

Engaging Patients as Partners in Preclinical Laboratory Research

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The Blueprint Translational Research Group is a preclinical to clinical research team based at the Ottawa Hospital Research Institute, Ottawa, Canada. They are working to accelerate clinical translation of novel therapies. The group is multidisciplinary with current interests in early phase clinical trials, patient engagement, knowledge synthesis (i.e., systematic reviews and meta-analysis), and preclinical multicenter studies. For more information, please visit our website at <https://www.ohri.ca/blueprint/>.

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EXECUTIVE SUMMARY – KEY MESSAGES

Patient engagement, the active involvement of individuals with lived experience of a health condition as partners in research, has demonstrated many benefits in *clinical* research.¹⁻⁴ To date, patient engagement in the preclinical stages of research (e.g., laboratory research conducted in cell and animal models rather than humans) has not been as widely adopted. This policy brief provides recommendations to institutions, funding agencies and research groups, with a focus on preclinical researchers, to address perceived challenges to patient engagement in preclinical research. Additionally, this brief may be helpful to patients who are interested in partnering with preclinical researchers.

What are the challenges?

- **Challenge 1. Culture & Awareness:** The current scientific culture must shift to promote awareness, understanding and appreciation of the benefits of patient engagement in preclinical research. There is a need to provide guidance on how to meaningfully engage patient partners in preclinical settings.⁵
- **Challenge 2. Support & Resources:** Both, in addition to effort, are required for meaningful patient engagement which can impact study timelines, and also requires financial and educational resources to support meaningful patient partner involvement.⁵⁻⁸
- **Challenge 3. Capacity & Competencies:** Preclinical researchers and patient partners typically do not have experience interacting and communicating with each other, given that preclinical laboratory research is not patient/public-facing. Patient partners, researchers and trainees also have varied goals, backgrounds, communication skills, vocabulary and language (e.g., differences in knowledge, experience, priorities).^{5,6} These differences may hinder effective partnerships.

Solution to Challenge 1.

Foster an inclusive culture toward patient partners & raise awareness and appreciation for the value of preclinical patient engagement

- Encouraging adoption of preclinical patient engagement will require a shift in scientific culture.^{5,7,9} Policies, resources and strategies are required to raise awareness (amongst researchers, funding agencies and institutions) of the value of patient engagement in preclinical research, foster an inclusive environment within laboratories, implement considerations for accessibility and guide practice. This needs to be coupled with evaluation strategies to document the impact of engagement, increase researcher and patient partner confidence, and to inform changes at the institutional level. Additionally, there is a need to raise awareness and understanding at the patient level of the processes, objectives, benefits and challenges associated with preclinical research. One element to be aware of when implementing this option is that a change in scientific culture will occur iteratively and take time to be accepted and actualized.

Solution to Challenge 2.

Create a well-defined strategy to incorporate patient engagement into study timelines and budgets

- Establishing a well-defined patient engagement strategy at the beginning of a study can strengthen collaboration efforts by encouraging priority setting during time and resource allocation.^{6,7,10} Where possible, patient partners can be engaged in co-creating these strategies for engagement throughout the research project. We summarize strategies to incorporate patient engagement into the study timeline as early as possible and point to supplementary external resources and tools that can offer additional support.

Solution to Challenge 3.

Take a thoughtful and tailored approach to engagement (take time to develop partnerships, create a common ground/vocabulary, and identify shared goals for preclinical research)

- Bi-directional knowledge sharing requires relationship building and time. A thoughtful and tailored approach will allow members to get to know each other and to build meaningful partnerships. This will enable more productive collaboration efforts and increase the likelihood of team psychological safety. These discussions will also help researchers and patient partners establish a common vocabulary and processes to work towards common goals.

Conclusion: This brief provides three recommendations for research groups, funding agencies and institutions to engage patients as partners in preclinical laboratory research. Though each option will require further evaluation and monitoring to assess effectiveness, we propose these as viable options that may be implemented both at an individual level (e.g., by preclinical researchers, trainees, patient partners) as well as at an institutional level (e.g., funding agencies universities, research institutes).

Background and Context

Patient engagement in scientific research refers to collaboration between researchers and ‘patients’ (i.e., a broad term that includes individuals with lived experience including informal caregivers, family, and friends) in developing or conducting research, where the perspectives and the feedback from both parties is considered throughout the research process (see **Box 1** for key terminology). Engaging patients in research relevant to their health, well-being and expertise improves the quality of research. It also increases relevance of study outputs to these ‘ultimate end-users’ of health research. It is now becoming commonplace for patients to engage in the process of making personal health decisions, contributing to the design of healthcare policies and practices, and forming guidelines for the delivery of care.

Some observed benefits of engaging patients in the development and dissemination of *clinical* research include: 1) helping to ensure that the research being conducted is relevant and valuable to the patients it affects; 2) ensuring diverse perspectives; 3) increasing trial recruitment/retention; and 4) creating a mutual learning opportunity, building new skills, knowledge, and interest.¹¹ Additionally, it identifies areas of unmet need, and facilitates dialogue between patients and researchers.¹²

Although patient engagement within *clinical* research has been well documented,¹ the prevalence, methods and effects of patient engagement in *preclinical* research (i.e., laboratory research conducted in cell and animal models, not humans) remain unclear. Since there is no patient-facing element to preclinical laboratory research, and basic scientists rarely interact with patients (unlike clinical researchers), the extent to which patients have been engaged in preclinical research, and methods for engagement in this type of research are less intuitive.

To address this lack of methods for engagement, our team conducted a **Scoping Review**⁶ to identify published examples of patient engagement in preclinical laboratory research and synthesize recent trends in this setting (**Box 2**). In addition, we conducted **interviews**⁵ with researchers and patient partners who had previous experience in this area to identify approaches, barriers, and enablers to patient engagement in preclinical research (**Box 3**). In this brief, this work forms the foundation on which we outline potential challenges to implementing patient engagement in preclinical research and propose recommendations to address these challenges.

Box 1. Patient Engagement Terminology

The term *Patient Engagement (PE)* refers to “meaningful and active collaboration in governance, priority setting, conducting research and knowledge translation”¹³. The term *Patient* encompasses “individuals with personal experience of a health issue and informal caregivers, including family and friends”¹³. It differs from the more traditional role of participating in research studies, as the research is designed, conducted, and reported “with” patients, not “about” or “on” them¹¹. Patients that become members of research teams or collaborate in the research process are also commonly referred to as *patient partners*.

Patient partners can engage at different levels, including sharing, consulting, deliberating, and collaborating, depending on the issue, and the goals of the engagement. The Ontario Patient Engagement Framework demonstrates the various levels of engagement and stages of research at which each can occur¹⁴. The four levels are outlined below with potential preclinical examples:

Share: when sharing, communication is one-way, from the health organizations to patient partners. Typically, patient partners receive information about the project to have a sufficient background that helps them form personal opinions. Examples here are a research group hosting an information session, or forums to share their ongoing lab research to test a new cancer therapy in mice, with the public.

Consult: when consulting, opinion and feedback is obtained and acknowledged from patient partners on an issue or decision of interest. For example, a research group can have a roundtable, focus group, discussions between patient partners and researchers about a new cancer therapy in development, to get their perspective and inform the downstream research projects.

Deliberate: when deliberating, patients are involved in discussions on an issue or decision and look to identify ways to address these questions. For example, a partnership between researchers and patients to inform a preclinical research project’s deliverables.

