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Patient Engagement in Research: A Toolkit for Patient Partners

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PERC Patient Engagement Resource Centre

The goal of the Primary Health Care Patient Engagement Resource Centre is to promote and support meaningful and appropriate engagement of patients (people with lived experience of a health issue, their families, friends and caregivers) in primary health care research in Ontario.

The Resource Centre provides information, resources, and methods support to foster partnerships between researchers and patients to conduct research that addresses patients' needs, preferences and priorities for their health and health care.

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PURPOSE OF THIS TOOLKIT

The purpose of this toolkit is to support patient engagement (PE) in research. The term "patient" describes an individual who has had personal experience with healthcare, as well as the caregivers of such individuals and members of communities who speak to the experience of that community. This is a working document that will be modified as our understanding of the success factors in patient partnership in research expands. It will also grow as we explore new areas to address. This first version addresses themes prioritized by the PERC Advisory Board. It provides information on the research cycle, roles & responsibilities, tips for effective communication, collaboration, and resolving conflicts within the team. This toolkit also contains templates that patient partners (PPs) can use to facilitate their engagement throughout the research process. PERC will continue to identify areas of partnership where it can offer support, and to develop this document and its associated tools to provide that support. This document is the work of a group of individuals with personal experience in PE who have devoted their time to translating their rich experience into concrete recommendations. Most are experienced patient partners. Some are researchers with experience and expertise in PE. We recognize that its content and recommendations are not applicable to all circumstances. This should be considered in the context in which the research is being conducted.

We encourage PPs to share the information, tips and templates presented here with their research teams to facilitate communication about their needs, so as to fully realize their intended contributions during the partnership.

Much of the information contained in this toolkit is derived from existing tools and publications related to the topic of patient engagement in research. In addition, two face-to-face workshops were conducted, one in August 2018 and the other in February 2019, involving patient advisory board members, PERC project team members, experts in the field of PE, and a member of the National SPOR-PIHCIN. The SPOR-PIHCIN is the Strategy for Patient-Oriented Research (SPOR) Primary and Integrated Health Care Innovations Network (PIHCIN), a pan-Canadian network that aims to improve patient experience and health, health equity, and health system outcomes by including the voices and perspectives of citizens in research. Readers are encouraged to explore the tips, templates, videos and information provided in this toolkit to support their effective participation in research.

How to Use this Toolkit

We hope that this toolkit can be used to enrich participation when working on a research team. The ideal time to start using it is when considering joining a research team. The templates will guide PPs through the process, including introduction to the other research team members, sharing of their stories, basis of the terms of reference for participation, review of project information, understanding the steps of the research cycle, and awareness of the roles and responsibilities of each member of the team including the PP themselves. It also provides tips for effective communication. In addition, the toolkit can be used throughout the study by the PP to document the study background, expectations, and roles that foster meaningful engagement in the research process. From your perspective as a PP, you can add notes wherever required and revisit the toolkit periodically to add new information as the team or the project evolves.

A FOUNDATION FOR PATIENT ENGAGEMENT

Traditionally, patient *contributions* to research and research-related activities were restricted to the role of "research participant". Patient *engagement*, however, is about meaningful collaboration. Patients who become patient partners (PPs) in a project can actively engage in governance, priority setting, developing the research questions, and even conducting parts of the research itself. This type of participation helps ensure that the research being conducted is relevant and valuable to the patients it affects. PPs can also collaborate with the research team to help summarize results or share them with target audiences, especially other patients, and with policy makers or other decision makers who may apply the results in a health or community setting.

WHAT IS PATIENT ENGAGEMENT IN RESEARCH?

In Canada, patient engagement is an emerging approach to research. It signifies the meaningful involvement of individuals in research, from agenda-setting and planning to decision-making, implementation and review (CIHR, 2012). In this approach, research is carried out 'with' or 'by' members of the public rather than 'to', 'about', or 'for' them (INVOLVE, 2012). There are multiple ways and levels of engaging patients (see Figure.1), and the degree of patient engagement can vary. Some researchers only provide information to or collect it from their patient participants, while others fully engage patients as partners. The Canadian Institutes of Health Research (CIHR) encourages researchers to actively engage patients (levels 3-5) (CIHR, 2014). When you become an active partner on a research team, it is important to identify your capacity in terms of roles, attributes and areas of participation depending on the research phase and your own knowledge and skills.

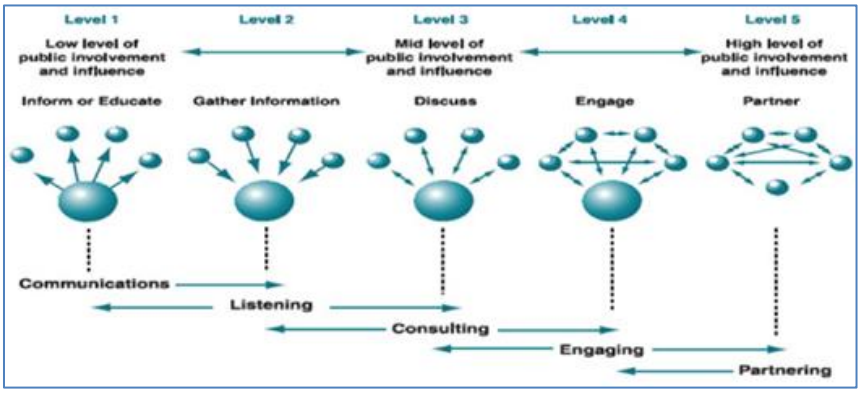


Figure.1 CIHR Levels of patient engagement *(CIHR 2014)*

REFERENCES:

CIHR. (2012). Guide to Knowledge Translation Planning at CIHR. Retrieved from: http://www.cihr-irsc.gc.ca/e/45321.html

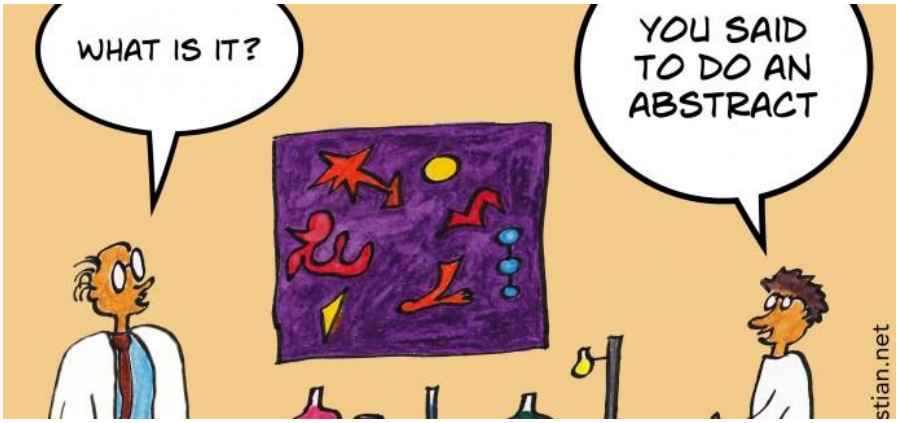
CIHR's SPOR. (2014). Strategy for Patient-Oriented Research Patient Engagement Framework. Retrieved online at: http://www.cihr-irsc.gc.ca/e/documents/spor_framework-en.pdf

INVOLVE's Briefing Notes for Researchers. (2012). http://www.invo.org.uk/wp-content/uploads/2014/11/9938_INVOLVE_Briefing_Notes_WEB.pdf

Research Glossary: Common Terms in Primary Health Care

RESEARCH JARGON: SIMPLER IS BETTER

This area of work, the research partnership, may be new to you. As with any field, this area has its own jargon, and without some form of glossary as a reference it can quickly become discouraging. Another challenge is that researchers often use acronyms and absentmindedly employ them in their communication.



An abstract is a short document that provides a summary of the work.

Research Glossary) contains a list of common terms and acronyms arranged in alphabetical order. It provides definitions and examples for frequently used research terms. You may find it a helpful resource when working on a research team. Our advice is to ask for clarification and never hesitate to ask any questions you have. Acronyms have become such a common part of communication in the research field that new terms are guaranteed to come up often.

RESEARCH GLOSSARY

G L O S S A R Y

A

- **Adverse Events/Effects:**
  Adverse Events or Adverse Effects (AE) are harmful or undesirable consequences of a medication or treatment[1] *(CIHR).*
- **Advocacy:**
  Interventions in the forms of writing, speaking or performing about an issue or for population groups.
- **Applied Research:**
  Research (using a variety of methodologies) that aims to solve practical problems, or answer specific questions. It has a practical application[2] *(CDRIN).*

B

- **Baseline:**
  A starting point or initial measurements taken to establish a picture of what subjects know or are experiencing, or what some physical value is, such as blood pressure. At the end of the study, the results of the research can then be compared to the baseline measurements to assess change[2] *(CDRIN).*
- **Bias:**
  Bias is an error that distorts the objectivity of a study and affects the results. It can arise if a researcher does not adhere to rigorous standards in designing the study, selecting the subjects, administering the treatments, analyzing the data, or reporting and interpreting the study results. It can also result from circumstances beyond a researcher's control, as when there is an uneven distribution of some characteristic between groups as a result of randomization or during the data collection. *For example: when a respondent answers a question in a way that they think is accepted or liked by the researchers. In this process, a respondent may report inaccurate or sensitive information to present themselves in the best possible way. Researchers may reduce such bias by framing the questions correctly or avoiding indirect questions*[1] *(CIHR).*
- **Blinding and its types:**
  Blinding is a method of controlling for bias in study by ensuring that those involved are unable to tell if they are in an experimental group (receiving the intervention) or the control group (not receiving the intervention)[1] *(CIHR)*.
  -In a **single blind experiment**, subjects/patients do not know whether they are receiving the active drug or a placebo in a clinical trial. In health services research, it can relate to a study intervention versus an alternative. For example; a group of

[1] CIHR Glossary of Funding-Related Terms. Retrieved from: http://www.cihr-irsc.gc.ca/e/34190.html
[2] The Canadian Depression Research & Intervention Network (CDRIN). Retrieved from: https://documentcloud.adobe.com/link/track?uri=urn:aaid:scds:US:8f7923ef-8fd7-45fc-aba0-d2acab0bd6b2

patients will receive a patient navigator to assist with organizing their care (intervention) versus another group of patients who receive regular health care resources[1].

