered prior to recruiting patient partners[14]. In addition to ethical requirements mandated under TCPS 2, POR research teams may tackle a myriad of ethical considerations within the context of POR that do not fall under the scrutiny REBs or manifest in a manner not typical of traditional ethical concern. For example, tokenism in regard to patient engagement would not typically be an area under REB scrutiny while conflict of interest, which is an area of concern for REBs, may have added layers of complexity when considering the dual role as both a patient and a research team member. Research ethics processes are constantly evolving, and an ethical lens may still be applied to build meaningful collaborative patient-researcher partnerships, even in the absence of a prescribed ethical policy or framework. The following sections outline some of the ethical issues commonly noted in the research literature on POR and, where possible, provide some suggestions to overcome ethical barriers. The following ethical considerations are presented as separate topics for simplicity, however, there is much overlap among them and they should not be considered as discrete categories as a result of this interconnectedness.

5.1: Tokenism

Tokenism in POR is a superficial or symbolic attempt to incorporate patient partners into the research team[15]. When considering if engagement is sincere or superficial, consider both the method and the intent which can be assessed along a continum from genuine engagement to token engagement[15]. Genuine engagement results from shared responsibilities, open communication, and enduring relationships built upon strong partnerships[15]. The lynchpin of a genuine partnership is intention. Researchers may be operating with the best of intentions to include patient partners in their research, however, attempts may fall short due to lack of training or understanding how to authentically engage with patient partners. Hahn et al.'s "genuine-token engagement continuum in medical research" (see Table 1) provides a helpful framework for considering authentic patient engagement across three domains: method/structure of research, intent, and relationship building[15] (pp.291-292). The "genuine-

token engagement continuum" builds upon earlier work by Concannon et al. to incorporate their "7-Item Questionnaire for Reporting Stakeholder Engagement in Research" (see Table A3) [15, 16].

Table 1
Adapted from Hahn et al.'s Domains Along the 'Genuine-Token' Engagement Continuum

Domain	More Genuine<----------	----------> More Tokenistic
1. Method/Structure of Engagement	Diverse and representative patient partners have been engaged.	Lack of diversity among patient partners, including a single patient partner just to be able to claim patient engagement has occurred.
Team Composition/Management	Include patient partners as research co-leads; power sharing	Top-down structure where patient partners are not given a leadership role or encouraged to take ownership of their role in the research.
Scheduling	Be considerate of patient partners' time, ensuring they have adequate time to complete tasks Make every effort to schedule meetings at locations and times that are convenient for all team members to attend. Ensure ample time for discussion and responding to questions.	Not providing adequate notice of project timelines, meetings, allowing for patient partner input. Leaving little time for patient partners to make arrangements to attend meetings, not scheduling meetings at a location or through a medium that permits maximal participation. Not scheduling enough time to address comments, questions, or concerns.
Communication and Feedback	Open, honest, inclusive communication in lay terms that everyone can understand. Report results back to partners and show them how their input was incorporated. Train and educate patient partners so they are prepared to be actively engaged in the research. Clear roles and expectations are defined and discussed at the onset of the project.	Use of technical or scientific terms that lay team members may not understand. Failure to share results with patient partners. Exclude their input in the end-product. Failure to provide patient partners with the education and tools they need to be full members of the team. Neglect defining roles and project expectations.
2. Intent	Early engagement to include patient partners in planning and determining the research priorities, goals, and objectives.	Research priorities, goals, and outcomes are pre-determined and patient input is sought out as a "rubber stamp".

