

Patient Partnership in Chronic Complex Disease Research:

A Toolkit for Researchers

This guide was prepared by the Community Advisory Committee (CAC) for Columbia University's [Center for Solutions for ME/CFS](#). The CAC provides patient and caregiver input to the NIH-funded ME/CFS Clinical Research Centers.

Patients as Research Partners

Patient-oriented research (POR), defined by Baumgardner (2019)¹ as “research... that meaningfully partners with patients to plan, conduct, or interpret the study.” Research quality increases when patient partners are involved. Researchers state that patient participation improves quality, validity, and perceived credibility of their results.^{2,3} One study showed that 85% of participants agreed that the quality of research improved when patients were involved.⁴ After researchers participated in POR, they reported an increased appreciation for the value of patient input.^{2,5,6}

While patient inclusion during recruitment and data collection phases is relatively standard, participation both before and after these phases is far less common. However, studies demonstrate the value of inclusion at every stage, and early, consistent involvement is crucial.⁸ POR is not a final step in the translational process but should be involved in **every stage of the research cycle**, including **foundation, preparation, execution, and translation**.

Patient involvement improves research quality. Studies show patient participation is useful in identification of research priorities, grant writing, recruitment strategy development, tool development and refinement, patient interviews, and dissemination strategies.⁸ Patient involvement in research has also been shown to affect healthcare outcomes like diagnostic rate and lead to earlier interventions.⁸ In addition, patient partners can direct researchers to the questions that matter most to their healthcare.^{2,9,10}

In response to the emergence of Long COVID, the University of Zurich created the Participatory Science Academy in 2021 incorporating a Long COVID citizen science board including 21 people with Long COVID and seven with ME/CFS. The group developed a methodology incorporating different stakeholders that can be used to co-create person-centered research agendas to capture the impact of the disease.¹³

ME/CFS is rarely diagnosed, making incorporating patient expertise more valuable than ever. Beyond the clear ethical considerations, the role of POR is critical in studies on rare or rarely-diagnosed diseases like ME/CFS, where clinical knowledge is not widespread.⁷

Impact of Patient Inclusion:

Better quality research

- Patients' direct knowledge and personal experience leads to better research questions

Expanded applicability of research, particularly in 'hard-to-reach' populations

- Through more active engagement, you can solicit help of patients to engage others who are challenging to reach
- May address disparities by actively reaching out to under-represented subjects
- Feeling of 'ownership' and genuine engagement leads to better retention

Empowering patients

Increased translation, dissemination, & uptake of results

- Patients can serve as 'early ambassadors' for research
- Increased interest in the field = more funding over time

Democracy and accountability

Moral obligation

- Patients have a fundamental right to be involved in research that directly affects them ("nothing about us without us")

Consistent engagement across studies requires buy-in from the research group and beyond. Research teams require **structural support** for patient engagement from departmental heads, universities, and hospitals with whom they are working.

Extrapolated from: Esmail et al., 2015

Roadmap to success for engagement:

Recruiting partners with lived experience

1. Diversity of representation (age, gender, ethnicity, race, socioeconomic status) should be considered. Not all patients will have similar perspectives.
2. Recruit through personal connections and/or via announcements from major advocacy organizations such as #MEAction, Solve ME, or the Open Medicine Foundation.

3. Anticipate a 25% dropoff in participation due to inevitable increases in symptoms; recruit accordingly.

Cultivating a successful collaborative environment

1. Funding should be allocated to the recruitment, retention, and engagement of people with lived experience. They should be considered members of the research team, and funding for their participation should be commensurate with that of other research consultants. Conceptualizing POR as the establishment of **long-term partnerships** will guide researchers to recruit *and* retain people with lived experience for the current study as well as future studies.
2. Formal infrastructure outlining **clear expectations** for the type of input, time/energy required, and early establishment of timelines is vital. Lack of 'role clarity' and expectations has been cited as the most significant barrier to effective patient participation in study design by both researchers and people with lived experience.
3. **Flexibility in timing, method, and modes of communication** is vital for people with complex chronic disease.
4. Meetings should be **brief** with **set agendas** in order to reduce strain on participants. If in person, meetings should be accessible and have an area in which patients may rest nearby.
5. The process by which patient **input will be incorporated** into each phase of research (foundation, preparation, execution, and translation) should be outlined clearly in the research plan. This will help set clear expectations for both patients and researchers to ensure genuine partnership. Authentic patient engagement requires patient involvement in decision-making.

For more, refer to [Engaging with People with ME as Partners](#).

Bibliography and Recommended Resources

- 1) Baumgardner D, (2019). Defining Patient-Oriented Research for the Average Person (and Potential Research Partner). *Journal of patient-centered research and reviews*, 6(1), 4–6.
<https://doi.org/10.17294/2330-0698.1697>
- 2) Williamson T, Brogden J, Jones E, & Ryan J. (2010). Impact of public involvement in research on quality of life and society: a case study of research career trajectories. *Int. J. Consumer Studies* 34, 551–557,
- 3) Wyatt K, Carter M, Mahtani V, Barnard A, Hawton A, & Britten N, (2008).The impact of consumer involvement in research: an evaluation of consumer involvement in the London Primary Care Studies Programme. *Family Practice* 25, 154–161.
- 4) Weglicki L, Rice V, & Hammad A, (2005), Science and the community: a collaborative model for integration of research within the community. *Ethn. Dis.* 15(Suppl. 1), S135–S138.
- 5) Barber R, Beresford P, Boote J, Cooper C, & Faulkner A (2011). Evaluating the impact of service user involvement on research: a prospective case study. *Int. J. Consumer Studies* 35, 609–615 .

- 6) Howe A, MacDonald H, Barrett B, & Little B, (2006). Ensuring public and patient participation in research: a case study in infrastructure development in one UK Research and Development consortium. *Primary Health Care Res. Develop.* 7, 60–67 .
- 7) Cordier J, (2014).The expert patient: Towards a novel definition. *Eur Respir J.*44(4),853-857. doi:10.1183/09031936.00027414
- 8) Esmail L, Moore E, & Rein A,(2015). Evaluating patient and stakeholder engagement in research: moving from theory to practice. *Eff Res.*4(2),133-145. doi:10.2217/CER.14.79
- 9) Abma T, Nierse C, & Widdershoven G, (2009). Patients as partners in responsive research: methodological notions for collaborations in mixed research teams. *Qual. Health Res.* 19, 401–415 .
- 10) Woolf B, Zimmerman E, Haley A, & Krist A, (2016), Authentic Engagement Of Patients And Communities Can Transform Research, *Practice, And Policy*, 4(4):590-594.
- 11) Lindenmeyer A, Hearnshaw H, Sturt J, Ormerod R, & Aitchison G,(2007). Assessment of the benefits of user involvement in health research from the Warwick Diabetes Care Research User Group: a qualitative case study, *Health Expect.* 10, 268–277 .
- 12) Dillon E, Tuzzio L, Madrid S, Olden H, & Greenlee R, (2017). Measuring the Impact of Patient-Engaged Research: How a Methods Workshop Identified Critical Outcomes of Research Engagement. *J Patient-Centered Res Rev.* 4(4):237-246. doi:10.17294/2330-0698.1458.
- 13) Ziegler, S, Raineri, A, Nittas, V, Rangelov, N, Vollrath, F, Britt, C, & Puhan.M, (28 April 2022) Long COVID Citizen Scientists: Developing a Needs Based Research Agenda by Persons Affected by Long COVID. *The Patient – Patient-Centered Outcomes Research*. DOI: 10.1007/s40271-022-00579-7