-In a **<u>double blind experiment</u>**, neither the subjects/patients nor the persons administering the treatments know which subjects are receiving the active drug treatment or intervention[1].

-In a **<u>triple blind experiment</u>**, neither the subjects/patients, the persons administering the treatments, *nor* the persons evaluating the results are know who is receiving treatment/intervention and who is not[1] *(CIHR).*

C

- **Citizen Engagement:**
  The meaningful involvement of citizens in research or program activities, from agenda-setting and planning to decision making, implementation and review[1] *(CIHR).*
- **Clinical Research:**
  Clinical research is health research on people, typically to evaluate the effectiveness of drugs, devices or medical practices. It may involve researchers asking questions, administering drugs, taking blood or tissue samples, or checking the progress of patients as they are receiving treatment according to a study's protocol. Clinical research studies often have specific criteria such as gender and type of disease to define who can be recruited or enrolled in a particular study[1] *(CIHR).*
- **Clinical Trial & Phases:**
  Clinical trials are pre-planned studies used to evaluate the safety and effectiveness of a pharmaceutical drug treatment. All clinical trials conducted in Canada must first have Health Canada approval[1] *(CIHR).*

  -**<u>Phase- I:</u>** Testing a drug on a very small number of healthy volunteers to establish overall safety and identify side effects, and determine the safe & tolerable dose levels.

  -**<u>Phase- II:</u>** Testing a drug on a **small** number of people who have the condition the drug is designed to treat.

  -**<u>Phase- III:</u>** Testing a drug on a **large** number of people who have the condition the drug is designed to treat.

  -**<u>Phase- IV:</u>** Investigating uses of the drug for other conditions, on a broader patient base (e.g. elderly patients), or for longer term use.
- **Comparator:**
  In clinical trials, the best existing treatment, used as a basis of comparison. When a treatment for a specific medical condition already exists, it would be unethical to do a randomized controlled trial that would require some participants to be given an ineffective substitute (for example, cancer treatment). In this case, new treatments are compared to the best existing treatment, known as the 'gold standard'[1] *(CIHR).*
- **Causal research:**
  Research that looks at what effect one variable has on another.
  For example: A research study may reveal that people who spend a lot of time doing gymnastics are more likely to develop acute joint problems, in this case it might be

tempting to conclude that doing gymnastics causes joint problems. However, it is possible the people who do gymnastics in the study were also long distance runners. Therefore, it is possible to say that there is a ***correlation*** *between gymnastics and joint problems, but we are not sure whether gymnastics is the* ***cause*** *of the joint problems.* ***Randomized control trials****, which try to control factors (i.e., long distance running) not related to the main variable (gymnastics activity) are considered the "gold standard" for establishing causality.*

- **Cohort:**
  The word 'cohort' means a group of people that share defining characteristics among a tested population. Common characteristics are a specific time period (e.g., birth or graduation year), an activity (e.g., playing a sport) and a particular disease or condition[1] *(CIHR).*
  For example: In a cohort of beach volleyball players, a study was designed to assess the impact of sun exposure on skin damage. During a tournament, players from one team wore waterproof, SPF 35 sunscreen, while players from the other team did not wear any sunscreen. At the end of the tournament the skin of players on both teams was analyzed for texture, sun damage, and burns. Comparisons of skin damage were then made based on the use of sunscreen. The analysis showed a significant difference between the cohorts in terms of the skin damage.
- **Control group:**
  A group of subjects who are matched in as many ways as possible (e.g., age, sex, education) to the experimental group but who do not receive the treatment[2] *(CDRIN)*.
- **Collaboration**:
  A mutually beneficial and well-defined relationship entered into by two or more people and/or organizations to achieve common goals. Collaborations include a commitment to mutual objectives, a jointly developed structure, shared responsibility, mutual authority, and accountability for success, and sharing of resources and rewards[3] *(Huang et al., 2018)*
- **Correlational research:**
  Research that looks at relationships between two variables (for example, age of a patient is related to the number of medications prescribed). After statistical analysis that shows a significant result, conclusions can be drawn about the relationship. However, correlational research does not allow researcher to say that one variable *caused* the other[2] *(CDRIN)*.
- **Cross-sectional research:**
  A cross-sectional research study involves looking at people who differ on one key characteristic at one specific time. Data are collected at the same time from people who are similar in other respects. *For example: particular health condition but different in a characteristic of interest such as age, income levels, or geographic*

[3] Huang, K. Y., Kwon, S. C., Cheng, S., et al. (2018). Unpacking Partnership, Engagement, and Collaboration Research to Inform Implementation Strategies Development: Theoretical Frameworks and Emerging Methodologies. *Frontiers in public health*, *6*, 190. doi:10.3389/fpubh.2018.00190

location. These participants can be separated into groups known as **cohorts**[2] *(CDRIN).*
Example 1: A group of participants suffering from asthma in different age groups i.e. 20-30 years, 31-40 years and 41-50 years.
Example 2: A group of participants suffering from asthma in different locations i.e. Town A, B and C of Ontario.

- **Community-based research:**
  Research that is conducted in community settings and is intended to improve community-based interventions and community health[4] *(NAPCRG).*
- **Community Health Centers:**
  Community Health Centres (CHCs) are non-profit organizations that provide primary health care for individuals, families and communities. CHCs provide a wide range of health services which may include prenatal, postpartum, health promotion, disease and injury prevention, bereavement services, communicable disease and school health, immunization and many other community care public health and wellness programs[5] *(PVN).*

D

- **Dissemination:**
  Dissemination involves identifying the appropriate audience and tailoring the message and medium to the audience. Dissemination activities can include such things as summaries for / briefings to stakeholders, educational sessions with patients, practitioners and/or policy makers, engaging knowledge users in developing and executing dissemination/implementation plan, tools creation, and media engagement.[1] *(CIHR)*
  For example: a dietary intervention is proved to help control diabetes complications so this information is shared with family physicians to include when meeting with patients with diabetes so they can implement this diet at home.

E

- **Efficacy:**
  Efficacy can be defined as the performance of an intervention under controlled circumstances. Efficacy answers the question; did the drug or activities being studied produce the intended result? The controlled circumstances can be a highly selective homogeneous population (people with many of the same characteristics) with strict inclusion (can be in the study) and exclusion criteria (characteristics that do not fit with the study)[1] *(CIHR).*

- **Effectiveness:**
  The term effectiveness is applied to the success of the treatment when representative patients are evaluated[1] *(CIHR).* An effectiveness study can be carried out in a real-world setting with a heterogeneous population (people with differing

[4] A glossary for primary care. (1977). *Report of the North American Primary Care Research Group (NAPCRG) Committee on Standard Terminology.* Journal of Family Practice. 5(4):633-8.

[5] Patient Voices Network glossary. Retrieved from: https://patientvoicesbc.ca/resources-old/resources-for-volunteers/glossary-of-terms/

characteristics).

- **Engagement Opportunity:**
  Any process, event or committee in which patient volunteers are invited and supported to share their experiences and perspectives, with the goal of contributing to health care system improvement[5] *(PVN).*
- **Ethics:**
  The branch of philosophy dealing with distinctions between right and wrong, and with the moral consequences of human actions
- **Research Ethics Board:**
  An independent body established in universities and health sciences centers (where research is conducted) that receives and reviews all research proposals involving human subjects to determine the degree to which they may be put at risk. The study can go forward only if the Ethics Review Board grants approval[2] *(CDRIN)*.
- **Epidemiology:**
  Epidemiology is the study of how and why different patterns of health and disease occur among various subgroups in a population[1] *(CIHR)*.
- **Evaluation:**
  Evaluation is the collection of information about a program or process in order to determine whether it achieved its goal. Both research and evaluation have features that center on answering a question but the purpose of evaluation is essentially to improve an existing program, while research is intended to provide support for a theory or hypothesis[1] *(CIHR)*.
- **Evidence based medicine:**
  Medical decisions are made based on the best research available as assessed through a process called critical appraisal. Evidence based medicine, as a model, has expanded to many health disciplines and is called evidence based decision making in this wider context[2] *(CDRIN)*.
- **Experimental group:**
  A group of subjects who will receive the experimental treatment under investigation in a randomized control trial (RCT)[2] *(CDRIN)*.

F

- **Family Health Teams:**
  Primary health care organizations in Ontario that include a team of family physicians, nurse practitioners, registered nurses, social workers, dietitians, and other professionals who work together to provide primary health care for their community. They ensure that people receive the care they need in their communities, as each team is set-up based on local health and community needs.[6] *(MOHLTC).*
- **Family Physician:**
  A doctor who specializes in family medicine and provides health care to people of all ages. Family Physicians are sometimes referred to as General Practitioners (GPs)[5]

[6] Ontario Ministry of Health and Long-Term Care. Retrieved from: http://www.health.gov.on.ca/en/pro/programs/fht/fht_understanding.aspx

(PVN).

G

- **Generalizability:**
  When the results of research can be thought to be true for a larger population than just the study population.
- **Gender:**
  Gender refers to the socially constructed roles, behaviors, expressions and identities of girls, women, boys, men, and gender diverse people. It influences how people perceive themselves and each other, how they act and interact, and the distribution of power and resources in society. Gender is usually conceptualized as a binary (girl/woman and boy/man) yet there is considerable diversity in how individuals and groups understand, experience, and express it[1] *(CIHR).*

H

- **Health care:**
  Health care is the diagnosis, treatment, and prevention of disease, illness, injury and other physical and mental impairments[5] *(PVN).*
- **Health Care Partner:**
  Any health care staff member or similar stakeholder who, in the course of their work, seeks out, supports, and facilitates patient engagement opportunities. These HCPs are often the main point-of-contact for patient partners taking part in engagement opportunities[5] *(PVN).*
- **Health Services Research and its Phases:**
  Health services research is a multidisciplinary field of inquiry, both basic and applied, that examines access to and the use, costs, quality, delivery, organization, financing, and outcomes of health care services to produce new knowledge about the structure, processes, and effects of health services for individuals and populations[7] *(Institute of Medicine, 1979).*

  Health services research phases:

  -Planning: Defining objectives, identifying the problem statement and literature review, formulating research questions, working on study design and defining sample size.

