Patient Engagement and Research Ethics

These guidelines have been developed by the Newfoundland and Labrador Health Research Ethics Authority (NL HREA) and NL SUPPORT for researchers who will be submitting applications for ethics review.

These guidelines provide clarity on patient engagement in research and how this can be reflected in applications that are submitted for ethics review. They might also be of interest to research funders and organizations providing advice and support to researchers and members of a research ethics board (REB).

These guidelines are informed by both INVOLVE (a government-funded entity supporting public involvement in the National Health Service in the United Kingdom) and the recent Canadian Institutes of Health Research Ethics Guidance (2020). They are further informed by the practical and concrete experiences of patients and researchers in NL engaged in patient oriented research.

What do we mean by Patient Engagement in Research?

"Patient Partners" are people who are engaged in a research project in any way other than as a person being studied (i.e. research participant). Some examples of patient engagement are: patients on decision-making boards, research teams or committees; patients being asked what they think about a questionnaire for a study; patients taking part in identifying which areas of research are important, etc. Patient Partners collaborate in research using their lived experience to provide advice and guidance across all stages of a research project.

Amid the growth of patient engagement in health research, the Canadian Institutes of Health Research (CIHR) Ethics Office instituted a project in 2015 to produce ethics guidance for developing partnerships between patients and researchers. A working group led national consultations and the final guidance document was made publicly available in 2020 (https://cihr-irsc.gc.ca/e/documents/ethics_guidance_partnerships-en.pdf). The guidance offers core reflections on trust between patients and researchers, reviews ethical concerns across the research life cycle, and offers guidance for specific patient partner roles in the research life cycle. This national guidance informed the creation of NL SUPPORT's ethics guidance and we encourage patient partners and researchers to refer to CIHR's ethics guidance for a fuller discussion of ethical issues across the research life cycle.

Public involvement throughout a study can help to make research more ethical by (INVOLVE, 2012):

- Making research more relevant
- Helping to define what is ethically acceptable
- Improving the process of informed consent
- Improving the experience of participating in research
- Dissemination of research results to both the participants and the wider public

Further, the CIHR (2020) ethics guidance document suggests that "from an ethical perspective, meaningful patient engagement:

- grounds research in a deep understanding of the health situations and the living or lived experiences of actual patients, including groups that are typically under-represented in research, to make research more relevant and usable by those patients;
- promotes research methods that are culturally safe, respectful, and appropriate;
- legitimizes research in the eyes of the community that the research is intended to benefit;
- strengthens capacity of patients to shape research that matters to them;
- builds relationships among patients and others involved in research that are mutually respectful; and
- creates an ethical space for respectful dialogue and discussion wherein each person can speak in their own voice." (Box 1, page 5)

Is ethics approval required to engage patients as partners in research?

You do **not** need to apply for ethics approval to engage patients as partners in research. In reviewing the application, the REB will need to address any ethical issues that may arise from patients being involved in conducting and managing the research.

There are some situations where the engagement of patients may raise ethical concerns, for example, when they will be involved with collecting and analyzing data. Furthermore, the well-being and safety of Patient Partners are important things to consider, as well as adequate training and support. However, patient engagement is not the same as patients participating as subjects in a research study.

Where can things get confusing?

There are times when methods for engaging with patients can appear to look like research methods. For example, when a group of Patient Partners is brought together to provide insight and opinion to researchers in a focus group setting or when an advisory council of patients/members of the public is created to provide ongoing input to researchers. In these instances, Patient Partners will need to be recruited, necessitating the collection of personal information about them for purposes of the patient engagement activities. Group discussions are usually recorded in some way, even in note-taking form if not audio recordings, and may later be compiled to produce a summary of the group's opinions and suggestions. These summaries are normally meant to be shared with relevant audiences in a variety of ways. In such cases, it can be difficult to determine whether ethics approval is needed to bring these groups of patient together and publish (in whatever format) a summary of their discussions. Generally speaking, as these patient engagement activities are not data collection, nor meant to answer a specific

research question, they do not require ethics approval. However, we highly recommend organizers of patient engagement activities follow all ethical and privacy best practices for the collection and use of personal information for recruitment purposes and in the reporting of such events (e.g., ensuring anonymity of participants). NL SUPPORT is happy to offer guidance on a case-by-case basis and we further recommend discussion with the HREB in these individual circumstances.

Should Patient Partners be involved before ethics approval?

We highly encourage research teams to engage patients as early as possible (before obtaining ethics approval) to ensure that patient perspectives are taken into account early on in the research process.

Patient Partners may be involved in all phases of research (including after ethics approval). Patient perspectives can lead to improved recruitment strategies, proposal development, design, interpretation of results, knowledge translation and implementation strategies. If Patient Partners are added to the project at a later phase and there are changes to the study design as a result, an amendment would need to be submitted to the REB for review and approval. Adding a patient partner to an application after it has already been approved is done in the same way as any other new team member is added or removed.