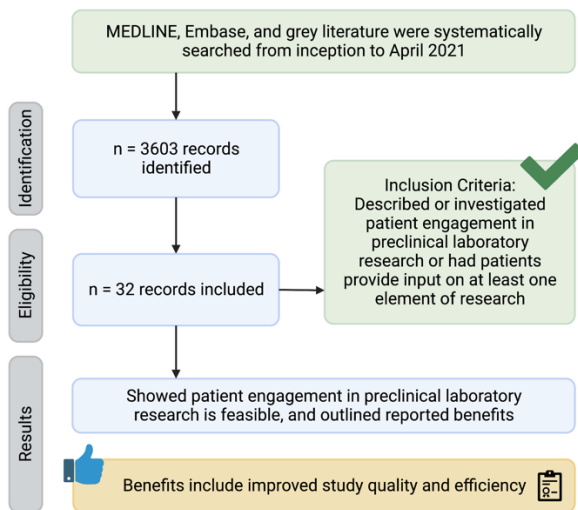
Collaborate: when collaborating, all members of deliberations (i.e., patient partners, researchers, planners, etc.) work together to implement strategies to address the issue or decision of interest. For example, patients and researchers may work together on a systematic review to answer knowledge gaps about a cancer therapy in development.

Challenges

The following challenges were identified in our work to date: (1) the need for a shift in current scientific culture to promote awareness and understanding of preclinical patient engagement, as well as a need for provision of guidance on how to meaningfully engage patient partners in preclinical settings; (2) time and resource limitations; and (3) preclinical laboratory research is not typically patient/public facing, and preclinical researchers/trainees and patients typically do not have experience interacting with each other in this research setting. These challenges can be viewed at two levels: the researcher/patient partner level, as well as institutionally.

Box 2. Summary of Scoping Review Findings - Patient Engagement in Preclinical Laboratory Research

The evidence indicates that patient engagement is becoming increasingly common in clinical research, but little is known about the prevalence and effects of patient involvement in preclinical laboratory research. This scoping review aimed to map and synthesize the current patient engagement practices in the domain of preclinical laboratory research.



Despite these promising findings, barriers were also identified. A key reported barrier was that differences in knowledge can complicate communication efforts (e.g., researchers require more knowledge about the patient experience of a condition; patients require more knowledge about preclinical research, Appendix A, [Fig 1](#)).

Box 3. Engaging Patients in Preclinical Laboratory Research: An Interview Study - Summary

An interview study was conducted to better understand how patient partners and researchers have worked together in the space of preclinical research, and to identify existing barriers and enablers. We recruited researchers (n=14) and patient partners (n=15) with previous experience in a preclinical patient engagement initiative. We identified the following themes through a formal analysis of transcribed interviews.

1) 'A shift in research culture is required'

- Preclinical researchers often have limited experience in interacting with patients as preclinical research is typically not patient-facing. Cultural changes (e.g., providing resources, guidance, support) may help to encourage adopting patient engagement, a new practice in this domain of research.

2) 'Understanding the value of patient engagement in preclinical research'

- The value of patient engagement may be less intuitive in preclinical research. Educational resources and case studies are needed to provide rationale for patient engagement in this early stage of research and clarify perceptions hindering patient engagement.
- From our Patient Engagement in Basic Science Working group discussions, we note that it will be important for patient partners to understand the value of their contributions to preclinical research.

3) 'Clear and common vocabulary is required'

- Effort should be made by teams to explain the research in non-technical language and encourage questions and comments from patient partners to ensure understanding.
- We note that it will be important for researchers to complete training to develop the appropriate skills for communicating effectively with patient partners about their condition and collaborating as partners (e.g., science communication, taking a trauma-informed approach, etc.).

4) 'Need to take a thoughtful and tailored approach'

- Involve patient partners early and throughout the research project; establish a relationship and keep lines of communication open by accounting for patient partner needs, preferences, burden, and contributions.
- Avoid tokenism (the "false appearance of inclusiveness") and engage patient partners purposefully¹.

5) 'Varied goals for engagement in preclinical research'

- It is important for teams to discuss aims for both patient partners and researchers to identify activities that are valuable and beneficial to both groups.

These findings also highlight a number of practical considerations for implementing patient engagement in preclinical laboratory research.

Options for addressing the challenges

Based on the 3 key identified challenges from our scoping review and interview study, we propose 3 solutions for research groups, and stakeholders that support them, such as research institutions and funding agencies. The 3 options are:

- 1) Raising awareness of the value of patient engagement in and to preclinical research and fostering an inclusive culture in the laboratory.
- 2) Working with patient partners to co-create a well-defined plan to incorporate patient engagement into the study timeline and budget.
- 3) Taking a thoughtful and tailored approach to engagement, by taking the time to develop partnerships, create a common ground/vocabulary and identify shared goals for preclinical research, which may need to be done outside the confines of a research study.

The focus of this policy brief is to help institutions, funding agencies and preclinical research groups determine which solution(s) are most feasible or needed. This brief may additionally be helpful to patients interested in partnering with preclinical research groups. The following sections will discuss each challenge and outline suggested strategies to overcome these challenges.

Challenge #1: The need for a shift in scientific culture to promote awareness and understanding of preclinical patient engagement

Although patients are the ‘ultimate end-users’ of therapies and treatments developed by efforts that start with preclinical research, the non-patient/public facing nature of this research poses a challenge to engagement.^{5,9} This includes both physical barriers, in that labs are often in secure, locked areas of research buildings, and cultural barriers, as patients have typically been quite removed from preclinical research (e.g., most lab-based researchers don’t interact on a daily basis with patients like many clinical researchers do). The traditional culture of preclinical laboratory research, and certain preconceptions about patient engagement, thus present as barriers to adoption of this novel practice.^{5,6} Our interviews of preclinical researchers and patient partners and reports from others, have helped highlight the following factors that may impede patient engagement in preclinical work:^{5,9}

- It may be difficult to pinpoint advantages as benefits (e.g., bi-directional learning, strengthening motivation) are often considered

to be less tangible and more subtle in comparison to clinical research (e.g., feedback on patient-facing documents, recruitment strategies).⁵

- Both patient partners and researchers have expressed it is inappropriate for patients to provide input on experimental methods/techniques.⁵
- Some researchers have identified concerns that incorporating patients unfamiliar with the scientific method, and who hold divergent agendas, could disrupt the long-established paradigm for conducting research, consequently deviating from the research objectives.⁹
- Patient engagement is rarely a requisite for career advancement. Traditional metrics such as number of publications, citations, and time spent in labs, etc. are viewed as more impactful for a researcher’s career trajectory, and are prioritized over patient engagement.⁵
- Though researchers may have concerns that patients will not be as interested in engaging in preclinical research and are difficult to recruit,^{5,15} our interviews suggest there is enthusiasm for engagement in lab-based research.
- Researchers and patient partners may not feel confident to undertake an engagement initiative due to a lack of preclinical specific engagement guidance and training.^{5,9,15}
- Conversely, patient partners have noted that training/required skills have presented as barriers to becoming involved in research.⁵
- It may be more challenging for patient partners and preclinical researchers to connect, as compared to clinical engagement opportunities.^{5,15}

However, it has been noted that investigators’ negative preconceptions of preclinical and clinical patient engagement can be attributed to not having engaged patients or being less familiar with the practice.^{9,12} Our interviews indicate that ‘early adopters’ of preclinical patient engagement have recognized the benefits of engaging patients in preclinical research. These benefits include learning more about the patient perspective and day to day life, which improved the alignment of their research with patient priorities and interests (see **Box 4** for example). Reciprocally, it provided an opportunity for patients to learn more about their condition.⁵

Box 4. Case Study: Identifying New Research Priorities and Questions



Image from BMJ Open Science¹⁶

Patient engagement can have important and profound impacts on preclinical research. One example that showcases this well, is the work of Dr. David Weinstein.^{16,17}

His laboratory focused on studying Glycogen Storage Disease Type 1a, a rare pediatric disease which requires regular administration of corn starch every few hours to meet basic metabolic requirements. When discussing with parents of patients, his team discovered a more immediate need than a cure: a slow-release supplement that would allow pediatric patients to receive the treatment they need for an extended period of time. Importantly, as pointed out by parents of patients, this would allow them to sleep through the night uninterrupted. Dr. Weinstein's team was able to research and develop this slow-release supplement (now an approved therapy). Partnering with families helped to shape the team's research according to patient and parent needs, improving the existing therapy to better address patient and caregiver quality of life.