  -Conduct: Recruitment, preparing data collection, analysis and interpretation.

  -Close-out: Dissemination and publishing results.
- **Home Care:**
  A range of health care and support services in their own home for individuals who have acute, chronic, palliative or rehabilitative health care needs. . In-home services include nursing (e.g., wound care, assistance with medication, etc.), rehabilitation, home support and palliative care[5] *(PVN).*
- **Hypothesis:**
  A proposed explanation for some event or phenomenon when the actual cause is either not known or does not adequately explain what is observed. A scientific hypothesis must explain all of the results of a study, and be testable, repeatable, and

[7] Institute of Medicine. Report on health services research. Washington, DC: National Academy Press; 1979.

	refutable (capable of being proven wrong). However, a scientific hypothesis can never be absolutely proven correct, because there is always the possibility that the real explanation is beyond our present state of knowledge[1] *(CIHR).*
I	❖ **Informed consent:** The full knowledge of the possible risks and benefits of participation. In any study involving humans, it is crucial that the participants voluntarily agree to take part in the research, and that they do so with a full understanding of their rights and the possible risks associated with participating in the study. Throughout the entire study, the researcher has an ethical obligation to share plain-language information with all participants that will enable them to give their free and informed consent[1] *(CIHR).* ❖ **Intervention:** In a **clinical trial**, the intervention is the treatment being studied. The intervention group consists of the study participants that have been randomly assigned to receive the actual treatment[1] *(CIHR).* ❖ **Implementation research:** The study of how a specific set of activities and designed strategies affect the integration of evidence-based information and interventions into health care and community health practices[4] *(NAPCRG).*
K	❖ **Knowledge translation in research:** A process of summarizing, distributing, sharing, and applying the knowledge developed by researchers [1] *(CIHR).* It involves making sure your research results are usable and understood by many people, including the public, policy makers, clinicians etc.
L	❖ **Long Term Care:** Long-term residential care services provide 24-hour professional supervision and care in a protective, supportive environment for people who have complex care needs and can no longer be cared for in their own homes or in an assisted living residence[5] *(PVN).* ❖ **Longitudinal research:** Research that continues over a long period of time (sometimes decades) where the same variables are measured in the same subjects at pre-determined intervals (likely once a year) to see if there are variations over time[2] *(CDRIN).* *For example, people exposed to e-coli were followed for 10 years to assess potential damage to their kidneys as damage may not be immediate but can develop over time.*
M	❖ **Methodology:** A set of research methods and techniques applied to a particular field of study. (*Statistics Canada*) Researchers typically specialize in a certain methodology as well as a field of interest. Qualitative research (e.g., using interviews, focus groups etc. to understand a concept) and quantitative research (e.g., using information from surveys or existing databases to understand a concept) are examples of major

	methodologies[2] *(CDRIN).*
N	❖ **N:** N refers to the number of subjects who participated in the study, e.g., n = 250 means 250 subjects participated in the study[2] *(CDRIN).* Also see **Sample size** ❖ **Null hypothesis:** Most research studies start with the assumption of 'no effect'. A null hypothesis assumes there is no relationship between the variables under study so a positive result can be said to have been found when the research can demonstrate that there is a relationship[2] *(CDRIN).*
O	❖ **Observational study:** An observational study, as distinguished from a randomized study, is usually undertaken when it is impossible, impractical or unethical to have a control group of patients who don't receive the extra or different care (e.g., treatment for cancer patients). They are useful for generating hypotheses that can be more rigorously tested in **randomized controlled trials**[1] *(CIHR).* ❖ **Outpatient:** A person not admitted to the hospital for an overnight stay, but still comes to a physician's office, clinic, hospital, day surgery office or other healthcare facility for diagnosis, treatment or to receive care. See also **inpatient**[5] *(PVN).*
P	❖ **P-value:** P stands for probability. Statistical analyses of research findings most often conclude with a P value rating. If the P value is less than .05% it means that the likelihood (probability) that the findings were simply random is less than .05% [2] *(CDRIN).* ❖ **Palliative Care:** Care and supports for patients and families who are dealing with a progressive, life-limiting illness[5] *(PVN).* ❖ **Participatory research:** Research with the **collaboration** of those affected by the issue being studied (includes individuals and organizations), for the purpose of taking action or effecting change[4] *(NAPCRG).* ❖ **Partnerships:** Collaboration between individuals, groups, organizations, governments or sectors for the purpose of joint action to achieve a common goal. The concept of partnership implies that there is an informal understanding or a more formal agreement among the parties regarding roles and responsibilities, as well as the nature of the goal and how it will be pursued. ❖ **Patient:** A person who is receiving, has received, or has requested health care. This term includes **caregiver**s (people whom the patient wishes to be involved with them in their care, and act on behalf of and in the interest of the patient). Other terms sometimes used for "patient" are: client, resident, person, consumer[5] *(PVN).*

- **Patient Advisors:**
  Individuals who represent the patient perspective at all system levels. It includes champions, advocates, representatives, etc.[5] *(PVN).*
- **Patient Engagement:**
  Meaningful and active collaboration in governance, priority setting, conducting research and knowledge translation. **Error! Bookmark not defined.** *(CIHR-SPOR).*
- **Patient-Oriented Research:**
  Refers to a continuum of research that engages patients as partners, focusses on patient-identified priorities and improves patient outcomes. This research, conducted by multidisciplinary teams in partnership with relevant stakeholders, aims to apply the knowledge generated to improve healthcare systems and practices. Depending on the context, patient-oriented research may also engage people who bring the collective voice of specific, affected communities (e.g., people with diabetes)**Error! ookmark not defined.** *(CIHR-SPOR).*
- **Patient Partner:**
  Includes patients (those with "lived experience"), family members, caregivers, and organizations that are representative of the population of interest in a particular study. Patient partners are members of the research team and involved in the planning, conduct, and dissemination of the research. *(PCORI)*
- **Patient Safety:**
  The reduction and mitigation of unsafe acts in the health care system, as well as the use of best practices shown to lead to optimal patient outcomes[5] *(PVN)*. Reducing unsafe acts before they occur as well as mitigating or reducing the effects of unsafe acts if they do occur, are important patient safety issues.
- **Peer review:**
  When researchers from the same field (peers) review a research proposal submitted to a funder and provide critical feedback to the funder (often anonymously). Peer review also occurs when researchers submit articles to a journal for publication. The peers' opinions determine if the article is or is not published[2] *(CDRIN).*
- **Placebo:**
  In clinical trials, a placebo is usually a tablet or capsule with no active ingredients, or a sham treatment that is meant to make the patient believe that a medical procedure has occurred. Placebos are used so that the subjects in the control group (and often researchers involved in administering or evaluating the trial as well) are unable to tell who is receiving the active drug or treatment. Using placebos prevents **bias** in judging the effects of the medical intervention being tested[1] *(CIHR).*
- **Prevention - Primary, Secondary and Tertiary**[1] *(CIHR)***:**
  -**Primary Prevention** means preventing a disease before it occurs. *Example: a healthy person with a family history of heart disease takes a blood pressure-reducing medication to prevent a heart problem in the future.*
  -**Secondary Prevention** means preventing a worsening or future occurrence of a disease after evidence of the disease has already been found. *Example: a doctor removes a suspicious growth before it becomes cancerous and spreads.*

-**Tertiary Prevention** means treatment for an ongoing disease., and can include reducing the effect of symptoms, slowing the progress of the disease, or taking steps to cure the disease.

- **Primary Care:**
  Health care provided by a health care professional who acts as a first point of consultation for patients in the health care system, and is usually a general practitioner or family physician, or a non-physician such as a nurse practitioner, but can also include speaking to a pharmacist or calling a health information line[5] *(PVN).*
- **Primary Health Care (PHC):**
  A set of universally accessible first-level services that promote health, prevent disease, and provide diagnostic, curative, rehabilitative, supportive and palliative services[8] *(Lamarche et al., 2003).*
- **Primary Care Home:**
  A collaborative and interdisciplinary primary care approach that brings together a range of health and social care professionals to work together to provide enhanced personalized and preventive care to the local community. Primary care homes aim to provide accessible, continuous, coordinated and client-centered care. Key features are: first point of contact, person-centered, comprehensive in nature, and coordinating and integrating care when it requires special services or provision[9] *(NAPC).*
- **Principal Investigator:**
  The lead researcher who manages all aspects of a study. Principal investigators' salaries are typically paid by the university or health science center that employs them, and not by a research grant[2] *(CDRIN).*

Q

- **Qualitative Analysis:**
  The purpose of a qualitative analysis is to get a range of responses on an issue from a variety of perspectives, valuing unique responses as much as consistent ones. Qualitative analysis methods can include focus groups, individual observations, in-depth interviews, or documentary accounts. Qualitative analyses are subjective, meaning that they depend on the particular people included, and can be shaped by interactions with the researcher or other participants[1] *(CIHR).*
- **Quantitative Analysis:**
  Quantitative analysis attempts to understand the world objectively, rather than as different individuals might perceive it. It relies on compiling numerical data from many individuals into a single value, such as an average, or mean, that can be assessed by statistical tests. The goal of quantitative analysis is to be un**bias**ed, which is why **control group** and **blinding** are important considerations in constructing