	Mutual learning, accepting that you do not know all the answers and willingness to find the answers together with patient partners. Define issues collaboratively with patient partners. Research direction and priorities are patient-led. Reciprocal learning. All research team members' voices are heard and carry equal weight, collective knowledge, authority, decision-making, goals, rewards, and challenges among researchers, clinicians, and patient partners.	Patient input sought out as an afterthought/after the research has started. Patient partners are asked to review research proposal after it is finalized. Set research agenda is imposed on patient partners despite differing from patient priorities. Unidirectional benefits. Top-down decision-making, failure to cultivate genuine partnerships.
3. Relationship Building **Before the Project** **During the Project** **After the Project**	Promoting a culture of mutual trust where patient partners feel valued, respected, and comfortable. Open and honest disclosure that meets the needs of patient partners. Address core perspectives and their roots (i.e. culture, myth, beliefs, etc.). Actively engaging patient partners to develop research priories and questions that are meaningful to the patients impacted. Partnerships are encouraged, strengthened, and valued. Patient partnerships are maintained after the project is complete and endure long-term. Longitudinal partnerships are encouraged.	Lack of validating patient partners' thoughts, feelings, and input. Lack of full disclosure. Patient partnerships as a means to an end. Patient partners are not engaged in the developmental stages of research. Partnerships are not created Relationship ends when project completes.

5.2: Tensions in POR

Tension 1: Conflict of Interest

A conflict of interest (COI) may arise when a research team member has competing roles or obligations[17]. While COIs are not specific to POR, they may present unique ethical challenges. Patient partners may simultaneously engage in a research program as a data provider and a research partner, raising issues of anonymity and objectivity[18]. When multiple roles are played by patient partners, it is essential that each role is clearly defined, discussed, and understood by all research team members[19]. Researchers should consider how potential COIs may arise and work collaboratively with patient partners to acknowledge and mitigate potential conflicts.

Tension 2: Wearing Two Hats, Patient Partners as Research Study Participants

Liabo suggests that researchers and patient partners consider the following questions to prevent a conflation of roles "Is this role one of active research partner or conventional research participant?" or "What will be done with the information provided by patients?" [18] (p.2). These questions can be helpful in determining the best course of action when patient partners are both research team members and research study participants. There is debate in the research community surrounding whether a patient partner may also be a research participant in the research they are working on. The consensus seems to be "it depends." Some research methodologies permit inclusion of patient partners as research participants, however, other instances may cause data contamination, for example in situations where the participant must be naïve to the study treatment. In other circumstances it could be considered a conflict of interest for a patient partner to play a dual role. Nevertheless, a strong justification to permit patient partners as research participants is required[20]. Generally, circumstances where a rare disease is being researched is considered a justifiable case for playing the dual patient partner/research participant role[20].

When patient partners are involved in a research study as both a research participant and research team member great care should be exercised to ensure that information shared is used for its intended purposes. There needs to be open and clear communication between researchers and patient partners regarding what information is shared in confidence, what information is shared to shape research protocols, and what information is shared as research data[8]. Research guidelines and protocols should clearly differentiate between roles, for example, patient partner participation in a discussion group would be considered research development activity whereas patient partner participation in a focus group would be research participation as a subject[8].

Tension 3: Potential for Coercion in Participant Recruitment

Patient partners may be ideal candidates to recruit research participants due to their proximity to potentially eligible individuals, however, situations may arise where coercion is a concern[19]. Potential participants may feel pressured to participate in a research study when invited by a peer, accordingly, steps should be made to mitigate coercions. If patient partners are making the initial contact with potential participants, they should provide the individual with a study information letter and contact of another research team member that is not connected to the patient community with whom they can discuss the study details[17]. This consideration extends to the consenting process which should be conducted by someone that does not have a pre-existing relationship with the research participants[17].

5.3: Benefits and Harms

Just as there are potential positive and negative outcomes of participating in research, there are also benefits and harms associated with being a patient partner. Patient partners are engaging with researchers because they have lived experience coping with illness. Illness, coupled with everyday life demands, can be taxing. Researchers should be responsive to the needs of their patient partners and make sure that their contributions are valued and heard[5]. By undervaluing or disrespecting patient partner contributions, patient partners risk feeling stress, guilt, inadequacy, and negativity about their interactions with researchers[5]. When fully integrated into a research team as a valued member, patient partners benefit from a sense of self-confidence, accomplishment and empowerment that their experience with illness may have a positive impact on the lives of others impacted by the same medical condition(s)[21]. Other benefits include developing relationships, better understanding of health research, coming to terms with their illness, and personal development[21].

