ECHO for Clinical Research Professionals (CRP) – Summary of (i) Key presentation and (ii) Problem discussion from session held on 21 November 2025

(i) KEY PRESENTATION:

Patients into participants: Engaging People with Lived Experience in Research by Matheus Wiest, Manager of Patient Engagement in Research, Pride in Patient Engagement in Research Initiative (PiPER), University Health Network (UHN) *(Slide deck attached).*

With regard to definition and terminology, "People with lived experience" (PLEX) is the preferred term instead of "patients" because it includes current and former patients, family members, and caregivers. All of these individuals bring valuable insight into health conditions and the healthcare system. This terminology also helps distinguish UHN's research engagement work (the PiPER team) from the patient experience team, which focuses on quality-improvement initiatives.

Engagement was described as active, meaningful, and collaborative involvement of people with lived experience throughout the planning, doing, and sharing of research. Importantly, this is not about enrolling them as study participants—they contribute as partners, not subjects.

The value of engagement is clear: involving PLEX strengthens research by making it more relevant, higher quality, and more meaningful to the people who will ultimately use the results. It also helps ensure publicly funded research responds to real needs and meets current expectations, as many funders now require engagement.

Five possible key roles were outlined, which PLEX can fulfil:

UHN Research

PLEX Roles

PiPER | Pride in Patient Engagement in Research

PLEX can play FIVE roles.
Find role-specific training resources in the PiPER Toolkit.

ROLE	SUMMARY OF RESPONSIBILITIES
Team Members	Can perform roles as members of a team alongside scientists, innovators, development teams, clinicians, students, and research staff, among others.
Knowledge Ambassadors	Can help create, communicate, and share materials and information about a project/product and its results for a number of audiences.
Peer Reviewers	Can play a role in reviewing research and products, providing feedback, and evaluating future or past research activities based on their lived experiences and insights.
Decision Makers	Can play a role in shared decision making with development teams, scientists, clinicians, and staff members when overseeing the activities of a organization or initiative.
Fundraising Ambassadors	Can play a role in fundraising.

PLEX can contribute in several ways:

- Team members: involved throughout the project
- Knowledge ambassadors: helping share information with different audiences
- Peer reviewers: reviewing abstracts and other materials
- Decision makers: serving on advisory or steering committees
- Fundraising ambassadors: supporting donor-related initiatives

The question of when to engage PLEX is an important one. Successful engagement starts early, ideally during grant development. This includes relationship-building, clear role definitions, communication plans and appropriate budgeting. To align the value of the expertise of PLEX with the expertise of research team members, UHN is developing a policy to align the hourly rate of PLEX within the minimum range of the Research Associate I hourly rate. Given that most PLEX will work only a few hours per year on a project, this hourly rate provides appropriate compensation without burdening overall budgets. For example, 10 hours of engagement per year will cost less than $500 per PLEX.

The Bare Bones Podcast project was given as a practical example of multiple engagement roles throughout a research project: https://www.scifragments.ca/barebonespodcast/episodes

Resources from PiPER:

PiPER Toolkit: https://perc-phc.mcmaster.ca/app/uploads/2023/12/piper-tool.pdf

- A free, open PDF resource accessible via QR code
- Contains information for planning, doing, and evaluating patient engagement in research
- Includes tools and checklists for implementation and evaluation
- Covers topics like what is research, who are people with lived experience, how to engage them, roles they can play, and evaluation methods

PiPER Community of Practice: where the PiPER team showcase and discuss examples of involving people with lived experience in research. If you are interested, you can become a PiPER member on their website: www.uhnpiper.ca (Scroll down and sign up on the left-hand side).

(ii) PROBLEM DISCUSSION:

"What happens when the requirements from the protocol or otherwise from the sponsor level conflict or disagree with site SOPs, with institutional policies?"

ECHO community members contributed their experiences and ideas as follows.

- Set up regular check-ins with major sponsors so issues can be raised early and worked through together.
- Build clear, protective wording into SOPs to help the site push back when sponsor requests don't align with policy.
- Look for leverage in the contract when sponsor requirements start to conflict with what the site can actually do.

- Note that some sites haven't run into this specific lab reference-range problem before, especially with IIT sponsors.
- Go ahead with standard-of-care procedures before consent when they would happen anyway and the protocol reflects that.
- Double-check internal processes with colleagues to make sure everyone handles these situations the same way.
- Ask sponsor partners directly whether other sites have pushed back on lab ranges and how they responded.
- Check whether the lab reports themselves already include reference ranges that could satisfy the requirement.
- Keep in mind that this type of issue usually falls outside what an REB can address.
- Remind labs that providing reference ranges is typically required, and that refusing may put study revenue at risk.
- Consider more flexible or adaptive research approaches when dealing with unexpected challenges like this.
- Take note of similar experiences where sponsor approval requirements (like qualified raters) have blocked sites from joining studies.
- Follow up internally or with partner organizations to gather more context or examples of how others have handled the same issue.
- Tap into regulatory expertise when needed to help clarify what is or isn't required.