[8] Lamarche P, Beaulieu M.D, Pineault R, Contandriopoulos A.P, Dennis J.L, Haggerty J. Choices for Change: *The Path for Restructuring Primary Healthcare Services in Canada*. Canadian Health Services Research Foundation, 2003.
[9] National Association of Primary Care. Retrieved from: https://napc.co.uk/primary-care-home/

	quantitative research studies[1] *(CIHR).*
R	❖ **Randomized control trial:** A trial design in which subjects/patients are randomly assigned to one of two groups, one group receiving the intervention being tested, and the other group receiving an alternative treatment or a **placebo**[10] *(NICHSR)*. *For example: A study designed to study the effect of 'X' oral inhaler in preventing pneumonia at children's hospital assigns patients to a group that receives 'X' oral inhaler or to a group that receives a placebo or standard care.* ❖ **Research:** Activities designed to develop or contribute to knowledge, e.g., theories, principles, relationships, or the information on which these are based[2] *(CDRIN).* ❖ **Reliability:** Reliability means that the research methodology should get the same or similar (enough) results when used over and over again[2] *(CDRIN).* ❖ **Risk Reduction:** A measure of how successful an intervention is when compared to patients not receiving the intervention in reducing the risk of a negative health outcome such as death, stroke, or bleeding[1] *(CIHR).*
S	❖ **Sample Size:** Samples are subsets of the population. Larger samples usually mean more precise results. Sample size usually depends on the purpose of the study, the population size from which the sample will be pulled, as well as the level of precision and the level of confidence or risk that is acceptable, and the degree of variability in the attributes being measured[11] *(CDISC)* ❖ **Screening:** Screening is a method of **secondary prevention**. Screening programs check large numbers of individuals who are otherwise healthy for known symptoms before a disease is established. Screening is presently offered through programs such as mammography for breast cancer or skin examinations for melanoma[1] *(CIHR).* ❖ **Serious Adverse Events/Effects:** Serious Adverse Events or Serious Adverse Effects are events that cause death, permanent damage, birth defects, hospitalization, or are life threatening[1] *(CIHR).* ❖ **Statistical significance:** A measurement of the magnitude of the difference between the results from the groups under study that, if it passes a pre-determined bar (the **P-value** is the most common one used), provides confidence that the research results could not have occurred by chance but can be attributed to the effect of treatment/therapy/intervention that was part of the research[2] *(CDRIN).*

[10] National Information Center on Health Services Research and Health Care Technology. Retrieved from: https://www.nlm.nih.gov/nichsr/hta101/ta101014.html

[11] Clinical Data Interchange Standards Consortium glossary. Retrieved from: https://www.cdisc.org/system/files/all/article/application/pdf/cdisc_2009_glossary.pdf

	❖ **Subjects:** In clinical trials, the people selected to take part, both those receiving the treatment being investigated and those receiving a placebo or alternate treatment[1] *(CIHR)*. ❖ **Summary (lay language):** Summaries are a less formal way of pulling research together, generally using a more conversational tone[Error! Bookmark not defined.] *(CFHI).*
V	❖ **Validity:** Did the research measure what it set out to measure? Are the methods sound (or not), is the analysis accurate (or not), is the statistical analysis accurate (or not), and so on. With valid research, all aspects of the study are considered to be well done and accurate[2] *(CDRIN)*. ❖ **Variable and types:** Any factor in an experiment that can be changed[1] *(CIHR)*. There are three kinds of variables in an experiment: -An **independent variable** is a factor in the experiment that is manipulated by the experimenter. *Example: three dose levels of the same drug.* - A **dependent variable** is something over which the experimenter has no control, but that is expected to change in a systematic way, depending on the independent variable, for example a decrease in coughing at higher dose levels of the drug. The change in the dependent variable is what gets recorded as data in a research study. - A **controlled variable** is something that does not change. *Example: the number of times per day that each subject is expected to take the trial medication.*
W	❖ **Webinar:** A presentation, lecture, workshop or seminar that is transmitted over the internet. Short for web-based seminar. In a webinar each participant sits at his or her own computer and is connected to other participants via the Internet and/or teleconference[5] *(PVN).*

THE RESEARCH CYCLE

Regardless of the area and purpose of research, all projects follow a similar cycle with similar phases. These phases are described in more detail in this section. A brief overview is provided here (Edinburg Napier University).

In the first phase, **Think and Plan,** the research team begins by selecting a topic. That topic is usually related to the lead researcher's area of expertise. The research team then identifies the research problem related to the topic that should be addressed, and articulates a specific question forming a hypothesis. The research team then establishes the study design that will be used to answer the question. The study proposal is then submitted to the Research Ethics Board of the institution for approval.

In the second phase, **Conduct,** the research team carries out the study procedures, which usually include collecting and analyzing data. Then they interpret the results, and develop findings.

In the third phase, **Knowledge Mobilization,** the research team creates messages about their findings that will be shared. This usually involves publication in scientific journals, but can also include other methods such as newsletters to reach a broader population, which can include health planners, patient groups, etc.

This approach is called a **Research Cycle,** because based on the knowledge generated in that study (and other existing knowledge), that team or another team seeks to answer a new research question. The cycle is repeated to deepen our understanding of the subject matter. When PPs understand the broad phases involved in research, they are in a better position to contribute to each phase. In the next section, we briefly review these key phases.

STAKEHOLDERS IN THE RESEARCH

Researchers have become increasingly aware that research is a "team sport". While the expertise researchers bring to the work is essential, the contribution of people whose lives or work can be impacted by the study and its results is equally important. In health services research, we can broadly define three types of important stakeholders.

Policy makers/health planners: Are in a position to inform the work in the broader context (geographical or policy-wise) and potentially sustain or even scale up the intervention if it should prove successful.

Health care providers: If the intervention relies on care providers for its delivery, these health professionals can help direct the study so that it is feasible in the context where they work and more likely to be acceptable to care providers.

Patients/ Individuals: Ultimately, health services research is about improving how care is delivered so that individuals have a better experience and better outcomes. The involvement of PPs brings a unique richness and perspective. They can help identify priorities in the field of study and the outcomes that are most important to them, and develop an approach to care delivery that is equitable to patients and respectful to patients' competing priorities. They can also help interpret the data and share the findings.

OVERVIEW OF THE RESEARCH CYCLE

Research is basically a process for discovering new knowledge or evidence. The Canadian Institutes of Health Research (CIHR, 2014) defines health research as:

> "*a multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviors affect access to health care, the quality and cost of health care, and, ultimately, Canadians' health and well-being*".

Phases in the research cycle: We like the way Edinburgh Napier University has depicted the research cycle:

Figure.2 Research Cycle

Source: Edinburg Napier University

Research is conceptualized as a cycle, because the knowledge obtained at the end of a research project is never final, but rather leads to thinking and planning to inform new avenues of research.

Research activities can be grouped into three phases:

1) **Planning**: Thinking & Planning;

2) **Conduct**: Discover, Gather & Analyze and;

3) **Knowledge Mobilization**: Sharing Impact and Dissemination.

These are covered in the following sections:

Phase 1: Planning

Thinking & Planning

- **Establishing the priority focus/choosing a topic:** The team needs to understand what knowledge exists and what gaps need to be filled. They also need to ensure that their work is addressing an important issue in the area of interest. Ideas may germinate from a review of literature, from policy documents, or from the team's previous work.
- **Identify gaps:** It is important to do groundwork in existing knowledge. Nothing replaces the active contributions of stakeholders, people whose lives or work can be impacted by the study. AFor example, PPs can help the team identify the priorities that should be addressed, the components of the intervention, the target population that would best benefit, and how they may be reached to become involved in the study.
- **Performing a SWOT analysis:** The team also needs to understand the internal strengths (S) and weaknesses (W) of the research project, as well as external factors such as opportunities (O) and threats (T) (adapted from Mintzberg and Quinn, 1992). The analysis helps the research teams to explore the best plan to move forward. The figure below illustrates the key elements of the SWOT analysis in a research project:

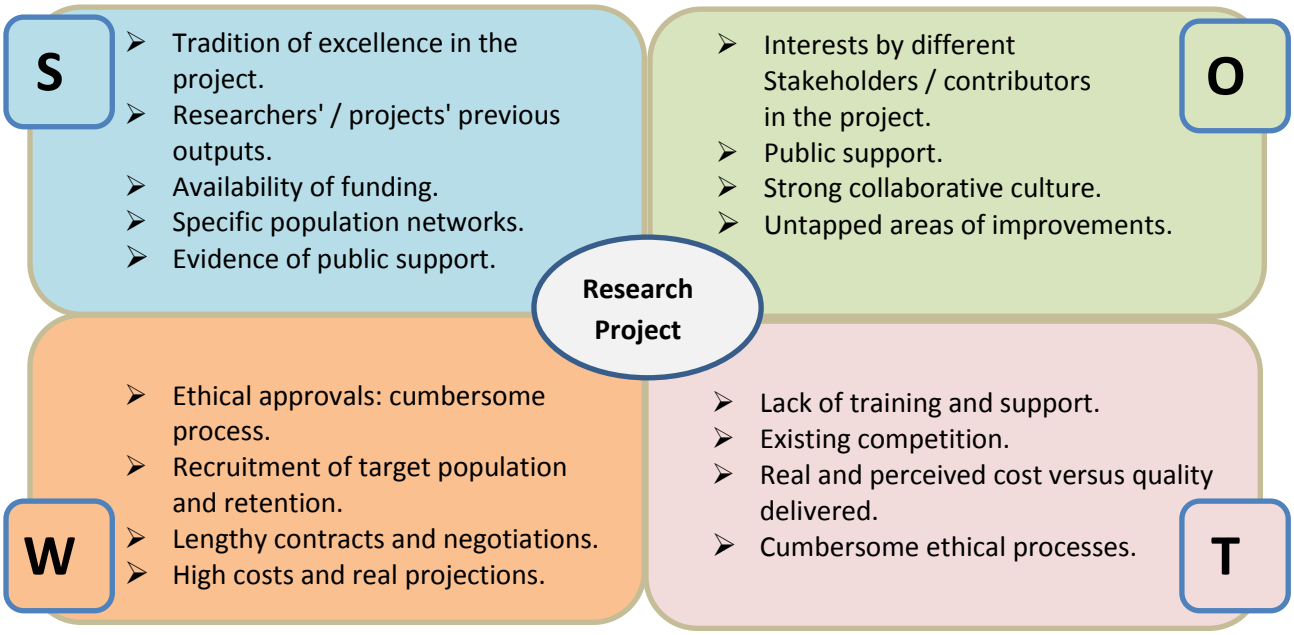


Figure.3 Example of SWOT analysis for a health service research project

- **Applying ethical principles:** It is important for the research team to understand the rules (moral principles) that define what is 'right' and 'wrong' and govern a person's behavior or the conduct of an activity. In Canada, the ***T***ri-***C***ouncil ***P***olicy ***S***tatement (TCPS, 2014) is the guide for the ethical conduct of research involving humans, to which Canadian researchers adhere to. Patient partners involved in aspects of a study that directly involve patients or their information will be required to complete TCPS training. The TCPS key principles include: **Respect for persons**, i.e. autonomous decision making, the notion of fair procedures, and voluntary participation; **Beneficence**, i.e. maximizing the benefits and reducing harm; and **Justice**, i.e. assessment of the risks and benefits of participation, and protection of the confidentiality of personal information (Belmont report, 1978).
- **Ethics approach and approval - adherence to international guidelines:** Research involving humans requires ethics review and approval by the hospital or institution's research ethics board (REB). The research team is responsible for the approvals and for informing the REB of any changes in the protocol that take place over the study duration, and any significant undesirable events (such as severe toxicity or patient complaints).