5.4: Confidentiality of Information

Confidentiality of information requires the protection of private and identifiable information provided within the context of research[17]. In POR, this is not only the responsibility of patient partners, it may also extend to them as well. Researchers must ensure that patient partners are provided with appropriate training and support regarding their responsibilities to maintain confidentiality[17]. This is particularly salient when patient partners know participants personally. Furthermore, researchers should always seek clarity when patient partners share private details regarding their healthcare journies[18]. Any information provided in confidence by a patient partner to a researcher must be respected to ensure authentic and meaningful engagement.

5.5: Power Dynamics and Imbalances

Power differentials may be embedded in the researcher-patient partner relationship due to a range of individual, social, and structural factors. Recognizing that patients are not a homogenous group and that health care research has historically operated upon inverse care law, where those with the greatest need for access to good health care and social services are the least likely to receive it, researchers can develop an approach to POR that serves the interests of those most at risk as well as the general population[22]. Researchers should consider the following when engaging with patient partners:

- Consider how *social categories* (i.e. race, ethnicity, indigeneity, gender identity, gender expression, socioeconomic status, sexuality, geography, age, ability, immigration status, and religion) and *social systems* (i.e. racism, colonialism, classism, sexism, ableism, and homophobia) may interact and impact the patient population and how a voice will be given to those typically voiceless in the health care system[22].
- Consider including more than one patient partner in the research team from a variety of backgrounds to develop a research program that is reflexive to the needs of the whole community, not just a subset.
- When working with vulnerable populations, researchers should inform themselves on systemic traumas, inequities, and power differentials that may impact them[22]. For example, it may be difficult for a patient partner that has been involuntarily hospitalized for mental health issues to feel comfortable providing constructive criticism to a lead researcher who is a psychiatrist. Understanding this at the onset and developing a plan to promote safe and equitable discourse with patient partners will improve the experience for all involved and produce a strong research program.

SECTION 6: POR WITH A VULNERABLE COMMUNITY: PERSPECTIVES FROM VANCOUVER'S DOWNTOWN EASTSIDE

A collaborative working group from Vancouver's Downtown Eastside (DTES) tackled the issue of ethics in research and advocates for community-based ethical reviews when researching vulnerable communities[23]. The DTES is a community characterised by high levels of poverty, crime, mental illness, infectious diseases, and substance abuse and is disproportionately the target of research[24]. In response to the oversaturation of research occurring in their community, the DTES working group developed *Research 101: Manifesto for Ethical Research in the DTES* outlining the following ethical concerns of relevance to community-based researchers, some of which are echoed in considerations raised above[23]:

- Reciprocity: How will the researchers ensure that their work is mutually beneficial for both themselves and the community?
- Is the research trauma-informed? Have potential harms been considered and is there a mitigation plan to support patient partners and participants should they require it (i.e. access to mental health services)?
- Is consent accessible to all? TCPS 2 requires consent to be voluntary, informed, ongoing, and accessible. Mechanisms should be in place to better communicate and inform consent processes with individuals who may find the informed consent form difficult to understand.
- How will informed consent remain an ongoing process?
- Will community partners be included in the final review of the research prior to dissemination to ensure that the data accurately represents that community and researcher interpretations are correct?
- Are all aspects of the research guided by ethical considerations?
- Have unintended consequences of the research been considered?

The DTES working group went on to highlight ways in which POR can harm the community in which it aims to serve. Research can contribute to the further stigmatization, be exploitive, disrespectful, trauma inducing, and inequitably beneficial to the researcher[23]. Furthermore, DTES community members have noted that research can be taxing on both individuals within the community as well as limited community resources. The lack of researcher reflexivity is problematic when the community is not provided a mechanism to respond to research findings or even receive research results in the first place[23].