Later, building on these partnerships, an international multi-stakeholder workshop involving both patient partners and healthcare professionals agreed on the top 11 priorities for liver Glycogen Storage Disease.¹⁷

mindset. This shift to acceptance of preclinical patient engagement will need to occur at both an institutional and an individual level.

At an institutional level, funding agencies, universities and research institutes can begin this shift (and countering of any negative preconceptions) by making research/patient teams aware of existing guidance to better understand the value of patient engagement and resources on 'how-to'. A number of guides, educational modules, examples of good practice, and evaluation tools already exist (see **Appendix A, Table 2**). Our team is collating existing evidence into a guiding framework and a "one-stop-shop" of online resources. Opportunities may also exist for collaboration between preclinical and clinical researchers working in patient engagement. Institutions may also help to showcase the benefits of preclinical patient engagement (**Box 5**) and adopt methods to recognize patient engagement (e.g., credit towards hiring and promotion). Similarly, funders can encourage patient engagement by incorporating this into their evaluation rubrics of proposals, and involving patients in governance positions (e.g., review of grant proposals, engagement strategies, etc.).

To enhance capability, it is essential to incorporate patient engagement training throughout all levels of a researcher's education and professional development (see **Box 6**). Similarly, training for patient partners should also be offered to ensure they understand the preclinical concepts at hand, vocabulary and scientific methods and feel confident to contribute. This will involve the participation of many groups beyond the preclinical space and will require time, financial resources, and coordination of multiple stakeholders.

An opportunity must also be provided for patient engagement to "take up space" in preclinical laboratory research. At an individual level, researchers and patients may help to do this by addressing physical barriers that exist, and through developing a metaphorical space/inclusive culture. As noted, preclinical researchers may find it difficult to connect with patients, while patients may not be aware of preclinical engagement opportunities, or face challenges with connecting and getting entry to the lab. Teams may work towards addressing these challenges by connecting with their funders/hospitals/research institutes to help publicize opportunities for engagement, connecting with clinicians, clinical researchers or other relevant organizations such as health charities to help recruit interested patient partners,⁵ and defining processes for lab access (or by holding meetings at a neutral location).¹⁸

Solution #1: Raising awareness about the value and 'how-to' of patient engagement in preclinical research & fostering an inclusive culture in the laboratory

Acceptance of patient engagement in preclinical research requires a deliberate shift in current scientific culture, as well as appreciation for the value of experience-based knowledge.^{5,7} This entails a rethinking of the conventional research models that are deeply engrained in preclinical research. Additionally, this requires realizing that input from patients, who have not traditionally been a part of research teams, and a divergence from the traditional research agenda may not be a risk, but rather the desired outcome to better align research with patient priorities.⁷ This shift will allow for research to better align with patient priorities and can improve researcher communication skills in explaining science to a non-expert; it also allows for meaningful input from individuals outside the traditional research

Box 5. Motivations for and Benefits of Preclinical Patient Engagement

- Opportunity for researchers to learn about and appreciate patient experiences and for patients to learn more about ongoing research and potential impact for future patients and research studies (e.g., exchange of knowledge)^{5,6,15}
- Empowering and rewarding for patient partners; may allow patient partners to feel more confident and knowledgeable about their condition^{5,15}
- Developing new skills (including communications skills), knowledge, interests, perspectives, projects/collaborations and priorities^{6,15}
- Improving motivation for the research/collaborations and/or retention of trainees^{5,6,15}
- Enhances study quality, efficiency and relevance^{5,6,15}
- Strengthens communication/dissemination/trust, by bridging the gap between the public and science^{5,6,15}
- Patient partners can contribute to science in a way they did not realize was possible
- Have the opportunity to learn about cutting edge technologies and scientific methods
- Interactions between patient partners and trainees can be very rewarding

Creation of a ‘psychological safe space’ will also be required to help patients feel welcome, included and comfortable to share their experiences and engage in research (e.g., establishing accountability among lab members for the patient partners involved, ensuring that the vocabulary is accessible to everyone, and supporting mutual knowledge sharing).⁵ Patient partners who had been a part of an inclusive preclinical space identified a number of benefits including patient empowerment, feeling confident and knowledgeable to talk about their disease, and gaining a valuable experience.⁵ Meanwhile, researcher-centered benefits of engagement included being able to connect a story to their research, and in doing so, being reminded of why they are conducting their research.⁵

Box 6. Case Study: Emma Gerber’s Experience Engaging Patients in her PhD



Left to right: Yelena Aizenberg, Shannon Kadar, Julie Mulligan, Emma Gerber, Karen Bemister, Donna Pepin, Peggy Pickett

As an ovarian cancer research trainee, I know the important statistics and molecular mechanisms related to this disease. However, I lacked a human connection to what I was studying. After learning about patient engagement, I recognized its potential value, but did not know how to begin engaging patient partners in my research. Thanks to support from my university and Ovarian Cancer Canada’s Patient Partners in Research group, I was able to connect with a panel of patient partners with lived experience of ovarian cancer to discuss engagement opportunities in my PhD thesis project.

The prospect of engaging with patients in discussions excited me, and the panel’s enthusiasm was contagious. Based on their lived experiences they highlighted the importance of identifying minimally invasive biomarkers to guide ovarian cancer treatment. Importantly, input provided by patient partners enhanced my planned studies. For example, comparing biomarkers of interest at initial diagnosis and in a recurrent setting was suggested, which had not been originally included in my research plan.

Embarking on this journey of patient engagement as a graduate student has been immensely rewarding. As someone without a personal connection to ovarian cancer, this experience has transformed my research, infusing it with a sense of grounding and humanity. Amidst the challenges of academic research, this has been a powerful source of motivation. Having had this experience early in my career motivates me to pursue future research collaboratively with those who have lived experience of the conditions being studied.