The section entitled **Ethical Principles in Research** will provide you with examples of principles and their application in research.

The **Worksheet: Application of Ethical Principles** shows how different ethical issues are linked to key principles. If ethical issues are encountered during the research, these should be reported immediately to the research teams.

Phase 2: Conduct

Discover the best ways to move forward

- **Ways to work together/collaborate:** The research team looks for potential collaborations such as working with other researchers in different contexts or even different geographical locations. Interdisciplinary collaborations can help to conceptualize the research in better ways.
- **Type of information required:** The research team collects more information on the target population to be studied, the intervention required, decisions about the control or comparator, and the desired outcome.
- **Developing the research question**: The research team will then establish the study design and specific research questions to be answered. The type of design is driven by various factors, such as the nature of the research question and the type of information required. Some of the terms that may be encountered in that development include *qualitative, quantitative, mixed methods, randomized, cross sectional, case-control study, cohort study (*refer to the **Research Glossary**).

Gather & analyze

- **Choosing and collaborating with the target group:** The study team will determine specifically who is eligible for the study with clearly stated inclusion and exclusion criteria. The research team proceeds in collaborating with individuals who are eligible for the study with their informed consent. PPs can be instrumental in the recruitment/collaborating with individuals from disenfranchised populations.
- **Collecting information:** The team then plans to collect data from those who are involved in an intervention. Or, when the study does not include an intervention, the target group and other individuals (such as policy makers) can provide important information to help achieve the study goal. It is important to distinguish patients

participating in the study from PPs. The latter are involved in guiding the study and are not the target of data collection. The research team applies the data collection method and tools that were developed during the planning phase. PPs may be ideally suited to deliver surveys to patients or conduct interviews and focus groups. Their involvement can be reassuring to study participants, especially if they share a common background or experience.

- **Analyzing the data:** The collected data is stored securely to ensure the privacy and confidentiality of the participants. Data analysis may involve the use of software to calculate measures for quantitative data, and different software to code and help interpret qualitative data.
- **Drawing conclusions:** Once a full set of results has been produced, the research team reviews and interprets the findings, and relates these to previous knowledge. PPs provide unique perspectives that can be incorporated into the messages about the research that the team will share.

Phase 3: Knowledge mobilization

Sharing the research

- The team should establish a plan of what aspects of the research are to be shared among team members, collaborators and partners, and the mechanism(s) to be used to distribute it. It is important to consult stakeholders/collaborators/partners, as they may have issues that could impede the free flow of information, for example, absence of appropriate platform to share findings. It is equally important to reinforce the sense of trust and collegiality that forms the basis of the collaborative relationship.
  Examples of information to be shared: project progress reports, ideas generated from the research, material for patient education, any amendments in protocols, preliminary and final data, sustainability plans or next steps.

Dissemination, writing and publication

- **Widespread dissemination and application in the community:** When stakeholders have been involved in the study throughout all of its stages, they often feel compelled to share the findings because that data belongs to them as much as anyone else on the team. Depending on the findings, it may be advisable to apply the approach of sharing

more broadly in other regions or contexts. Health planners and policy makers play an important role in helping the research team increase uptake. Projects can offer PPs opportunities to present findings at academic conferences and other venues that are more likely to reach the study's intended population.

- **Writing and publication:** A clearly written paper that carries a meaningful message and is scientifically sound will attract readers. Research teams should report on the study results regardless of whether the findings were "positive" and achieved the intended goal or not. The writing should be tailored to the intended audience. PPs can participate in the writing of reports aimed at both academic and non-academic audiences.

REFERENCES:

- Belmont Report: National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1978). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research*. [Bethesda, Md.]: The Commission. Retrieved from: https://videocase.nih.gov/pdf/ohrp_belmont_report.pdf
- 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
- CIHR's SPOR . (2014). *Strategy for Patient-Oriented Research Patient Engagement Framework*. Retrieved from: http://www.cihr-irsc.gc.ca/e/documents/spor_framework-en.pdf
- Cavoukian A. (2004). *A Guide to the Personal Health Information Protection Act* and its regulations. Office of the Information and Privacy Commissioner of Ontario. Retrieved from: https://www.ipc.on.ca/wp-content/uploads/Resources/hguide-e.pdf
- Mintzberg H, Quinn JB. (1992). The Strategy Process: Concepts and Context. Prentice Hall International: London.
- Research Cycle and phases (Edinburgh Napier University): https://staff.napier.ac.uk/services/information-services/research-cycle/Pages/home.aspx
- TCPS-2 Tutorial link: http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/

ETHICAL PRINCIPLES IN RESEARCH

Respect for Persons	Beneficence	Justice	Privacy & Confidentiality
Individuals as 'autonomous' beings in research Informed consent process Information provided, comprehensiveness, voluntariness	Protecting individuals from harm and securing their well-being. Nature and scope of risks involved Corresponding benefits to the	Fairness in distribution, i.e. fair selection and outcomes in selection of research subjects Avoiding selection bias, i.e. not favoring any individual or class	Privacy: The individual's right to be free from any interference (bodily, personal opinions, personal communication, and the space they require). Confidentiality: Safeguarding entrusted information from unauthorized access, use,

Source: Belmont report (1978), TCPS-2 (2014) and Protection of Personal Health Information Act (PHIPA) (2004)

WORKSHEET: APPLICATION OF ETHICAL PRINCIPLES

Principles	Related components in research	Description (*please work in consultation with research team, then mark (✓) in the appropriate 'Yes / No' box*)	Yes	No
Respect for persons	Informed consent form/ process *(*explain what informed consent process is & why it is necessary)*	Does the informed consent form provide all the information?		
		Is consent written in understandable language?		
		Does consent state that participation is voluntary?		
		Does it maintain the autonomy of decision making?		
Beneficence	Applicable risks and benefits in the study *(*explain in this study what risk versus benefits are)*	Does the study explain all the risks of harm?		
		Does the study explain the benefits to the participant or community?		
		Does the study have processes to reduce risks & maximize benefits?		
Justice	Research participant selection *(*explain what vulnerable population is)*	Is the recruitment process fair (to include vulnerable populations)?		
		Does the study have appropriate inclusion/exclusion criteria for participant selection?		
Privacy & Confidentiality	Information & entity *(*explain what protected health information is)*	Does the study have processes to de-identify personal and health information?		
		Does the study have procedures to safeguard personal and health information?		

**Instructions for research team*

RESEARCH TEAM

As a patient partner, joining a new research team can be an exciting adventure especially if the other team members already know each other. For those who are new to PE in research, there's the added challenge of understanding the role(s) that different individuals play on the team, and even what role patient partners will play. In this section, we provide some guidance about what to expect and offer tools that can help make building these new relationships a little easier.

BIOGRAPHICAL TEMPLATE

To understand the nature and value of the contribution each team member brings to the team, each team member can introduce themselves. Sharing a little information about themselves provides a small personal connection that can help make a team more effective and personable.

That information should contain a description of the individual's role on the project, but can also include some personal facts to facilitate connections, which can help break down the sense that power is held by a few members of the team. After all, at the research table everyone plays an important role and, as the saying goes, "we all put our pants on one leg at a time".

There are a few simple questions a patient partner can ask before joining a research team:

- About other members on the research team
- The reasons for inviting patient partners
- Each role on the team
- Availability of training, mentoring or a buddy system to help ease the transition

We offer a biographical template (**Biographical Template – All Team Members**) that teams may adopt, or adapt for their own specific purposes. The template captures the team member's role, affiliations and anticipated contribution to the team. It also allows for a picture to be attached and some personal information shared. What skills would you want to share with the team? Maybe you're a great cook, care provider, teacher, photographer, or advocate for human rights. What interests would you like the team to know about? Maybe you like to skate, play with your grandchildren, or maybe you are writing a book, taking a new course, getting a degree or trying out a new hobby.

Biographical Template – All Team Members

3 Skills you are proud of:

1.
2.
3.

NAME:

(Write your name and what you would like to be called)

AFFILIATION:

(Are you affiliated with an organization?)

CONTRIBUTION TO THIS TEAM:

What is your area of expertise?

What can you contribute to the team?

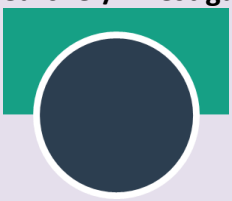
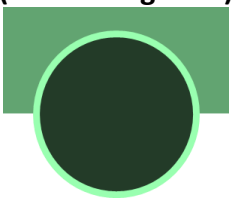
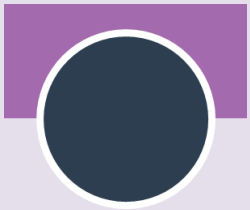
Why is this project important to you?

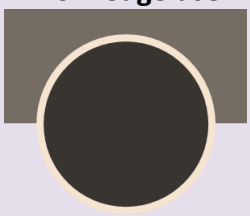
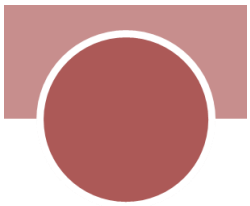
INTERESTS:

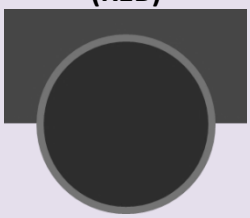
(Write your hobbies)

COMMON ROLES ON A RESEARCH TEAM

As a first step in a research partnership, it is important to know the research team. The following table provides a general description of some of the roles research team members may have on a research project:

Title	Role description
Principal Researcher/Investigator 	The one who leads and has ultimate oversight and responsibility for the research study. They would have been central in study concept building and obtaining funding. **On a research team:** - Oversees the entire study process, administers funds, patient recruitment, ongoing monitoring, and end-of-study knowledge mobilization. - May be a doctor, another clinical professional or a scientist (PhD).
Other Researchers on the team (Co-investigators) 	Other researchers who are either responsible for the study delivery within a designated region or for a specific component of the study. They may have a specific expertise. They support the Principal Researcher in their responsibilities. **On a research team:** - May be a statistician, geographer, clinical expert, methodologist, social scientist, or bring other types of expertise and skills. - Assists in writing the proposal, budget or other central documents. - Assists the Principal Researcher in presenting the research at scientific conferences or workshops.
Research Staff 	Research staff positions include research coordinator, assistant, associate, and manager. **On a research team, individuals in these positions**: - Monitor the progress of the research. - Coordinate the daily conduct of the research process. - Assist in preparing the project proposal, recruiting participants, preparing funding documentation, and completing paper work. - Facilitate data collection and analysis. - Coordinate internal and external work related to the research studies/projects. - Other functions as required for the smooth running of the team.