The DTES working group suggests the following:

- Inform the community on who the researchers are and why they want to research their community.
- Submit research projects to a community-based ethical review.
- Include peer researchers in all stages of the research project in an equitable and fair manner.
- Return to share research findings with the community and help the community incorporate findings into practice in a meaningful way.

SECTION 7: R-WORDS AND POR: MOVING TOWARDS A RELATIONAL ACCOUNTABILITY APPROACH

The above-mentioned ethical considerations share the common theme of urging researchers to behave in a reciprocal, reflexive, responsible, and respectful manner when engaging with patient

partners. To this end, a relational ethics framework can be implemented to overcome ethical dilemmas inherent in POR. Relational ethics can be understood as the process by which interactions and relationships are governed by mutual and ongoing ethical-reflective exchanges between patient partners and researchers throughout the research relationship[5]. POR requires a delicate balance to ensure that patient partners' voices are heard, and they are being treated equitably while also not diminishing the role of researchers' expertise in developing scientifically valid research protocols[5]. The relational accountability framework put forth by Kirkness & Barnhardt in *First Nations and Higher Education* has been successfully applied as an engagement method in CBPR and is a useful construct when considering how to develop ethical partnerships with patient partners in POR[25,26].

Relational accountability encompasses the 4Rs: respect, relevance, responsibility, and reciprocity, which can be applied using critical reflexivity to improve the ethical acceptability of research[26]. Appropriate engagement practices differ depending on the involvement of community, researcher, and, in POR, patients. Accordingly, relationality in the research process creates "ethical research space" compelling researchers to examine themselves to better understand how their position, experiences, and social identity influences their interactions with research participants, partners, and the research agenda[26,27]. This process also necessitates that researchers view patient partners as whole people with varying demands on their time and energy, encouraging them to be thoughtful of how the patient partner's role in the research impacts their overall well-being[5].

Henry, Tait, & STR8 UP's Relational Accountability Model (see Figure B1) is composed as a web to illustrate how any weakening of a single pillar risks dismantling the core relationship between the researcher and their community/patient partners, encroaching on ethical space[26]. Each pillar must be addressed in a manner appropriate to the researcher, their partners, and the research project to ensure the research process is conduced meaningfully and ethically. For a successful partnership, respect must be earned, relevance of the research project to the community is essential, reciprocity of knowledge, both scientific and experiential, is legitimized and valued, and responsibility in the way in which research is conducted, mobilized, and disseminated are central to an ethical research agenda[26].

SECTION 8: IS PATIENT-ORIENTED RESEARCH MORE ETHICAL?

POR can be more ethical and of higher quality if done well. Research literature suggests that patient involvement in research is ethically strengthened by improving relevance, acceptability, informed consent processes, and the dissemination of results[28]. Including patient partners at the initial stages of research design to assist with the development of consent forms, questionnaires, and provide feedback regarding study procedures improves the validity and ethical acceptability of a research program for patient participants[22]. Outlining patient engagement activities planned for each stage throughout the research lifecycle will help researchers and patient partners consider ethical issues that may arise and discuss mitigation plans to determine the appropriate course of action to prevent ethical oversights from occurring. The inclusion of patient input may be especially helpful when considering novel treatments or protocols that deviate from standard practices to ensure that it is acceptable to the patient population that will be impacted[28]. POR involving patient partners in the earliest stages of research improves ethical acceptability by ensuring the research agenda aligns with the concerns of the patients impacted, is of value to the community it serves, improves the study design to meet the needs of patients, and enhances the informed consent process[29].

SECTION 9: WHERE TO FROM HERE?

Patient engagement in health research is a worthwhile endeavor to improve the quality of research and by extension, better inform evidence-based treatment. The research literature highlights areas of ethical consideration that require further analyses. To ensure that meaningful researcher-patient collaborations live up to their full potential of transforming health research and health care to better serve the needs of the population impacted, work needs to be done to improve the clarity of methods of ethical engagement. Employing a relational accountability approach when engaging in POR sets the tone for a mutually beneficial partnership grounded in ethical principles.