Box 7. Ideas to ‘make space’ for patient engagement in laboratory research	
Facilitate Connections	<ul style="list-style-type: none"> Funders, charities, patient organizations and institutions (e.g., hospitals, research institutes) can help to connect research teams with patients who are interested in partnering on research projects. For example, through our local institution, the Office for Patient Engagement in Research Activities (OPERA) has dedicated facilitators available to meet with Ottawa Hospital Research Institute teams for a consultation and to assist in identifying and connecting them with one or more interested patients through The Ottawa Hospital’s Patient and Family Advisory Council (PFAC). One of our funders (BioCanRx), is also currently developing a database/portal to help connect patients interested in collaborating with network investigators. Another (Stem Cell Network) includes patient and caregiver champions who assist in communications and knowledge mobilization initiatives and programs. Health charities (such as Ovarian Cancer Canada and Cystic Fibrosis Canada) can also be excellent partners and collaborators in identifying patient champions within their networks. Through facilitating such connections, these organizations aim to encourage meaningful engagement, where patient partners can reach out to get involved in projects that suit their interests, while also allowing research teams to connect with patients early on in the process (from the beginning of their projects).
Address Accessibility and Logistics	<ul style="list-style-type: none"> There is a need to work out logistics for patients to access the institution. Patient partners noted that institutional training can sometimes be a barrier. It is therefore important to consider necessary onboarding processes (e.g., will an ID badge and/or IT access be necessary?). It is important to consider ways to ensure patient partners are comfortable at meetings or events – e.g., use of a neutral location should be considered. Ensuring active engagement through asking for feedback, having more than one patient partner in attendance or having a familiar face present should also be considered.¹⁸ Our interview study and a recent scoping review also identified that patient partners can help to support logistics of preclinical engagement initiatives (e.g. providing input on recruitment approaches).^{5,15}
Invite to conferences and meetings	<ul style="list-style-type: none"> In a case study, patients attended a pre-conference workshop, which included key Alport syndrome stakeholders (patients, preclinical and clinical researchers, clinicians and industry).¹⁹ In this workshop, patients were included in various activities such as patients sharing about their condition/experiences, and viewing of patient-developed resources on Alport syndrome to make space for patients at the conference.
Engrain in practice through training	<ul style="list-style-type: none"> Our team now asks all members (trainees, research staff, patient partners) to complete the Canadian Institutes of Health Research – Institute of Musculoskeletal Health and Arthritis’ patient engagement training modules.²⁰ These four online training modules encompass defining patient engagement, details on the research process and how to support patient partners through it, how to set up a research project with patient engagement, and how to engage patients on a research team. A certificate is earned once each of the training modules is completed. Case studies identified through our scoping review, interviews and more recent literature scans demonstrated that some funders or institutions are providing training for patient partners (on research or patient engagement in research) and/or for researchers (on engagement, though not necessarily specific to preclinical engagement).^{5,21} One study showcased how patient engagement can be incorporated into a university curriculum as part of a course.²²2023-10-20 11:35:00 AM
Engrain in institutional practices and team roles	<ul style="list-style-type: none"> Institutions may involve patients in governance positions. For instance, the University College Dublin (UCD) Centre for Arthritis Research includes patient representative positions within both a steering committee and interview panels for certain staff selections.¹⁸ The Alzheimer’s Society has also engrained patient engagement through incorporation of a patient ‘monitor’ position to review progress and provide input on funded projects at certain check-points.^{21,23} The Ottawa Hospital ELEVATE grant competition has performed patient engagement since inception with 2 patients as peer reviewers (see Appendix B, Table 3 for further examples)

Though this proposed strategy of raising awareness may improve wider implementation of preclinical patient engagement, it should be noted that a change in the scientific culture will take time to be accepted and implemented by the wide range of individuals/organizations involved. Furthermore, an unintended consequence may be ‘tokenistic’ engagement (the “false appearance of inclusiveness”), where patients are not truly participating in research.¹ Preclinical researchers and patients should therefore use existing tools to evaluate their engagement processes and document impacts.⁹ This is particularly important to help develop the growing body of evidence to support preclinical patient engagement.⁷ Additionally, it can be used to recognize efforts, inform changes at the institutional level, and identify areas for improvement.⁷

Challenge #2: Time and resource limitations

Meaningful patient engagement requires time and financial commitments.⁷ To ensure that patient partners are successfully integrated into the research team, study timelines may need to be modified to account for their involvement.⁵ However, in many cases, patient engagement activities may not be considered ahead of time in the study budget, which can lead to funding and time constraints. These issues may limit the involvement of patient partners. Although the largest proportion of health research funding in many countries is largely directed to preclinical and fundamental research (e.g. Canada, UK, USA, Australia), the extent to which it is allocated towards patient engagement in this field is unclear.

Overall, practical resource allocation in relation to institutional funding competitions and internal team budgeting is an important step for establishing productive collaboration with patients in preclinical research.⁹ In terms of supporting patient partners, time and financial resources are necessary for aspects related to recruitment, onboarding and training, travel/accommodation reimbursement, and compensation.^{6,12,24–27} It is also important to consider the resources required for patient engagement by means of appointing staff to provide facilitative support, such as planning patient engagement activities, and maintaining patient partner involvement in the study.^{6,12,24,28}

Consequently, resource limitations can lead to lack of patient diversity, time conflicts between researchers and patient partners, insufficient time for patient partners to review study documents, and increased workload for the researchers.^{28–31} These limitations, as seen in survey and interview studies, have been emphasized by researchers as well as patient partners.^{5,9,12,28} For example,

preclinical researchers and patient partners have indicated that negative interactions or experiences can in part be owed to lack of investing appropriate time and effort into patient engagement.⁵ Overall, a lack of resources and tools may delay inclusion of patient partners in preclinical research and hinder the impact of patient engagement efforts.

Solution #2: Create a well-defined strategy to incorporate patient engagement into the study timeline and budget

Efficient resource and time allocation, both with respect to calls put forth by institutions/funding agencies and internal team budgeting, will be important steps to establishing meaningful patient engagement in preclinical research.⁹ Appropriate budgeting at the time of the grant application may allow for better allocation of resources towards support for patient engagement, patient partner reimbursement, and patient partner recognition (i.e., offering something of monetary value, goods or services in exchange for patient partner involvement) to recognize their time and contributions. Recognition of patient partners is an important consideration highlighted by the Canadian Institutes of Health Research (CIHR),³² and can help to allow for improved diversity, and creation of meaningful, long-term, sustainable partnerships [ref]. As such, patient engagement activities should be incorporated into the study timeline and budget as early as possible.¹⁰

A well-defined written patient engagement strategy can establish how early priority-setting for patient engagement will be achieved, help prepare for collaboration, and allow for the explicit distribution of roles and responsibilities.^{6,7} Further, it allows for realistic, clear expectations to be established and communicated to patient partners from the outset of a research study. It can also facilitate internal conversations that address how the timeframe, budget, and project-specific goals will be influenced by patient engagement, as well as identify candidates to lead collaboration efforts (i.e., oversee internal tasks, communicate with patient organizations, etc.).^{7,10} Once patient partners have been onboarded, this can be further expanded into a co-developed project to ensure that the expectations and purpose of this partnership are clear, and to then identify strategies to optimize the productivity of the partnership.¹⁰ At this time, the team should also discuss with patient partners how they would like to be acknowledged throughout the project. Recognition can take several forms including non-financial compensation (e.g., co-authorship, gift, acknowledgement) and financial compensation (e.g.,

check, honoraria, salary). However, it is important to consider **how** patient partners would like to receive compensation for their contributions. For example, some may prefer to receive a gift, to donate their financial compensation, or not to receive compensation in any form. Financial compensation may have impacts on a patient partner's income tax or ability to accept disability payments. Similarly, though some patient partners may like to be recognized through authorship or in the acknowledgements, others may wish to remain anonymous. As noted by patient partners in our Patient

Box 8. The Need to Incorporate Patient Engagement into the Study Timeline and Budget

In one study identified by our scoping review, the authors outline a problematic example where a board member of the research consortium cold called a patient organization the evening before a board meeting to propose picking up a patient member the next morning (6:30am), as patient engagement in the study was a requirement by the funder and was to be evaluated.³³ Though an extreme example, this case study showcases poor planning and behaviour from the team. Patient partners should be treated respectfully, as should any member of the team. To work towards this, **time should be taken to develop the partnership and to incorporate plans for patient engagement into the study (e.g., introductions to the team, providing onboarding, attending meetings, and taking part in study tasks).**

Our scoping review also found that relatively few of the identified studies reported on patient partner compensation/reimbursement (23 did not report on whether patients were compensated, while 3 papers reported financial/gift card compensation, and 2 reported on reimbursement of costs).⁶ As described in the excerpt in Box 9 (editorial by Richards et al. on patient partner compensation), patient partners dedicate a significant amount of time towards projects. **It is therefore crucial to consider in advance how patient partners will be compensated and/or acknowledged for their contributions, and to discuss with patient partners what their preferences are (some may want to receive compensation and acknowledgement, while others may not).** The Strategy for Patient Oriented Research (SPOR) Evidence Alliance, the Canadian Institutes of Health Research (CIHR) and the SPOR Networks in Chronic Diseases and the Primary and Integrated Health Care Innovations (PICH) Network provide guidance on patient partner recognition (outlined further in Appendix A, Table 2).^{26,27,32}

Engagement in Basic Science Working Group, although authorship of publications is a major currency in academic research, this type of recognition may or may not be meaningful to patient partners.

