PATIENT-LED RESEARCH COLLABORATIVE

Response to Federal Register Notice/OMB RFI 89 FR 19885
Methods and Leading Practices for Advancing Public Participation and Community Engagement With the Federal Government

Submitted by the
Patient-Led Research Collaborative
May 17, 2024

The Patient-Led Research Collaborative (PLRC) is pleased to respond to OMB RFI 2024-05882, which seeks input on advancing public participation and community engagement with the federal government. PLRC is a group of patients with Long COVID and other infection-associated chronic conditions that conducts its own research on these conditions, consults on research, advances frameworks for patient-led research models, and advocates for better policies for the patient population. PLRC's experience is most relevant to the issues raised under Question 2 in the RFI, notably "the types of content (e.g., methods, tools, definitions, research on the value of participation and engagement, promising practices) could OMB include in a Federal framework for PPCE that would be effective and informative for Federal agencies to initiate or improve their participation and engagement activities, including those carried out with underserved communities…"

Of particular relevance to Question 2 is work PLRC undertook in partnership with the Council of Medical Specialty Societies (CMSS) to develop a set of scorecards that help to identify effective and sustainable models for collaboration in comparative effectiveness research (CER).[1] (More information on the scorecards is provided below.)

Starting Points for Engagements

In its work on patient engagement in research more broadly, PLRC has observed a number of fundamental building blocks for successful engagements. These are reflected in the scorecards, and we believe they are directly relevant to PPCE efforts generally.

- The lived experience of patients and community representatives *must* be valued by all participants.
- People with lived experience must have equal weight to other participants in decision-making.
- The participation of the most impacted populations must be prioritized, especially in the leadership and design of engagement activities.
- Accommodations that overcome barriers to participation must be provided. (See discussion below on "Engagement Considerations for People with Conditions like Long COVID.)
- Educate all stakeholders ahead of time on key terms and on background information and context.

[1] https://patientresearchcovid19.com/storage/2023/02/Patient-Led-Research-Scorecards.pdf

Key PPCE Principles Embedded in the Scorecards

To develop the scorecards, PLRC drew on a number of sources of information and expertise, including our own experiences as patients leading research, other patient communities, researchers, funders, and clinical research organizations, and it also collected data through baseline assessments and environmental scans. From these inputs, the project team identified a number of key themes that can inform PPCE more broadly.

- **Motivations of involvement of all and their biases:** Consider what motivates people (patients, family, researchers) to work on research. Patients are highly and intrinsically motivated to work on research – it helps them understand and inform treatment of their disease, especially when the medical field does not have the answers, gives them hope, and empowers them. Their motivations are not career-related.
- **Power dynamic in collaboration - Patients in the driver's seat:** Meaningful collaboration requires that power imbalances be addressed. Patients need to be in the "driver's seat" to select collaborative models that work for them. It is important to avoid low-level non-meaningful "collaboration" that is not a true partnership, and where patient input has little to no weight.
- **Roles of data and digital tools in shaping relationships – empowering patients or reinforcing problematic dynamics:** Inequitable access to data and digital tools reinforces unequal collaboration dynamic. It is important to understand the influence of data and digital tools, how they can empower patients, and how unequal collaboration dynamics are reinforced.
- **Build capacity with both soft and hard skills:** Patients bring their lived experience to the research, which is extremely valuable. To be most effective, particularly in research environments, patient researchers may also need capacity building of both soft (e.g. communication, time management) and hard (e.g. data analysis) research skills.
- **Value of "nimbleness" with rigor:** The ability to embrace both a rigorous approach to the science and the flexibility to be nimble and adapt when needed is essential, especially in rapidly changing environments like those during the early days of the pandemic.
- **Dynamic and non-linear paths of models of operation of patient groups:** Many patient organizations follow dynamic and non-linear paths to successfully achieve desired outcomes, which differ from academic or industry-led activities. It is important to recognize that these strategies can contribute to effective collaborations.
- **Funding dilemmas for patients: Losing autonomy, moral alignment, lacking resources:** Patient and community organizations face real challenges regarding funding, as they must balance the threat of losing autonomy with the need to secure resources to continue their work. Even when groups might be in full moral or

philosophical alignment on a given issue, resource challenges can prevent them from fulfilling their commitment to their mission.

- **Patient-centric values and awareness:** There is a burden to participating in any endeavor, and patients need to see the direct value of their participation. Collaborators should be cognizant of potential triggers of traumatic experiences while promoting community values of trust, respect, and reciprocity.

The team then delved further into these key themes and reviewed existing models of collaboration in light of these important values.

While these themes and the scorecards that embody them are focused on the engagement of patients in research activities, we believe that insights from them can be applied to PPCE more broadly. In particular, since many forms of PPCE occur in situations with significant power imbalances (real or perceived), understanding and addressing those imbalances is an essential starting point, and community participants must be engaged as full partners throughout the process, including in the design of the process for the engagement.