Appendix A

Table A1

Public Participation Spectrum in Research: CIHR Table of Citizen Engagement [30]

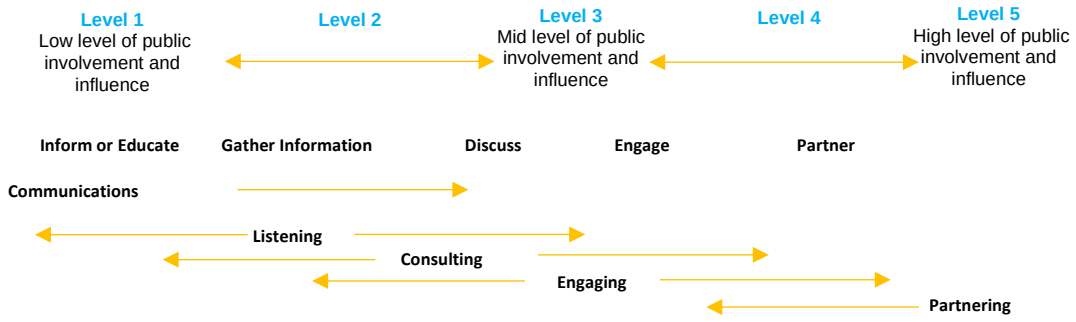


Table A2

International Association for Public Participation 2 Spectrum of Public Participation [30]

	Inform	**Consult**	**Involve**	**Collaborate**	**Empower**
Patient Participation Goal	To provide the patient with balanced and objective information to assist them in understanding the problems, alternatives, opportunities, and/or solutions.	To obtain patient feedback on analysis, alternatives, and/or decisions.	To work directly with the patient throughout the process to ensure that patient concerns and aspirations are consistently understood and considered.	To partner with the patient in each aspect of the decision including the development of alternatives and the identification of the preferred solution.	To place the final decision-making in the hands of the patient.
Promise to the Patient	We will keep you informed.	We will keep you informed, listen to and acknowledge concerns and provide feedback on how patient input influenced the decision.	We will work with you to ensure that your concerns and issues are directly reflected in the alternatives developed and provide feedback on how patient input influenced the decision	We will look to you for direct advice and innovation in formulating solutions and incorporate your advice and recommendations into the decisions to the maximum extent possible.	We will implement what you decide.
Example Tools	• Fact sheets • Websites • Open houses	• Patient comment • Focus groups • Surveys • Public Meetings	• Workshops • Deliberate polling	• Patient advisory committees • Consensus-building • Participatory decision-making	• Patient juries • Ballots • Delegate decisions