Discussing in advance and taking a transparent approach to partnership ensures that associated patient engagement timelines and costs are agreed upon by all collaborators or adjusted in a manner that meets the needs of all parties involved.¹⁰

Bearing in mind the above-mentioned factors which must be accounted for during the planning and priority setting stages, several resources for incorporating patient engagement into the study timeline and budget as early as possible do exist. These include budget templates,^{34–37} patient engagement planning templates/tools (e.g. Terms of Reference),^{38–41} how-to guides,^{10,42–44} guidance on patient partner recognition and compensation,^{26,27,32} as well as other educational/training modules^{11,45,46} (also outlined in **Appendix A, Table 2**). Successfully implementing and expanding patient engagement in preclinical research will also require support from funders.²⁸ Many organizations provide funding opportunities as well as educational and planning help to maximize the impact of patient engagement across health research.^{45–48} These resources highlight key considerations and optimize the funding and time needed for patient engagement and strengthen the collaboration efforts between patient partners and preclinical researchers.

Box 9. Reflection from Richards et al.

“Imagine you are the only person on a research team who does not work in academia or health care—that is, your participation on the team is not part of your job. Because the team meetings are held during your normal working hours, you must take time off work or make up for missed work to attend. You need hours to prepare for each meeting: to read the agenda and materials, research many of the terms, and look up information. On most project calls, you worry that the questions and comments you have will sound silly, off topic, or irrelevant.

For the annual in-person team meeting, you need an additional day of travel on each side of the meeting due to your medical condition's debilitating fatigue, which is something you need to ask for and justify. The meeting format of 8 am to 5 pm, along with a dinner off site for 2 days straight, is exhausting. You are passionate about the research and want to contribute the sole patient perspective to the team.”⁴⁹

Several potential barriers to implementing a patient engagement strategy should also be considered for this solution. For research teams, there may be challenges to involving patient partners early within the project, prior to funding (e.g., it may not be possible to reimburse expenses incurred from engagement (e.g., transportation, parking) let alone provide recognition for patient partner time. However, patient partners have expressed a desire to be involved from the very beginning of a project, and that it can be frustrating to join a project later (when many key decisions have already been made).⁵ One way to address this barrier is to be transparent about funding when identifying and recruiting patient partners, and discuss patient partner preferences. If possible, the team should ensure the budget encompasses funds to reimburse patient partners for any costs and compensate for the estimated time/contributions (if desired by patient partners) if/when the grant is successful. As patient partners should not be required to pay out of pocket to be engaged in research, the team should ensure any expenses are covered or reimbursed.

There may also be concerns that patient engagement will lead to potential disagreements between collaborators when allocating and prioritizing resources (e.g., reducing budget and time from other areas). Discussions with team members about the value of patient engagement (as suggested in Solution #1) may help to address such concerns. Few funding calls exist exclusively for preclinical patient engagement. Until these become more common, teams should consider applying to funding opportunities available for patient engagement within the umbrella of health research.

Challenge #3: Preclinical research is not typically patient-facing and preclinical researchers and patient partners do not typically have experience interacting and communicating with each other in research settings

Patient engagement in research aims to bring together various perspectives, and recognizes different types of expertise (e.g., lived experience, professional knowledge, and skills).⁵⁻⁷ Differing perspectives and life experiences are in fact a core component of patient engagement and are beneficial in identifying new ideas for research projects. For example, patient partner perspectives can oftentimes identify new priorities and shape the trajectory of the research project¹⁶. Despite this, we anticipate that differing backgrounds and goals across team members (e.g., patients, caregivers, preclinical researchers, clinicians, patient engagement specialists) may also present challenges to implementation of preclinical patient engagement.

In our scoping review assessing the landscape of patient engagement in preclinical laboratory research, we conducted an analysis of challenges to this type of engagement.⁶ Three studies identified that differences in knowledge and research experience between researchers and patient partners can present challenges to engagement. These challenges may be attributed to the fact that laboratory research is traditionally non-patient-facing and preclinical researchers may not have adequate training and/or experience to communicate with patient partners.⁶ Without regular interaction with patients (as clinicians are accustomed to), preclinical researchers may not have developed the appropriate skills to communicate with patients about their condition. Training for preclinical researchers on communication, collaborating with diverse stakeholders, as well as specialized training depending on the condition (e.g., training on taking a trauma-informed approach) will be needed to ensure they are equipped to work with patient partners. Furthermore, development of such skills will help to allow for bidirectional discussions and learning. On the other hand, as patient partners typically do not have a background in preclinical research, it is also important for preclinical researchers to use non-technical vocabulary and to provide necessary background information and training to facilitate effective patient partner communication. Our interviews observed that both patient partners and researchers feel explaining or understanding scientific concepts can be challenging, and that a common vocabulary must be developed to allow for meaningful collaboration.⁵ While researchers felt it was their responsibility to provide information in a non-technical manner, patient partners saw this as a shared responsibility. In addition to research teams making an effort to communicate in an accessible manner and providing the necessary tools/information, patient partners felt it was their responsibility to work towards an understanding and to ask questions. Working towards clear communication and a common vocabulary therefore represents a key challenge in preclinical patient engagement.

Our interview study also suggests that patient partner and researcher motivations and aims for patient engagement may vary.⁵ For example, patient partners may be motivated by and focused on improving downstream care for future patients. Identifying engagement activities that align with this goal may therefore be difficult, as the preclinical stage of research is often exploratory, and may be years away from having a clinical impact. Conversely, researchers were found to have quite different and varied aims and motivations for patient engagement, including enhancing the research, improving and refining researcher communication, sharing or education about the ongoing research,

identifying new priorities, providing support to broader engagement initiatives, and input on how the research is disseminated. These varied aims and motivations can present challenges to coming to a consensus on the path forward for engagement. One researcher also noted that some teams may not know what their goal for engagement is (e.g., engaging patients because it is a new trend or encouraged by the funder), which may also raise concerns of the potential for tokenism.

Solution #3: Take a thoughtful and tailored approach by taking the time to develop partnerships, create a common ground/vocabulary and identify shared goals for preclinical research

Along with the approaches described in Solution #1 (establishing a physical and psychological safe space for patient engagement) and #2 (creating a well-defined plan through development of a terms of reference and budget), findings from our interview study suggest it is critical to take time at the beginning to introduce patient partners, to get to know each other, and to develop a true partnership.³ This will help create stronger relationships, engender trust and increase chances of developing team psychological safety. Social events are one such approach to getting to know each other better (as described by Kowatsch et al.)^{50,51} although the approach to fostering relationships should be tailored and adapted in ways that make sense to the particular patient partner and research team.

A secondary and related step is to determine common vocabulary or processes to work towards this. For example, one of our team's patient engagement programs (National Preclinical Sepsis Platform, **Box 10**) has identified providing non-technical introductions of the research/debriefs before or after meetings and co-creation of a glossary of terms can be beneficial to both patient partners and researchers. Participants from our recent interview study had suggested working as a team to co-develop resources/presentations, providing onboarding/training/information sessions (and discussing with patient partners the resources they need), focussing on high level concepts at a manageable pace, explicitly explaining links between concepts, using visual demonstrations, creating a glossary of terms, ensuring open communication and encouraging questions.⁵ Through use of more accessible vocabulary, teams may be able to develop scientists' abilities to communicate effectively generally, avoid confusion, and more efficiently collaborate through effective communication with a shared vocabulary. We also recommend research

teams explore available training in communication and collaboration (e.g., science communication, partnering with diverse stakeholders, taking a trauma-informed approach, working with vulnerable groups, etc.) to develop the necessary skillset to work with patients as the effort will also benefit their ability to communicate generally.