About the Scorecards

The PLRC scorecard project is formally known as *The Promise of Patient-Led Research Integration into Clinical Registries and Research* project. This project seeks to move beyond patient engagement toward a solution where patient-generated data and patient-led outcomes research become an essential component of medical research, leading to more patient-centric CER. Patients and patient organizations, funders, research institutions and other traditional biomedical research teams can collaboratively build the infrastructure and dynamics needed for patient-led CER.

The project team reviewed the following models and collaborative frameworks and incorporated elements from each into the models of patient-led research (for more information, see: The Promise of Patient-Led Research Integration into Clinical Registries and Research: Nested Playbook):

- Learning Health Systems[2]
- Arnstein's Ladder of Citizen Participation[3]
- Design Strategies in Online Citizen Science Platforms (Shirk, et al)[4]
- Forms and Functions of Participation (Sarah White)[5]
- Felicity Callard's Model[6]
- Research Partnership Maturity Model for Patient Organizations (FasterCures)[7]

[2] https://www.ahrq.gov/learning-health-systems/about.html
[3] https://www.tandfonline.com/doi/abs/10.1080/01944366908977225
[4] https://www.jstor.org/stable/26269051
[5] https://www.participatorymethods.org/method/levels-participation
[6] https://bmjopen.bmj.com/content/4/12/e005654
[7] https://milkeninstitute.org/article/RPMM-companion-guide

The scorecards serve to evaluate how effectively a patient group and research partner will collaborate when conducting truly patient-led research. The scorecards focus on the following four areas to advance patient-led research efforts:

- **Patient Burden:** Evaluates the degree to which patient burden and associated trauma is addressed, including accommodating patients who are dealing with illness and symptoms, compensation for patients' time and skills.
- **Patient/Partner Governance:** Evaluates the degree to which decision-making power and governance is shared between patient groups and partner groups
- **Research Organization Readiness:** Evaluates the ability of the research organization to engage in meaningful patient partnership. This readiness assessment allows patients to discern the research organization's level of collaboration and willingness to share control.
- **Integration into Research Process:** Evaluates the degree to which patients are involved in every phase of the research process and key committees, including study design, protocols, trial inclusion, analysis, and reporting.
- **Patient Group Readiness:** Measures the ability of the patient organization to engage in meaningful collaboration. This readiness assessment allows research organizations to discern the level of expertise, collaborative culture, and diversity of the patient group.

Copies of the scorecards are attached. They are available online at:
https://cmss.org/wp-content/uploads/2023/09/11246_CMSS_Plybk_Scorecards_REV-1.pdf

Engagement Considerations for People with Conditions like Long COVID

To ensure community engagement efforts are accessible, the federal government should make accommodating energy-limiting, episodic, and often invisible disabilities like Long COVID a norm. Examples for how to best include this:

- Providing breaks during meetings
- Not requiring long days of meetings
- Conducting virtual or hybrid meetings
- Ensuring reasonable and flexible deadlines
- Allowing for asynchronous input
- Allowing for alternates
- Providing ventilated and masked spaces to reduce risk of infection

More examples are provided through the Job Accommodation Network:
https://askjan.org/disabilities/Long-COVID.cfm.

Additionally, when engaging people with an illness, ensure that the people engaged are representative of the population impacted in terms of race, age (including children), sex, gender, etc. It is also important to Include different manifestations of a condition, including levels of severity and durations of illnesses.

About PLRC:

The Patient-Led Research Collaborative is a group of Long COVID patients and patients with associated illnesses such as ME/CFS and POTS, who are also researchers. We were born out of the Body Politic Slack support group and did the first research on Long COVID in April 2020. We are all researchers in relevant fields – biomedical research, participatory research, neuroscience, cognitive science, public policy, machine learning, human-centered design, health activism – in addition to having intimate knowledge of COVID-19.

Our mission is to facilitate patient-led and patient-involved research into Long COVID and associated conditions while following rigorous research methodology, and to advocate for policies that enable patients, particularly the most marginalized, to access care and live with dignity. We ground our work in the principles of disability justice and participatory research methods, and in the knowledge that those who experience an illness are best able to identify research questions and solutions.

The Promise of Patient-Led Research Integration into Clinical Registries and Research

CMSS Council of Medical Specialty Societies

PATIENT-LED RESEARCH COLLABORATIVE

Patient-Led Research Scorecards

The *Promise of Patient-Led Research Integration into Clinical Registries and Research* project moves beyond patient engagement toward a solution where patient-generated data and patient-led outcomes research become an essential component of medical research, leading to more patient-centric comparative effectiveness research (CER). Patients and patient organizations, funders, research institutions and other traditional biomedical research teams can collaboratively build the infrastructure and dynamics needed for patient-led CER.