Table A3

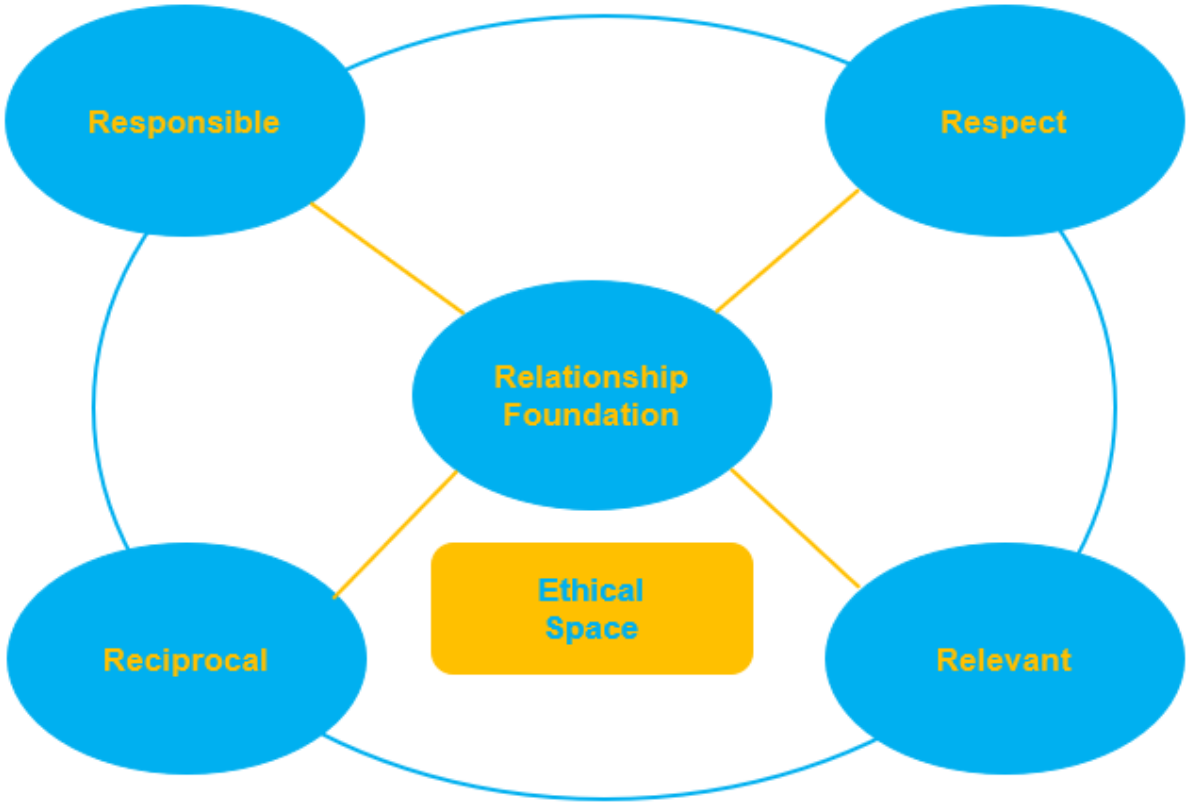
Questionnaire for Reporting Stakeholder Engagement in Research[15, 16].

7-Item Questionnaire	**Genuine Stakeholder Engagement**	**Token Stakeholder Engagement**
1. What types of stakeholders were engaged?	All relevant stakeholders were engaged	Only selected stakeholder groups were engaged
2. What were the a priori target number(s) for each type of stakeholder? Were targets met?	Target numbers were adequate to allow meaningful contributions from all groups	Target numbers were small in relation to the numbers of researchers and/ or other stakeholders
3. How was the balance of stakeholder perspectives considered and achieved?	Careful consideration was given to a variety of relevant factors	Perfunctory considerations determined the allocation
4. What methods were used to identify, recruit and enrol stakeholders in research activities?	Care was taken to include stakeholders capable of seeing 'the big picture'	No consideration for the ability to think beyond one's own situation was made
5. Did engagement occur: a. before? b. during? c. after?	Engagement occurred throughout the research process (before, during and after)	Engagement did not occur at one or more stages of the research process
6. What were the intensity, methods and modes of engagement?	Engagement was deep, extensive, and long-lasting.	Engagement was shallow, limited and short
7. What, if any, was the impact of stakeholder engagement on: a. relevance? b. transparency? c. adoption?	Engagement resulted in more relevant research questions, transparency and adoption	Engagement was insufficient to affect relevance, transparency and/or adoption

Appendix B

Figure B1

Relational Accountability Model [26]