As seen in our interviews and from our work with the Patient Engagement in Preclinical Research Working Group, team members may also have a variety of different priorities and goals. It is therefore important for the team to take time to discuss both groups' goals and work together to reach a consensus on shared objectives and determine next steps for the research engagement. By working towards this common ground at the beginning of the project, this may help to clarify goals and identify mutual benefits, which may enable a more productive collaboration.

We note that there may be barriers to implementation of the approaches for this solution. Additional education and training required for both researchers and patient partners to establish a common vocabulary and to unify the differences in knowledge may increase initial costs and time commitments. However, as described above, researchers and patient partners interviewed shared advice for working towards a common vocabulary by co-developing resources,⁵ which may be a less cost-intensive option for creating such educational and training resources. Furthermore, as such education and training may also work towards addressing challenges #1 and #2, we anticipate that this solution will have positive effects outweighing the cost and time commitments.

Another potential barrier may be that even when all the necessary steps are taken to establish a common ground, this does not necessarily guarantee cooperation to build consensus. Achieving agreement on goals and priorities may remain a challenge (e.g., patient partners may be more focused on having an impact on future care whereas preclinical researchers may be focused on improving the relevance of the preclinical research). To address such situations, teams may consider working with their local Strategy for Patient-Oriented Research (SPOR) unit, or incorporating a patient engagement facilitator on their team, to mediate and reach a decision on how to proceed in a manner that is agreeable to all team members.

Box 10. Patient Engagement - Shaping Research

In 2017, the Blueprint Translational Research Group at the Ottawa Hospital Research Institute partnered with patients to work together on knowledge synthesis studies to inform the design of an early phase clinical trial for a novel cancer immunotherapy⁵². Upon completion of the knowledge synthesis projects, the team discussed how they may continue to work together during conduct of the trial. Patient partners identified the need for trial participant resources to clarify the informed consent process. This has led to the prioritization of co-developing visual consent aids and a non-technical summary to supplement the standardized informed consent document⁵³, see Appendix A, [Fig 2](#).

Similarly, the National Preclinical Sepsis Platform (NPSP) provides an example of how patient engagement can shape *preclinical* laboratory research. The NPSP includes patient partners who are identifying new perspectives and priorities for sepsis (severe infection, which can lead to organ dysfunction) research. Though still in the early stages of their project, through attendance at laboratory meetings, patient partners have identified several clinically relevant outcomes that would be of interest to measure in animal experiments.

To take a thoughtful and tailored approach, the group held an icebreaker/ non-technical session to discuss the NPSP goals, the experimental model and patient partner questions, and worked as a team to co-develop terms of reference. Additionally, the team has worked together on several grant applications to fund a priority-setting exercise (to identify a patient-important question that could be assessed in a sepsis mouse model), co-conduct of a preclinical systematic review to address this question, and eventually co-development of a laboratory experiment to further study the identified question of interest. By working with patient partners from the start (e.g., grant/project development) to identify shared goals, the team believes this will have important downstream impact, by ensuring their research is relevant to the patient community.

Equity Considerations

One of the overarching goals of patient engagement is to promote health equity and health care quality.¹⁴ Health equity is achieved when the distinct needs of all patients are recognized and addressed, no matter their social position.¹⁴ This begins with establishing equitable access to patient partner opportunities.¹⁴ Doing so will ensure that engagement activities include a diverse variety of voices to help researchers and policy makers understand the experiences of the broader population that the research is targeting.⁵⁴ Equitable patient engagement will then influence downstream decision making across clinical practice and thus healthcare quality.¹⁴ By ensuring that the diversity of representation is increased in patient engagement, exclusion of historically marginalized groups through systematic discrimination can be reduced and prevent future exclusion.⁸ Diversity not only extends to patients who have had different physical experiences owing to a certain disease, but also patients who can provide insight on how social factors may impact lived experience.¹⁴ This can be achieved by including patients who have experienced different stages or severity of a disease, patient caregivers, and people belonging to social groups who have been historically disadvantaged within the health system.¹⁴

As patient engagement in preclinical research continues to grow, so will the need to address barriers to equity and diversity.⁵⁵ It can be incredibly difficult to attain appropriate representation, especially due to the limited number of patient partner collaborators that may be feasibly involved within each study.⁶ Awareness of patient engagement activities, as well as access and willingness to participate also reveals systematic biases, which can lead to a perspective that does not represent the general patient population.⁷ For example, the scientifically technical environment of preclinical research may lead to a selection of patient partners who are more familiar with the complex topics and vocabulary at hand to be able to easily communicate with collaborators.^{7,12} The educational and socio-demographic background of those individuals and their lived experiences may be vastly different than the overall population.⁷ To bridge this gap, focusing on training and education programs will ensure that patient engagement activities are accessible to all individuals interested in participating.¹⁰

Time and financial barriers may also inhibit individuals from joining patient engagement programs.¹² These factors must be taken into consideration when planning engagement programs to avoid prioritizing biased opinions from privileged groups.¹⁰ Coordinating with

patient organizations, offering accommodations to encourage participation, recognizing contributions, and emphasizing partnership are promising steps to overcoming these barriers to achieve widespread accessibility.⁶ This also includes ensuring that language used between researchers and patient partners is non-judgmental and does not create a power imbalance.⁸

Considerations for patient engagement in preclinical research

The strategies outlined in this policy brief must also be considered within the bigger picture of patient engagement in preclinical research. Given that this is a relatively new and emerging practice, the solutions will also be impacted by the potential benefits, potential disadvantages, and barriers to implementation (**Table 1**). As described above, future research will help evaluate, refine and establish ‘best practices’ for preclinical patient engagement. Our team’s future directions include development of a guiding framework to amalgamate existing evidence and experiences in this area, to promote and facilitate preclinical patient engagement. The solutions outlined in this brief are viable options that may be implemented both at an individual level (e.g., by preclinical researchers, trainees, staff and patient partners) as well as at an institutional level (e.g., funding agencies, universities, research institutes, patient organizations) to promote wider-spread consideration and adoption of patient engagement in preclinical research, with the goal of ensuring such research aligns with patient priorities and interests.

Table 1. Considerations for Patient Engagement in Preclinical Research:

Category of Finding	Summary of Key Findings
Potential Benefits	<ul style="list-style-type: none"> • Reports suggest that patient engagement can improve the relevance and quality of the research, through patient partners providing important insights (e.g., side effects, priorities).^{5,6,15} Patient engagement allows for mutual learning, development, and opportunities, helps to empower patient partners and motivate research teams, and strengthens communication between the public and scientists.^{5,6,15} • Can strengthen motivation of researchers and trainees to conduct research • Potential for decreasing downstream costs (e.g., involving the end-user improves real world applicability of the intervention which can reduce waste, and cut clinical research and healthcare costs). • More equitable approach to health research.
Potential Disadvantages	<ul style="list-style-type: none"> • May cause an initial increase in cost due increased timelines, patient engagement support staff, etc., however, it is anticipated that the benefits outweigh these initial burdens. A recent estimate using financial modelling has in fact suggested that patient engagement in a clinical trial may help to greatly improve expected net present value (e.g., impacts outweigh resource investment in the tens of millions of dollars).⁵⁶ We posit that the value of patient engagement in preclinical research, will also outweigh time and financial investments, through improving the relevance of the research to patients.
Barriers to Implementation	<ul style="list-style-type: none"> • Patient engagement as a common practice in preclinical research must involve the acceptance and support from many parties that span across educational and research institutions, as well as health systems. This will require resources, time, and collaboration among these groups. • Evidence demonstrating the impact of patient engagement in preclinical laboratory research is limited. This lack of guiding literature may prolong the implementation of patient engagement in this area. Further development of resources and documentation/reporting of patient engagement experiences in preclinical research, may help to facilitate engagement in this novel area.