Statistician and methodologist 	The statistician and methodologist are often co-investigators on the study. Their contribution relates specifically to minimizing bias to make the study credible. **On a research team, they can contribute to:** - Effective study design, sample size calculation, and endpoint selection. - Identifying the key study variables, laying out the data analysis plan, and interpreting the results.
Knowledge user 	Individuals who are likely to use the research knowledge or findings in order to make informed decisions about health policies and programs. **On a research team:** - Can be, but is not limited to, a practitioner, policy maker, educator, decision maker, health care administrator, community leader, health charity organization, volunteers' group, patient group or media person.
Collaborator 	Individual who provides specific services to the research team when required. **On a research team, they can provide:** - Access to specific equipment/data. - Training in a specialized technique. - Access to a special patient population.
Patient Partners 	Individuals with personal lived experience with the healthcare system as a patient and/or a caregiver. Their input serves to ensure that: patient priorities are addressed; what the study aims to change/improve is relevant to patients; and that the intervention processes (if applicable) are acceptable to patients. They can help the team understand the reason why certain results are observed. And they can help mobilize the study results. **On a research team, these individuals can contribute towards:** - Planning the research process - Conducting the study - Knowledge Mobilization
Policy makers/Health services planners	A policy maker is an individual responsible for creating and monitoring health care policies and regulations. A health services planner is responsible for ensuring that health services in a region respond to the needs of that population. Like patient partners, these individuals can help to inform the study so that it is workable and scalable. They can also help the research team understand the context in which the study is being

	conducted, promote the study results, and develop an adoption of the intervention. These individuals help support policy-relevant research and promote evidence-informed policy.
Research Ethics Board (REB) 	A group of individuals made up of clinicians, scientists, and members of the community who review protocols involving humans to ensure that agreed-upon ethical principles (such as the **TCPS** described earlier) are applied. While the board is not directly a member of the research team, it is an oversight body to which all research involving humans is accountable. **On a research team, these individuals:** - Ensure rights, safety and well-being of the research participants. - Identify and weigh the risks and potential benefits of research. - Evaluate the process and materials that will be used for seeking participants' informed consent. - Ensure there are no undue pressures to participate. - Examine any issues/violations that may affect the ethical acceptability of the research.
Funding entity/sponsor 	An individual, company, organization or entity that provides monetary support, equipment or materials needed for the research (e.g. CIHR, SSHRC, a foundation, a provincial fund). **On a research team, these individuals:** Ensure there is no undue influence on the study conduct. The study sponsor is never an active member of the team. The research team is accountable to that sponsor for the proper management of the study funds. The study must report periodically on budget spending and study progress to the sponsor.

Source: Adapted from The Children's Hospital of Eastern Ontario Research Institute (CHEO)

KNOW THE PROJECT AND TEAM NORMS

Teams come together to work towards a common goal, but how each team gets there may be quite different. Here are some things to consider when you are thinking of joining a team. A 'project/team norms' is a document that outlines the ways in which a group of people (i.e. researchers and patient partners) agree to work together to accomplish common goals. It is an important step in creating expectations and accountabilities for all team members.

VALUES / PRINCIPLES

Values are any concepts, key principles or beliefs that form the culture of any organization or a team (Fawcett S, 1991). These values are used to guide decisions and members' behavior on the team or project. Before becoming a team member, there are several questions that come to one's mind, such as:

- *Has this team established a list of common values and principles by which they agree to work? If they have, do these align with your own convictions?*

Most teams don't explicitly do that. Rather, the values likely tacitly evolve as the group works together or are mainly guided by the funder/institutional guidelines. But there are good reasons for taking the time to establish shared values and principles. They can help guide the team approach to various activities, such as behavior in meetings, how decisions are made, and many others. Also, when a team member is not comfortable with something that has taken place they can turn to the team's value statement and principles to express why the action has caused discomfort. Examples of values are: *integrity, trust, respect, teamwork, innovation, care, safety, excellence etc.*

The following is an example from CIHR Strategies- a national strategy for Patient Oriented Research (CIHR-SPOR, 2014), which represents the foundational framework has been adopted in the province of Ontario as the guide for patient and family partner engagement.

The key principles are:

- ***Inclusiveness*** *– Researchers should communicate and share complete, accurate, timely, and unbiased information with patients and families.*
- ***Mutual Respect*** *– Patient partners are listened to and their perspectives and choices are honored.*
- ***Support*** *– Team members can encourage each other to participate in their work and decisions at the level they choose.*

- ***Co-build*** – *Both research teams and patients are partners at all levels of planning, conduct and end of study.*

ROLES AND EXPECTATIONS FOR PATIENT PARTNERS

It is important for you to have clarity about your role on a team and the expectations for your participation in terms of time and commitment. In addition to understanding the activities, you should be clear about other expectations such as the anticipated frequency, location and duration of meetings you would be invited to attend, the duration of the study, and other commitments the team expects. A later section (**Patient Partner's Detailed Roles as a Member of a Research Team**) provides more information on the project information worksheet and patient partner-specific roles and commitment within each research phase.

NEEDS AND EXPECTATIONS OF PATIENT PARTNERS

You are eager to work on this project, and you probably have some idea of what would make this partnership strong. It's important that the team understands your needs and expectations. These should be made explicit; otherwise it is not likely that they will be met. We have outlined needs you may want to consider. These are not comprehensive, and each PP should consider their situation and how it influences their needs.

You cannot anticipate all the needs you will have at the start of your engagement. Things will become evident as the work progresses. This is fully expected, and won't be a surprise to anyone. So make sure that you continue to communicate your needs and expectations throughout the study.

A. Training and mentorship needs

You may know your roles from the description document and discussion with the research teams. However, at any point in time you may require personal and professional development. Hence, it is equally important to identify and convey to the researchers your training needs to work effectively. The training needs could be general, technical, or project specific. The **Training Checklist for Patient Partners** provides a checklist of skills where you may require training. You may answer 'No', 'Yes, or 'I need training' in the checkbox allocated to the training skill. You are also free to write additional training needs.

B. Communication with the team

Communication between you and the other team members can happen in different ways. It is important to know at the start of your involvement whether the regular communication will be through e-mail, telephone, mobile or face-to-face team meetings. For example, it would be useful if you know the frequency of e-mails sent by the team members or the regular team meetings schedule. However, in case of delay or non-attendance, it is the responsibility of both PPs and research teams to communicate with all members 24 hours prior to the meeting. Other communication materials may include timely research updates and any new trainings or events.

C. Travel, meals and accommodation needs

You may be eligible for reimbursement of any pre-approved expenses incurred for travel, meals, accommodations, and child/elder care as per funding/institutional expenses policy/guidelines and as may be amended or replaced from time to time. For timely reimbursement, you should provide receipts to support your expense claims, and have the necessary information about whom to approach in the case of any disagreements arising in the team in terms of compensation or logistic support.

D. Participatory compensation needs

You may be eligible for remuneration for participating in a PP event or engagement activity. It is important to understand that specific remuneration is decided as per funding/institutional expenses policy/guidelines and may be amended or replaced from time to time. It is also important for all the members to determine the best form of remuneration (as per % of time commitment per activity, $ amount or gift cards, honorarium, conference attendance opportunity, etc.). It is also important to understand cases in which a participant is potentially ineligible to receive any monetary benefits from the research teams, e.g. 'people with disabilities who receive some monetary benefits from the government'. For such individuals, there should be equal consensus on the best way of compensating them.

E. Confidentiality of information

As a member of the research team, you must not disclose or publicize any information related to the work you are part of, including the contents of meetings. For example, you may need to sign a *pledge of confidentiality* or a *statement of understanding agreement*.

F. Other / special needs

You should inform the research team of any accommodation needs you may have such as:

- ✓ Special transport needs- Wheelchair accessibility
- ✓ Elevator

- ✓ Parking
- ✓ Special meals
- ✓ Babysitting/childcare
- ✓ Personal helper
- ✓ Specific health conditions
- ✓ Teleconference arrangements
- ✓ Other (please specify)

ENDING THE PARTNERSHIP

A. By Research Team

There could be certain circumstances in which the research team decides your participation is no longer required before the end of your term. In this case the team is required to provide written notification of their decision in advance. This may happen due to reasons such as loss of funding, lack of representativeness/attendance at the meetings, lack of patient partner participation, conflict of interest or breach of confidentiality.

B. By Patient Partners

There could be certain circumstances in which you may need to leave the partnership before the end of your term. In this case you should elect to resign and provide written notification to the research team in advance. This may happen due to reasons such as health conditions, change of location, not willing to participate, etc.

The **Worksheet: Project and Team Norms** will help familiarize you and can be filled out in consultation with the researchers or you may ask this information of the research teams before you start your engagement.

PROJECT BRIEF – BEFORE YOU ENGAGE

This section gives you key headers that may be useful in understanding the project. The research teams can brief you with the following information before you start your engagement process.

PROJECT INFORMATION AND SUMMARY:

- *What is the project about/intent of the research?*
- *Type of research, e.g. focus group, survey, etc.*
- *Plain language project summary*

This sub-section should provide the information necessary for the reader to understand the purpose and intent of the project. By now, you have a brief idea about the research background and activities to be carried out in a project. The information here will come from the research teams explaining more about the area of research. This may be supported by a protocol or research proposal – a formal study document that defines all the key steps.