References

1. Canadian Institutes of Health Research. (2018). *Strategy for patient-oriented research.* Retrieved from http://www.cihr-irsc.gc.ca/e/41204.html [Accessed 4 June 2018].
2. INVOLVE. (2018). *What is public involvement in research?* Retrieved from http://www.invo.org.uk/find-out-more/what-is-public-involvement-in-research-2/ [Accessed 4 June 2018].
3. Patient-Centered Outcomes Research Institute. 2018. *About us.* Retrieved from https://www.pcori.org/about-us [Accessed 24 September 2018].
4. Tarpey, M., & Bite, S. (2014). *Public involvement in research applications to the National Research Ethics Services: comparative analysis of 2010 and 2012 data*. 2014. Retrieved from http://www.invo.org.uk/wpcontent/uploads/2015/02/INVOLVE _NRES _report_2014.pdf [Accessed 5 July 2018].
5. Leese, J., MacDonald, G., Kerr, S., Gulka, L., Hoens, A.M., Lum, W.,…Li, L.C. (2018). 'Adding another spinning plate to an already busy life.' Benefits and risk in patient-researcher relationships: a qualitative study of patient partners' experiences in a Canadian health research setting. *British Medical Journal, 8.* doi:10.1136/ bmjopen-2018-022154.
6. British Columbia SUPPORT Unit. (2018). *What's patient-oriented research? Retrieved* from http://bcsupportunit.ca/ [Accessed 4 June 2018].
7. Oelke, N., & Wick, U. (2018). *Patient-oriented research: ethical considerations when engaging patients in the research process.* Presented at REB WEST 2018 Conference on 22 June 2018. Retrieved from http://www.sfu.ca/content/dam/sfu/ore/REBWest2018/Presentations/Nelly %20Oelke.pdf [Accessed 11 September 2018].
8. Doria, N., Condran, B., Boulos, L., Maillet, D.G.C., Dowling, L., & Levy, A. (2018) Sharpening the focus: differentiating between focus group for patient engagement vs. qualitative research. *Research Involvement and Engagement, 4* (19). doi.org/10.1186/s40900-018-0102-6.
9. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada (2014). *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. Retrieved from http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL _Web.pdf [Accessed 4 June 2018].
10. Friedman Ross, L., Loup, A., Nelson, R.M., Botkin, J.R., Kost, R., Smith, G.R. Jr., & Gehlert, S. (2010). Human subject protections in community-engaged research: a research ethics framework. *J Journal of Empirical Research on Human Research Ethics, 5* (1), 5-17. doi: 10.1525/jer.2010.5.1.5.
11. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. (2014). *Tri-Council policy statement: ethical conduct for research involving humans, module 9: research involving First Nations, Inuit, and Metis peoples of Canada*. Retrieved from http://pre.ethics.gc.ca/education/Module9 _en.pdf [Accessed 4 June 2018].
12. First Nations Information Governance Centre. (2018). *The First Nations principles of* OCAP. Retrieved from https://fnigc.ca/ocapr.html [Accessed 5 July 2018].
13. Government of Canada Panel of Research Ethics. (2014). *The TCPS 2 tutorial course of*