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Appendix A

Table 2: Existing Supplementary Resources

Type of resource	Citation
How-To Guides	<ul style="list-style-type: none"> • A How-to Guide for Engaging Patients in Preclinical Research from an Industry Perspective: Patient Focused Medicines Development. How-to guide for patient engagement in the early discovery and preclinical phases [Internet]. – How-To Guides for Patient Engagement. 2021 [cited 2022 Nov 8]; Available from: https://pemsuite.org/How-to-Guides/Early-Discovery.pdf • A How-to Guide for Engaging Patients in Preclinical Research from a Charity Organization: Arthritis Research UK. Patient and public involvement: a researcher’s guide [Internet]. Available from: • A How-to Guide for Engaging Patients in Preclinical Research from Government/Charity Organizations: Parkinson’s UK, Alzheimer’s Society, National Institute for Health and Care Research. Planning for involvement [Internet]. [cited 2023 May 12]; Available from: https://sites.google.com/parkinsons.org.uk/ppi-in-lab-based-research/planning-for-involvement • A How-to Guide for Engaging Patients in Preclinical Animal Research from the Animal Research Nexus Programme: Davies G, Gorman R, King G. Informing involvement around animal research [Internet]. 2022; Available from: https://animalresearchnexus.org/sites/default/files/publications/other-files/Informing%20Involvement%20Final%20Report_0.pdf • A How-to Guide for supporting the development of diverse and include patient partnerships: https://www.womensresearch.ca/empact/
Planning	<ul style="list-style-type: none"> • Template of a Terms of Reference for Collaboration between Patient Partners and Researchers: INVOLVE. Template one: terms of reference [Internet]. [cited 2022 Nov 8]; Available from: https://www.invo.org.uk/getting-started/template-one/ • Template of How to Engage Patients in a Research Project: Patient Engagement Planning Tool [Internet]. Sask. Cent. Patient-Oriented Res. [cited 2023 May 12]; Available from: https://www.scpor.ca/patient-engagement-planning-tool • Template of Engagement Plans for Patients in Research: Patient-Centered Outcomes Research Institute (PCORI). PCORI Funded Projects: Sample Engagement Plans [Internet]. 2015 [cited 2023 May 12]; Available from: https://www.pcori.org/sites/default/files/PCORI-Sample-Engagement-Plans.pdf • Template of How to Engage Patients at any Stage of a Research Project: George & Fay Yee Centre for Healthcare Innovation. Methods of Patient & Public Engagement: A Guide. Published online May 20, 2020. Accessed May 12, 2023. https://umanitoba.ca/centre-for-healthcare-innovation/sites/centre-for-healthcare-innovation/files/2021-11/methods-of-patient-and-public-engagement-guide.pdf
Examples of engaging patients	<p>Studies within Scoping Reviews: https://doi.org/10.1016/j.ebiom.2021.103484</p> <ul style="list-style-type: none"> • Fox G, Fergusson DA, Daham Z, Youssef M, Foster M, Poole E, Sharif A, Richards DP, Hendrick K, Mendelson AA, Macala KF, Monfaredi Z, Montroy J, Fiest KM, Presseau J, Lalu MM. Patient engagement in preclinical laboratory research: a scoping review. <i>EBioMedicine</i>. 2021;70:103484 • Carroll P, Dervan A, Maher A, et al. Applying Patient and Public Involvement in preclinical research: A co-created scoping review. <i>Health Expect Int J Public Particip Health Care Health Policy</i>. 2022;25(6):2680-2699. doi:10.1111/hex.13615
Budget Templates	<ul style="list-style-type: none"> • A Guide to Budgeting for Patient Partner Engagement: Mental Health Research Network and INVOLVE. Budgeting for involvement: Practical advice on budgeting for actively involving the public in research studies. 2013; Mental Health Research Network, London and INVOLVE, Eastleigh. • A Guide to Reimbursing and Compensating Patients: Swiss Clinical Trial Organisation. SCTO Remuneration Policy for Patient and Public Involvement (PPI) Activities. 2020.

	<ul style="list-style-type: none"> • Budget Template Spreadsheet for Patient and Public Engagement: The George & Fay Yee Centre for Healthcare Innovation (CHI), University of Manitoba. CHI Patient and Public Engagement Budget Builder [Internet]. 2020 [cited 2023 May 12]; Available from: https://umanitoba.ca/centre-for-healthcare-innovation/sites/centre-for-healthcare-innovation/files/2022-02/2020-01-29_chi_pe_budget_tool_v2.8-3.xlsx • Patient and Public Involvement Cost Calculator: PPI Ignite Network, University College Dublin. Budgeting for PPI - PPI Ignite Network [Internet]. [cited 2023 May 12]; Available from: https://www.ucd.ie/ppi/plan/budgetingforppi/
Educational	<ul style="list-style-type: none"> • Educational Resource about the Potential Benefits of Patient Engagement: CIHR. Patient engagement [Internet]. Gov. Can. 2022 [cited 2022 Oct 11]; Available from: https://cihr-irsc.gc.ca/e/27297.html • Educational Support for Researchers Looking to Engage Patients in Research: OSSU. For researchers [Internet]. OSSU. [cited 2022 Nov 8]; Available from: https://ossu.ca/for-researchers/ • Educational Resource of the Type of Research Strategy for Patient-Oriented Research (SPOR) Funds: CIHR. Funding research [Internet]. Gov. Can. 2022 [cited 2022 Oct 11]; Available from: https://cihr-irsc.gc.ca/e/51038.html • Educational Resource on how to Compensate Patient Partners from the SPOR Network: SPOR Networks in Chronic Diseases, PICHI Network. Recommendations on patient engagement compensation [Internet]. SPOR. 2018; Available from: https://diabetesaction.ca/wp-content/uploads/2018/07/TASK-FORCE-IN-PATIENT-ENGAGEMENT-COMPENSATION-REPORT_FINAL-1.pdf • Educational Resource on how to Compensate Patient Partners from the SPOR Evidence Alliance: SPOR Evidence Alliance. Patient partner appreciation policy and protocol [Internet]. SPOR. 2019; Available from: https://sporevidencealliance.ca/wp-content/uploads/2019/08/SPOR-EA_Patient-Partner-Appreciation-Policy-and-Procedure.pdf
Evaluation	<ul style="list-style-type: none"> • Evaluation Toolkit for Patient Engagement: Center of Excellence on Partnership with Patients and the Public. Engagement assessment toolkit patients and the public [Internet]. Cent. Excell. Partnersh. Patients Public. [cited 2022 Nov 8]; Available from: https://ceppp.ca/en/evaluation-toolkit/
Funding	<p>Information on Funding for Patient Engagement</p> <ul style="list-style-type: none"> • CIHR. Funding research. Government of Canada. Published August 5, 2022. Accessed October 11, 2022. https://cihr-irsc.gc.ca/e/51038.html • Ontario SPOR SUPPORT Unit. OSSU EMPOWER Awards. Accessed May 12, 2023. https://ossu.ca
Reporting	<ul style="list-style-type: none"> • Reporting Guidelines for Patient Engagement: Staniszewska S, Brett J, Simera I, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. <i>BMJ</i>. 2017;358:j3453. doi:10.1136/bmj.j3453 • Patient Engagement Focused Journal: BMC. Research Involvement and Engagement. https://researchinvolvement.biomedcentral.com/
Patient Partner Recognition	<ul style="list-style-type: none"> • Guidance on how to show Patient Partner Appreciation: SPOR Evidence Alliance. Patient partner appreciation policy and protocol [Internet]. SPOR. 2019; Available from: https://sporevidencealliance.ca/wp-content/uploads/2019/08/SPOR-EA_Patient-Partner-Appreciation-Policy-and-Procedure.pdf • Guidance on how to Compensate Patient Partners: SPOR Networks in Chronic Diseases, PICHI Network. Recommendations on patient engagement compensation [Internet]. SPOR. 2018; Available from: https://diabetesaction.ca/wp-content/uploads/2018/07/TASK-FORCE-IN-PATIENT-ENGAGEMENT-COMPENSATION-REPORT_FINAL-1.pdf • Guidelines for how to Compensate Patient Partners: Government of Canada CIHR. Patient Partner Compensation Guidelines - CIHR [Internet]. 2022 [cited 2023 Jun 15]; Available from: https://cihr-irsc.gc.ca/e/53261.html