PRINCIPAL INVESTIGATOR'S NAME AND CONTACT INFORMATION

The names and contact information of the other team members should be available before you start:

For example:

- *Principle investigators/other researchers*
- *Other patient partners on project*

LOCATION OF RESEARCH

For example, single site, multiple sites etc.

TIME FRAME OF PROJECT

Length of the project *(starts date and end date).*

REQUIRED TIME AND COMMITMENT FROM PATIENT PARTNERS

Dates, times and frequency of meetings/teleconferences should be decided with input from all team members.

ENGAGING PATIENT PARTNERS WITH A SPECIFIC PROFILE: YES / NO

If yes, details (for example: age, socio-demographics, specific disease condition, previous experience etc.) should be provided.

OTHER DETAILS: AREAS OF INVOLVEMENT

The following example will provide specific questions and the phase of the study the patient partner is informing (*e.g. study design, recruitment, and result interpretation*) with task-specific details or more information about the questions put forth by the research team.

***Example**: Study title: Linking PHC capacity to population health needs.*

Questions	Phase of study	Details
How should the study define whether a patient has a primary care provider (attachment)? Precisely defining the 'attachment'. ***Study outcome:*** (Proportion of unattached patients)	Design phase: Defining attachment	We have access to the following information that can help us define attachment. Which of the following parameters can be used alone, or in combination, to define attachment? 1. A patient is officially registered to a primary care provider 2. A patient is not officially registered but sees someone "regularly" 3. A patient is registered but has not seen their provider in the past year 4. A patient is registered but has not seen their provider in the past two years 5. A patient self-reports that they "have" a primary care provider on a survey
We want to determine who should be counted as a primary care provider? ***Study outcomes:*** *(Characteristics of health care provider)* *(Adequacy of primary care capacity in relation to health care needs)*	Design phase: Defining primary care providers	What questions are best suited to get this information? For example: 1. Family physicians 2. Pediatricians 3. Nurse practitioners 4. Other

The **Worksheet: Project Brief** can be filled out in consultation with the researchers or you may ask this information of the research teams before you start your engagement.

TRAINING CHECKLIST FOR PATIENT PARTNERS

For Patient Partners: Other knowledge, experience and skills (please (✓) the appropriate box)			
	Training areas:	**Yes, I am confident:**	**I need training on:**
1.	Familiarity with patient engagement in research		
2.	Previous experience as a patient partner in the research process		
3.	Experience with patient advocacy groups		
4.	Familiarity with the health care system		
5.	Familiarity with research terminology		
6.	Familiarity with the phases of research		
7.	Understanding of concepts of ethics and their application to research		
8.	Familiarity with the data collection techniques - Qualitative methods		
9.	Familiarity with the data collection techniques - Quantitative methods		
10.	Familiarity with the data analysis techniques		
11.	Familiarity with the skills required by a patient partner in research		
12.	Familiarity with technical knowledge i.e. writing e-mails / making power point presentations		
13.	Familiarity with the benefits of research		
14.	Understanding of how the research results are disseminated		
15.	Understanding of how the research is funded		
16.	Familiarity with several ways to participate effectively on a team		
17.	Familiarity with key principles of effective communication		
18.	Knowledge about various approaches to prevent and manage conflicts		
19.	Other (please specify):		

WORKSHEET: PROJECT AND TEAM NORMS

Values / Principles:

Roles & Expectations for patient partners:

Needs & Expectations of patient partners:

- *Training and mentorship needs*
- *Communication with the team*
- *Travel, meals and accommodation needs*
- *Participatory compensation needs*
- *Confidentiality of information*
- *Other / special needs*

Ending the partnership:

- *From Research Teams:*

- *From Patient Partner:*

Principal Investigator/research staff Signature: _____

Patient Partner Signature: _____

WORKSHEET: PROJECT BRIEF

Project information & Summary:

Principal Investigator's Name and Contact Information:

Location of research:

Time frame of project:

Required time and commitment from patient partners:

Engaging patient partners with a specific profile: Yes / No

Other details: Areas of involvement:

Questions	Phase of study	Details

Principal Investigator/research staff Signature:_____

Patient Partner Signature:_____

PATIENT PARTNER'S DETAILED ROLES AS A MEMBER OF A RESEARCH TEAM

This section will help you to identify your roles as a patient partner before you start the engagement, and brief you on each phase (**Overview of the research cycle**) and your relevant roles. Additionally, **the Worksheet: Patient Partners' Roles in Research** can be used to fill out your specific roles when you participate in the study.

- **PLANNING THE STUDY:** In this phase, patient partners may help to ensure that the research is relevant to the needs of patients. Being involved at the early stages of design will help in building the relevance, quality and ethics of the research, in addition to improving the recruitment of participants (PCORI, 2016).

  The process may include different ways of gathering input such as:
  - Discussions with existing patient partner reference groups, stakeholders and networks.
  - Inviting people to an event or holding a workshop or focus group.
  - Attending meetings held by service user groups.

Research phase	Key activities performed by the patient partners	Description
Planning the study: *Planning & Thinking*	Identifying the problem to be investigated	Define the goal, help in designing clear problem & sub problem statements, importance of the topic being pursued, and review of the literature to support the study topic.
	Grant writing and proposal development	Support in writing the grant application for funding by developing some parts of the study protocol (performing literature searches, writing background, defining key concepts, planning resources, budgeting, and calculations.)
	Setting priorities (population / health issues)	Clearly identify the characteristics of the study population, existing health priorities and those that are relevant to research.
	Formulating research questions	A process to refine, identify and prioritize the research questions. It includes different methods such as: • Discussions with existing groups and networks. • Other patient partner interviews.
	Facilitating recruitment	Co-design the recruitment strategy, refine inclusion/exclusion criteria, assist in adapting culturally suitable ways to recruit specific populations and introduce the research to the patient groups, and ensure that the research is relevant to the needs of patients.
	Connecting with other stakeholders	Bring in other potential patient partners or health care experts.

	Providing feedback/ review of consent forms to support ethical review	Help shape and simplify the informed consent form and process.
	Study protocol	Help ensure the protocol is clear, easy to understand and acceptable.
	Identifying key outcomes	Help i define the key indicators and measures from patient perspective.
	Study design	Help plan the type of research, ways to choose a sample, and also design instruments such as questionnaires, interview guidelines, checklist etc.

- **STUDY CONDUCT:** In this phase, PPs can play the important role of co-collaborators and co-designers of the data collection tools. They may help in answering important questions such as: Can the question be answered by finding data already in existence or will data have to be collected from participants? Would interviews or focus groups be best or would a survey be more practical? The PP can help to situate the findings within the context of their own illness, their knowledge of other research, their community, and relationships with health care providers (PCORI, 2016).

Research phase	Key activities performed by the patient partners	Description
Conducting the study: *Gather, Analyze & Interpret*	Monitoring study conduct and progress	Help the team monitor the process conducted in a timely manner.
	Data collection	Play an important role as co-collaborator and as a research team member in co-designing the data collection tools. Identify specific modes of data collection (i.e. electronic versus phone, conduct interviews or administering the surveys)
	Data analysis and interpretation of findings	Understand and interpret the data from a patient lens and support the research team
	Translation of documents	Support the team with different language translations; interpret and write the results in a simple format.

- **KNOWLEDGE MOBILIZATION:** Patient partner involvement can also influence, support and add strength to the way research is taken up in practice. PPs' lived experience and relationships with health care providers provide a strong foundation for moving results into practice. In this step, the patient partner will work with the research team to ensure that all the information is included in the research reports, to help in co-writing journal articles, and to translate research

findings to patient groups and public-friendly wording. Patient partners can also identify how, when, where, and what knowledge should be disseminated through their knowledge of the community and their networks. If the PP has been involved at other stages of the research, they will be able to help summarize the research findings in clear and user-friendly language (PCORI, 2016).

Research phase	Key activities performed by the patient partners	Description
Knowledge mobilization: *Share, write & publish*	Writing reports, scientific papers, lay summaries	Review whether all the information is included in the report; co-write the report (in a user-friendly manner), manuscripts, and newsletters as well as provide information on other publication portals; present the findings with the research teams.
	Implementation of results	Application of results to wider audience and validate on the reporting. Help situate the findings within the context of own illness, knowledge of other research, community, and relationships with health care providers.
	Evaluation of their engagement with the research team	Help evaluate whether engagement as a patient partner made a difference in the research process or outcomes.
	Dissemination in the community	Influence, support and add strength to the way research is taken into practice by identifying how, when, where, and what knowledge should be disseminated through knowledge of the community and own networks.
	Foster better research	Help ensure that research will effect change and improvement in issues that concern people most and can lead to new improved services and changes in practice.

At the conclusion of the research project: Partnership Evaluation	The involvement of the patient partner at the end may be related to evaluating the partnership. It is important to know whether the public involvement worked well and what did not work, and to build an evidence base for the successful engagement of patients in research.

REFERENCES:

- Arthur A. and Hancock B. (2007). *Introduction to the Research Process*. The NIHR RDS for the East Midlands / Yorkshire & the Humber. Retrieved from: https://www.schulich.uwo.ca/pathol/research/pdf/2a_Introduction_to_the_Research_Process_Revision_2009.pdf
- Fawcett S. (1991). *Some Values Guiding Community Research and Action.* Journal of Applied Behavior Analysis, 24 (4), pp. 624-636.

Retrieved from: https://ctb.ku.edu/en/table-of-contents/overview/model-for-community-change-and-improvement/core-principles-and-values/main

- PCORI. (2016). *Engagement Rubric for Applicants*. Retrieved from: https://www.pcori.org/sites/default/files/Engagement-Rubric.pdf
- The Children's Hospital of Eastern Ontario Research Institute (CHEO). Retrieved from http://www.cheori.org/en/researchroles

WORKSHEET: PATIENT PARTNERS' ROLES IN RESEARCH

Research phases	Key activities carried out by the patient partners	Description
PLANNING THE STUDY		
CONDUCTING THE STUDY		
KNOWLEDGE MOBILIZATION		

SKILLS FOR EFFECTIVE ENGAGEMENT IN RESEARCH

It is important for you to get engaged in the research process. Your 'voice' should be heard and this requires skills on how to communicate in easy-to-understand language, collaborate effectively as a team member, express questions, and resolve conflicts or misunderstandings easily and professionally.