research ethics (CORE). Retrieved from https://tcps2core.ca/welcome [Accessed 27 September 2018].
14. Pandya-Wood, R., Barron, D.S., & Elliott, J. (2017). A framework for public involvement at the design stage of NHS health and social care research: time to develop ethically conscious standards. *Research Involvement and Engagement, 3*, 6-27. doi.org/10.1186/s40900-017-0058-y.
15. Hahn, D.L., Hoffman, A.E., Felzien, M., LeMaster, J.W., Xu, J.,…Fagnan, L.J. (2017). tokenism in patient engagement. *Family Practice,* 34 (3), 290-295.
16. Concannon, T.W., Fuster, M., Saunders, T., Patel, K., Wong, J.B., Leslie, L.K., Lau, J. (2014). A systematic review of stakeholder engagement in comparative effectiveness and patient-centered outcomes research. *Journal of General Internal Medicine, 26* (12), 1692-1701. doi: 10.1007/s11606-014-2878-x.
17. Flicker, S., Roche, B., & Guta, A. (2010). Peer research in action III: ethical issues. The Wellesley Institute. Retrieved from http://www.wellesleyinstitute.com/wp-content/uploads/2011/02/Ethical_Issues_WEB.pdf [Accessed 5 July 2018].
18. Liabo, K. (2018). Clarifying the roles of patients in research. *British Medical Journal, 361*, doi: https://doi.org/10.1136/bmj.k1463.
19. Salway, S., Chowbey, P., Such, E., & Ferguson, B. (2015). Researching health inequalities with community researchers: practical methodological and ethical challenges of an 'inclusive' research approach. *Research Involvement and Engagement, 1* (9). doi: https://doi.org/10.1186/s40900-015-0009-4
20. Alberta SPOR SUPPORT Unit. (2018). *Ethical guidelines for engaging with patients as partners in health research in Alberta.* Retrieved from https://albertainnovates.ca/wp-content/uploads/2018/05Ethics_doc-Version2.06_May.17.2018.pdf [Accessed 4 June 2018].
21. Ashcroft, J., Wykes, T., Taylor, J., Crowther, A., & Szmukler, G. (2016). Impact on the individual: what do patients and carers gain from being involved in research? *Journal of Mental Health, 25* (1), 1-9. doi: https://doi.org/10.3109/ 09638237.2015.1101424.
22. Shimmin, C., Wittmeier, K.D., Lavoie, E.D., & Sibley, K.M. (2017). Moving towards a more inclusive patient and public involvement in health research: the incorporation of a trauma-informed intersectional analysis. *BMC Health Service Research, 17*, 539-549. doi:.https://doi.org/10.1186/s12913-017-2463-1.
23. Boilevin, L., Chapman, J., Deane, L., Doerksen, C., Fresz, G., Joe, D.J., Leech-Crier, N. …Winter, P. (2018). *Research 101: a manifesto for ethical research in the Downtown Eastside.* Retrieved from http://bit.ly/R101Manifesto. [Accessed 28 July 2018].
24. Linden, I.A., Mar, M.Y., Werker, G.R., Jang, K., & Krausz, M.(2013). Research on a vulnerable neighbourhood- the Vancouver Downtown Eastside from 2001 to 2011. *Journal of Urban Health, 90* (3), 559-573.
25. Kirkness, V.J., & Barnhardt, R. (1991). First Nations and higher education: The four R's – respect, relevance, reciprocity, responsibility. *Journal of American Indian Education, 30*, 1-15.
26. Henry, R., Tait, C., & STR8 Up. (2016). Creating ethical research partnerships: relational accountability in action. *Engaging with Indigenous Communities*, *2* (1), 183 – 204.
27. Ermine, W. (2007). The ethical space of engagement. *Indigenous Law Journal, 6,* 193-203.
28. INVOLVE. (2012). *Public involvement in research: impact on ethical aspects of research*.

2012. Retrieved from http://www.invo.org.uk/wpcontent/uploads/2012/06 /INVOLVE evidenceresource.pdf. [Accessed 28 July 2018].
29. Staley, K., & Elliot, J. (2017). Public involvement could usefully inform ethical review, but rarely does: what are the implications? *Research Involvement and Engagement, 3,* 30-47. doi: https://doi.org/10.1186/s40900-017-0080-0.
30. PERC Advisory Board. (2017). *Building Patient Engagement in Research: A Guide for Research Teams. A product of the INSPIRE-PHC Patient Engagement Resource Centre (PERC)*. Retrieved from https://www.patientengagement-phcresearch.com/ . [Accessed 05 July 2018].

Further Reading

Flicker, S., Travers, R., Guta, A., McDonald, S., & Meagher, A. (2007). Ethical dilemmas in community-based participatory research: recommendations for institutional review boards. 2007. *Journal of Urban Health, 84* (4), 478-493.

Health Research Authority/INVOLVE. *Public involvement in research and research ethics committee review*. (2016). Retrieved from www.invo.org.uk/posttypepublication/patient-and-public-involvement-in-research-and-research-ethics-committee-review. [Accessed 05 July 2018].

INVOLVE. (2012). *Strategies for diversity and inclusion in public involvement: supplement to the briefing notes for researchers*. INVOLVE, Eastleigh.

Mitchell, D., Geissler, J., Parry-Jones, A., Keulen, H., Schmitt, D.C., Vavassori, R., & Matharoo-Ball, B. (2015). Biobanking from the patient perspective. Research Involvement and Engagement, 1 (4), doi:1 0.1186/s40900-015-0001-z

NL SUPPORT / Newfoundland and Labrador Research Ethics Authority. (2017). *Patient Engagement and Research Ethics.*