How do I record patient engagement in my application for ethics review?

When you submit an application for ethics review for your research, you should fully describe how Patients Partners contributed to the application or how they will be engaged in the research project. For example:

Project team information

- If Patient Partners are involved on the research team, they can – and should - be named on the application. There are two ways to be named on the application:
    - If a Patient Partner wishes to have access to the research ethics application, they must create a researcher portal account. A category "Patient Partner" has been added to the researcher portal account list. In the creation of the account, Patient Partners should know that they have to leave the employee ID, academic institution, etc. fields blank.
    - Alternatively, if a Patient Partner does not require access to the research ethics application, their name and role on the project team can be described in the ethics application in an open text box on the project team information tab of the online application form.

Conflict of interest

- Research team members, including Patient Partners, should declare any conflict of interest. For example, Patient Partners who are also involved in review activities or governance with a Unit funding the research, or in some cases, Patient Partners who are collecting data (e.g., conducting interviews or focus groups in a qualitative study or recruiting patients as participants for a research study).

Appreciation

- Patient Partners should be recognized for their time and input. NL SUPPORT encourages researchers and research partners to discuss appreciation options. Patient Partners may decline the offer; declining should not affect engagement in the project.
- Payments to Patient Partners should be included as part of the budget for review. For more information about appreciation of Patient Partners, you can refer to NL SUPPORT's website for local guidelines or contact NL SUPPORT for additional references or if you have questions on your specific project.

Dissemination

- We highly encourage teams to translate knowledge to patients and the wider public. Patient Engagement in the dissemination of findings helps to ensure that information is presented in a variety of accessible and useful formats that may be different from traditional academic publications. For example, Patient Partners can help ensure knowledge outputs use lay language and provide answers to questions patients and the public might have about the study and its findings. They can also advise on formats appealing to general public or patient audiences (e.g., infographics, how to present study findings in a town hall or on a social media platform).
- Patient Partners involved in knowledge translation activities should be acknowledged for their contributions. They may also be (co)author of an article.

Confidentiality

- All team members, including Patient Partners, with access to identifiable information are required to complete a free online education program about the Personal Health Information Act (PHIA). Available at: http://nlchi.skillbuilder.ca/home
- We recommend that research teams think about the need for a Confidentiality Agreement for all team members, including Patient Partners. This may be particularly relevant for research teams where members will have access to identifiable information. Please contact NL SUPPORT for a Patient Partner Confidentiality Agreement template.

Required information

- Patient Partners who are taking on a role as (co)-Principal Investigator must provide the REB with a CV – no set format.
- Patient Partners in the role of co-Principal Investigator and/or with access to identifiable information are required to upload a TCPS2 Tutorial Certificate of Completion to the ethics application in the Research Portal.

Research impacting Indigenous Groups

In 2020, Memorial University Board of Regents approved Memorial University's Research Impacting Indigenous Groups policy. The policy and associated information can be found here: https://www.mun.ca/research/Indigenous/

Further information about conducting research with Indigenous communities is available Chapter 9 of the TCPS 2 (2018) document.

More information

For further information about patient engagement in research and support, please go to the NL SUPPORT website or contact NL SUPPORT. Additional resources:

Canadian Institutes of Health Research (CIHR) (2020). Ethics Guidance for Developing Partnerships with Patients and Researchers. https://cihr-irsc.gc.ca/e/51910.html

INVOLVE, Health Research Authority (2016) The impact of public involvement on ethical aspects of research, INVOLVE: Southampton.

INVOLVE, Health Research Authority (2015) Public involvement in research applications to the National Research Ethics Service: Comparative analysis of 2010 and 2012 data, INVOLVE: Eastleigh.

About

These guidelines have been developed by NL SUPPORT: Newfoundland and Labrador's Support for People and Patient-Oriented Research and Trials Unit and the Newfoundland and Labrador Health Research Ethics Authority (NL HREA).

NL SUPPORT is part of The Canadian Institutes for Health Research (CIHR)'s Strategy for Patient-Oriented Research (SPOR). SPOR is a nationwide initiative focused on improving outcomes for users of Canada's healthcare system by fostering and supporting a research culture oriented around achieving real-world impacts for patients and their families.

We are happy to receive feedback on these guidelines. Please let us know if you have any questions or suggestions. Contact: NL SUPPORT at nlsupport@mun.ca. For more information, please visit www.nlsupport.ca

Reference

NL SUPPORT, Newfoundland and Labrador Health Research Ethics Authority (2021). Patient Engagement and Research Ethics. NL SUPPORT: Newfoundland and Labrador.