Communication is a two-way process. As a part of **effective communication**, it is important for you to understand other team members and for them to understand you. For example, if you are trying to think of a response, instead of listening intently to what's being said, the context of the message may not be received well. Here, you can be an effective communicator when the message received is interpreted in the way it was intended. In this section, there are various cues such as actively listening, maintaining appropriate eye contact without looking down, and using an open and approachable posture to show someone that you are open to receiving the message. The overall awareness of your body language and voice tone is also important. You also need to ask for clarification whenever required, rather than assume the meaning of what is being said. Another important aspect of your participation is **effective collaboration**, which includes cooperation and maintaining the quality of relationships.

A win/win outcome in collaboration is the ideal method to use in working out any problems on a team. If you have collaborated well, you will ultimately grow with knowledge, respect, and understanding between the team members (Eilerman D, 2007)

Another important aspect is **conflict**, which can occur at any time and at any place (Gottman J, 2002), originating among the team or between groups in case of disagreements in teams' personal values, attitudes or expectations. This section will also help you learn how to respond effectively to conflicts within the team.

This section provides important tips for a PP to engage effectively in a research project.

REFERENCE:

- Eilerman D. "Win/Win Solutions- The Role of Collaboration in Resolving Problems". *Mediate Canada*, January 2007.
  Retrieved from: https://www.mediate.com/articles/eilermanD8.cfm
- Gottman, John. (2002). The Relationship Cure. New York: Three Rivers Press
  Retrieved from:
  https://www.workplacestrategiesformentalhealth.com/mmhm/pdf/full_communicating_0.pdf

A patient partner wants to be heard by the research team…

"What should a patient partner do for effective and meaningful engagement?"

Be a…

Figure.4 Characteristics of effective and meaningful engagement

EFFECTIVE COMMUNICATION

Communication is the exchange of information, ideas, concepts, attitudes, trust and emotions with team members. People express and communicate verbally (i.e., speech) and non-verbally (i.e. body movements) and they tend to tell truths the latter way, rather than using words (Mehrabian A, 2007). In fact, the majority of communication is through body language – it's very powerful!

General cues for speaking, listening and body language:

You are Comfortable And Confident when you …

- **Smile when greeting someone;**
- **Greet with appropriate title (Mr./ Ms. / Dr.);**
- **Keep your face neutral or happy;**
- **Offer a firm but gentle handshake;**
- **Keep an appropriate distance from the other person;**
- **Keep and maintain eye contact while speaking to someone;**
- **Use plain language to explain complex things;**
- **Sit at the eye level of other person;**
- **Actively listen to your conversation partner;**
- **Give your full attention – listen carefully and give subtle responses;**
- **Nod your head when listening to your conversation partner;**
- **Offer brief verbal or physical confirmation that you are listening and understand;**
- **Appear open and undefended;**
- **Be positively curious to meet your team members.**

You are Uncomfortable and Not confident when you …

- **Cross your arms and talk;**
- **Lean on walls or objects while talking;**
- **Get distracted while listening or talking to someone;**
- **Show different negative emotions (anger, fear, frustration);**
- **Interrupt when someone is talking;**
- **Confront team members in an aggressive or harsh manner.**

REFERENCE:

- Mehrabian, A. (2007). Nonverbal Communication. New Brunswick, NJ: Aldine Transaction. Retrieved from: https://www.workplacestrategiesformentalhealth.com/mmhm/pdf/full_communicating_0.pdf

EFFECTIVE COLLABORATION

This section gives you useful tips on how to be an **effective collaborator** when participating in the research process. The spectrum of good collaboration is broad and can be applied throughout the process of engagement.

Collaborative research: Equal partnership between two parties builds a strong foundation!
(Research Team = Patient Partner)

SIMPLE TIPS FOR EFFECTIVE COLLABORATION:

It's your right to know!	• ASK FOR CLARIFICATION FROM THE RESEARCH TEAM
Show professional attitude	• SHOW UP, BE PUNCTUAL, BE PREPARED & BE ACCOUNTABLE
Aware of different cultural contexts	• RESPECT EACH OTHERS' BELIEFS • BE AWARE OF EXPECTATIONS & PRECONCEPTIONS
Need training & mentorship	• ASK FOR TRAINING FROM THE RESEARCH TEAM
Be positive	• FRAME FEEDBACK POSITIVELY • SUGGEST SOLUTIONS TO THE TEAM
Provide essential information	• SHARE LIVED EXPERIENCE WITH THE TEAM • HELP THE RESEARCH TEAM TO MOVE IN THE RIGHT DIRECTION
Aware of diversity	• EMBRACE THE DIFFERENCES OF TEAM MEMBERS • DIFFERENT PERSPECTIVES LEADS TO SOLUTIONS
Building trust	• STRENGTHEN THE AREAS OF TRUST WITHIN THE TEAM

VALUES THAT PROMOTE COLLABORATION:

COMMITMENT | TRUST | OPENNESS | FLEXIBILITY

PREPARATION | CONSTRUCTIVE SHARING | PASSION

UNDERSTANDING RELATIONSHIPS | SENSITIVITY | CONTRIBUTOR

At the end

HAVE FUN LEARNING

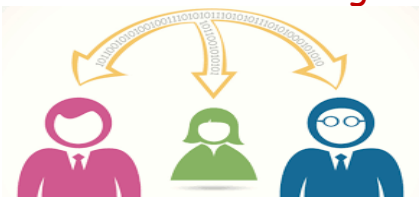
ELEMENTS OF GOOD COLLABORATION:

Have clarity on roles

Value own and others' expertise

Shared sense of purpose

Translate Knowledge



Do not tune out

Do not feel Intimidated

PERC

EFFECTIVE CONFLICT MANAGEMENT

Effective Conflict Management= Identifying and managing conflicts sensibly, fairly, and efficiently

SIMPLE TIPS FOR MANAGING CONFLICTS

Assume that others have different pieces of the answer and can create solutions together.
Team members' work together to find solutions on common ground.
Listen to your team members to understand each other's perspective.
Re-evaluate your assumptions and ask others' views and discuss.
Search for strengths and value others' points of view.
Genuine consideration, respect and value for other team members.
More about discovering new opportunities for effective collaboration and engagement.

CONCLUSION

Fostering meaningful PE is a complex but important task. The key to successful patient engagement lies not only in patient-centeredness, but in underlying norms and values that reinforce those practices as well. One of the new collaborative efforts is described as "bottom up", where local stakeholders (such as PPs) are involved in problem-solving. The traditional and standardized approach is "top down", where research teams/experts/policy makers contribute, make the plan and then share it with partners (Bengoa, 2013). Figure.5 illustrates use of these hybrid approaches in PE.

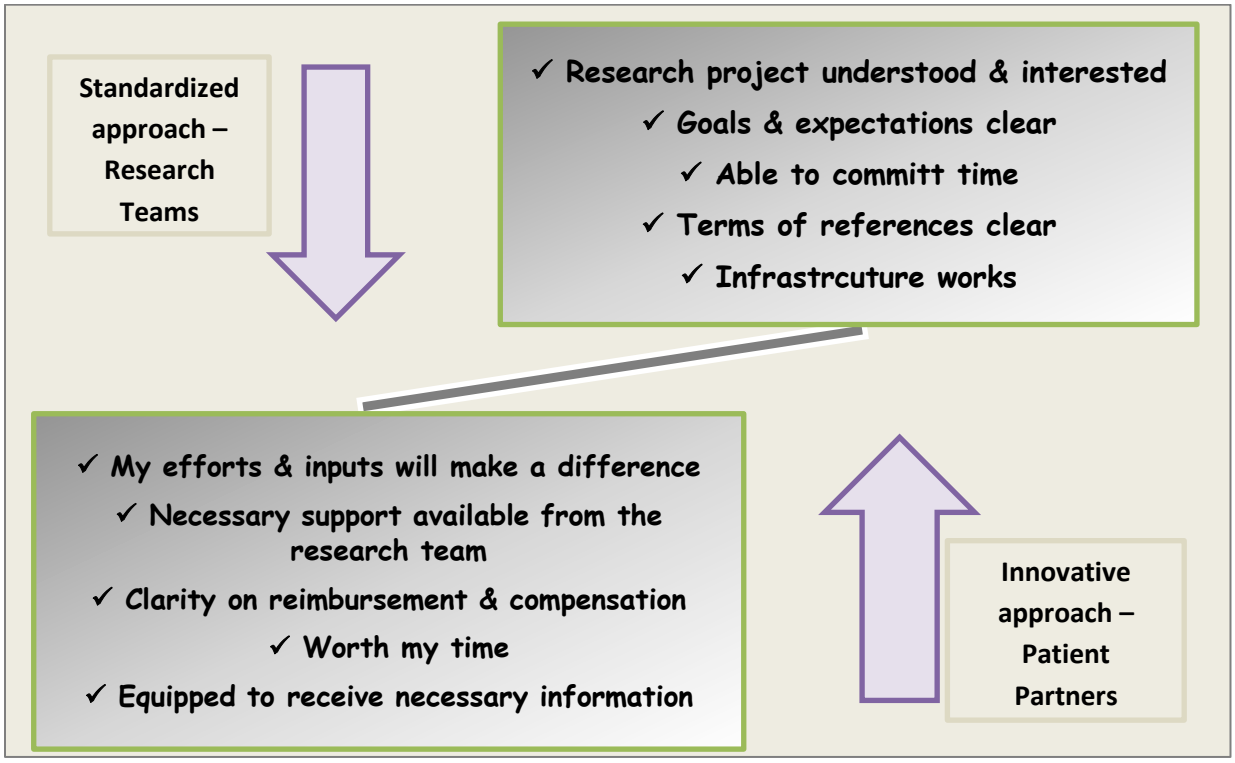


Figure.5 Example of 'top-down' & 'bottom-up' approach in Patient Engagement in research

For example, infrastructure support provided from a standardized top-down approach that is driven by the research teams facilitates bottom-up implementation of PPs' views.

As a PP on a research team, if you answer 'yes' to all the key points mentioned in the hybrid approach then 'go ahead' and 'participate'!

REFERENCE:

- Bengoa R. (2013).*Transforming health care: an approach to system-wide implementation*. International Journal of Integrated Care; 13(3. DOI: http://doi.org/10.5334/ijic.1206.

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