Appendix B

Table 3: Examples of Patient Engagement in Peer Review

<ul style="list-style-type: none">• The Ottawa Hospital ELEVATE grant competition has performed patient engagement since inception with two patients as peer reviewers.• https://www.ohri.ca/newsroom/story/view/1556?l=en
<ul style="list-style-type: none">• Kidney Research Scientist Core Education and National Training (KRESCENT) has included patients in peer review:• https://cansolveckd.ca/publications/involving-patient-partners-in-the-krescent-peer-review-intent-process-challenges-and-opportunities/• https://pubmed.ncbi.nlm.nih.gov/36406869/
<ul style="list-style-type: none">• Alberta Health Services Mental Health have engaged patients in the peer review process for funding:• https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6915892/
<ul style="list-style-type: none">• The OSSU EMPOWER awards include review comments from members of the Patient Partner Working Group:• https://ossu.ca/for-researchers/work-we-support/ossu-empower-awards/
<ul style="list-style-type: none">• Study on patient involvement in Dutch funding:• https://researchinvolvement.biomedcentral.com/articles/10.1186/s40900-019-0163-1
<ul style="list-style-type: none">• The British Medical Journal (BMJ) includes patient peer reviewers:• https://www.bmj.com/about-bmj/resources-reviewers/guidance-patient-reviewers
<ul style="list-style-type: none">• The journal Research Involvement and Engagement includes patient peer reviewers:• https://researchinvolvement.biomedcentral.com/about/reviewer-guidelines
<ul style="list-style-type: none">• Blog from Dr. Dawn Richards on the topic of patient peer reviewers, and includes tips for engaging patients as peer reviewers:• https://blogs.ubc.ca/imhablog/2023/06/28/engaging-patient-partners-as-peer-reviewers-of-grant-applications-tips-for-everyone-involved/

Figure 1: Summary of the Scoping Review of Patient Engagement in Preclinical Laboratory Research

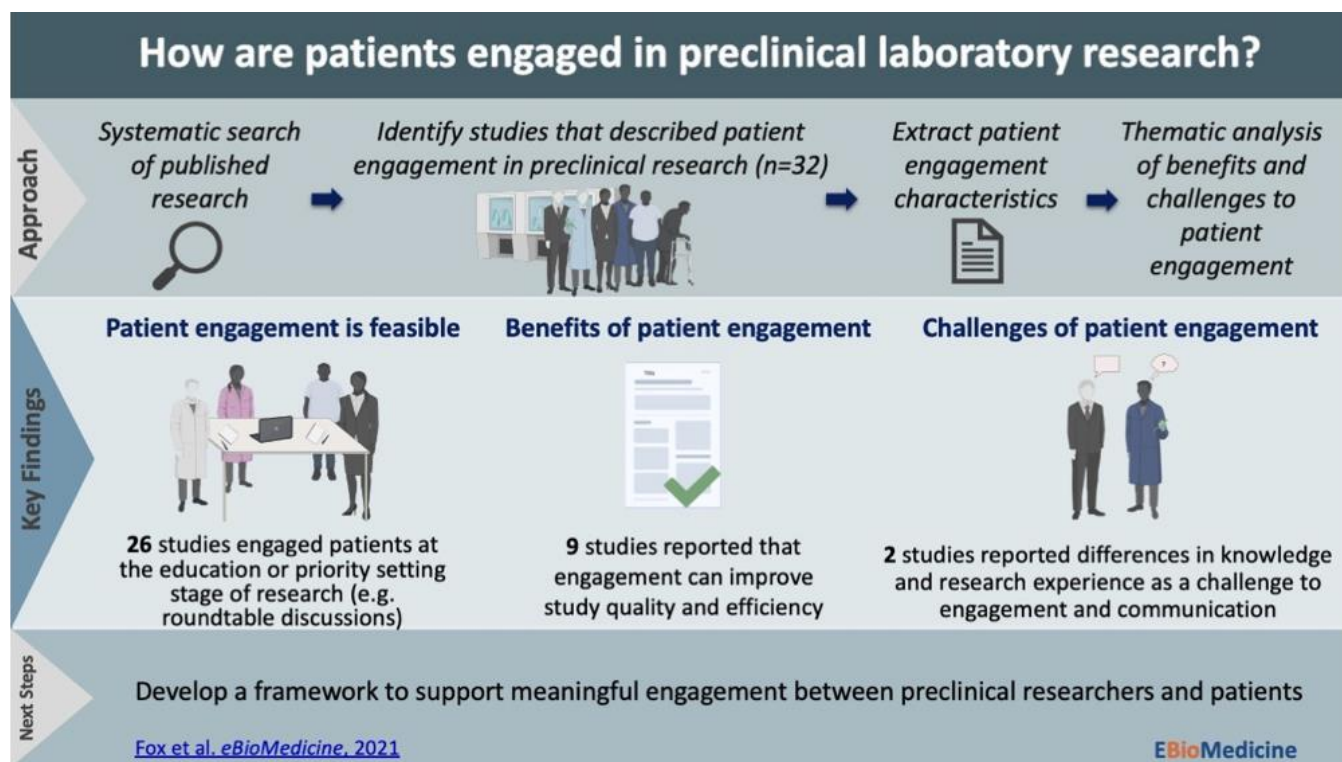


Figure 2: Visual Informed Consent document

Visit	Visit details	Caregiver details	Other activities	Notes
1 Screening Visit	You will be meeting with the study coordinator and the study investigator.	♥ ♥ ♥		
2 Enrollment Up to four weeks before leukapheresis	Tests to ensure you meet eligibility may be completed over multiple visits.	♥ ♥ ♥		
3 Leukapheresis	Your immune cells will be collected here.	♥ ♥ ♥		
4 Day -4, -3, -2	Intravenous chemotherapy: fludarabine, cyclophosphamide	♥ ♥ ♥		
5 Day -1	Checkup appointment	♥		
6 Day 0	CAR-T cell therapy infusion (CLIC-1901)	♥ ♥ ♥		
7 Day 1–13: Hospitalization	You will be hospitalized for a minimum of seven days after CAR-T infusion.	♥ ♥ ♥		
8 Day 14 (+/- 1 day)	Checkup appointment	♥ ♥ ♥		
9 Day 28 (+/- 3 days)	Checkup appointment	♥		
10 Month 2, 3, 4, 5 (+/- 7 days)	Checkup appointment	♥		
11 Month 6, 9, 12 (+/- 7 days)	Checkup appointment	♥		
12 Annual contact (+/- 2 months)	Telephone call			

Maximum half-day hospital visit	♥ ♥ ♥ Caregiver presence is highly encouraged	Blood work	Review of medications taken	You will undergo bone marrow biopsy or imaging (CT or PET); results can take up to two weeks to receive
Full-day hospital visit (maximum eight hours)	♥ Caregiver presence is not necessary but encouraged	Blood work and sample collection for research	Questionnaire	Physical exam
Overnight stay at the hospital				

Note. Visual Informed Consent document. Adopted from “Building a Platform for Meaningful Patient Partnership to Accelerate “Bench-to-Bedside” Translation of Promising New Therapies”, by G.Fox et al., 2022, *Healthcare quarterly (Toronto, Ont.)*, 24(SP), 74–79. Copyright © 2022 Longwoods Publishing. Adopted with permission.



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