The Council of Medical Specialty Societies (CMSS) and Patient-Led Research Collaborative (PLRC) have developed a sustainable collaborative model of CER based on information from and the expertise of patient communities, researchers, funders, and clinical research organizations. This model takes the form of scorecards which serve to evaluate how effective a patient group and research partner collaboration will be at conducting truly patient-led research.

These scorecards focus on the following areas to advance patient-led collaborative research efforts:

- **Patient/Partner Governance:** Evaluates the degree to which decision-making power and governance is shared between patient groups and partner groups
- **Integration into Research Process:** Evaluates the degree to which patients are involved in every phase of the research process and key committees, including study design, protocols, trial inclusion, analysis, and reporting.
- **Patient Burden:** Evaluates the degree to which patient burden and associated trauma is addressed, including accommodating patients who are dealing with illness and symptoms, compensation for patients' time and skills.
- **Research Organization Readiness:** Evaluates the ability of the research organization to engage in meaningful patient partnership. This readiness assessment allows patients to discern the research organization's level of collaboration and willingness to share control.
- **Patient Group Readiness:** Measures the ability of the patient organization to engage in meaningful collaboration. This readiness assessment allows research organizations to discern the level of expertise, collaborative culture, and diversity of the patient group.

For more information on this project and the organizations involved, visit: CMSS and PLRC.

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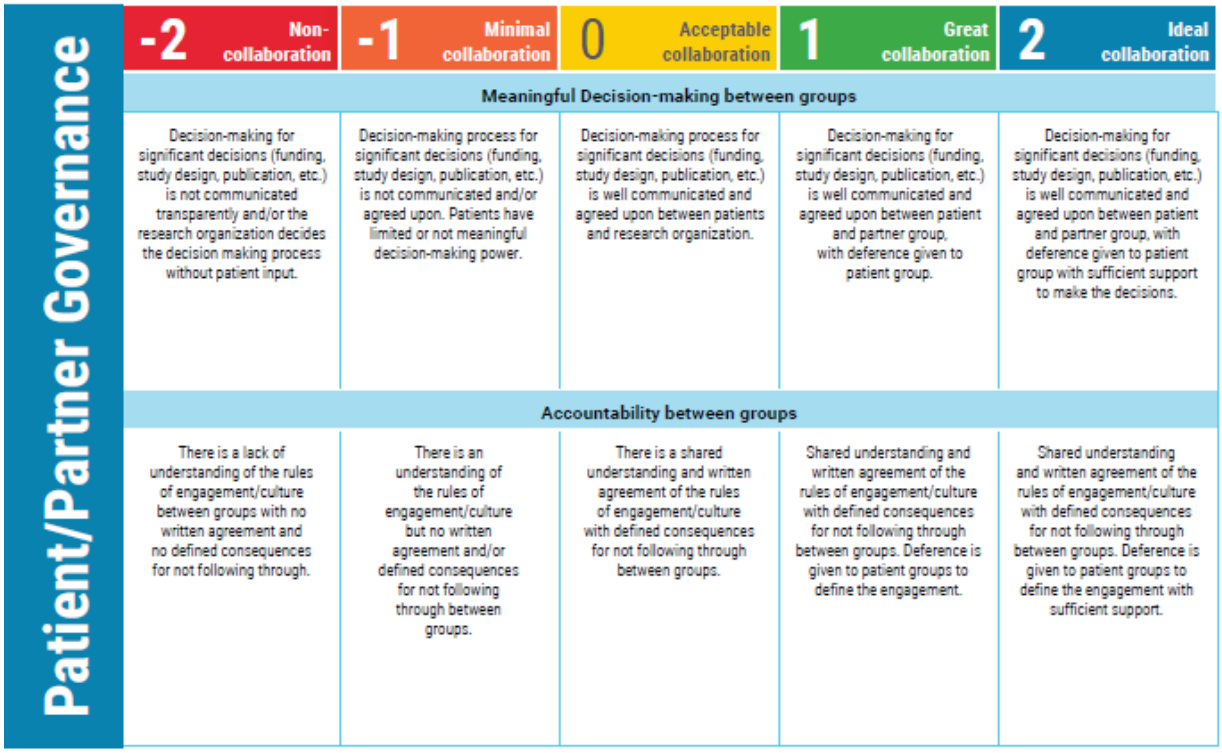
Patient Burden

-2 Non-collaboration	-1 Minimal collaboration	0 Acceptable collaboration	1 Great collaboration	2 Ideal collaboration
Accessible Engagement				
Research organization dictates engagement avenues with no consideration of the patient population's access needs. Full participation may be impossible; carry a high time, effort, or monetary cost; or cause patients harm.	Research organization considers the patient population when designing engagement avenues, but rarely provides additional accommodations when requested.	Research organization designs engagement avenues to offer sufficient time and accessibility for the patient population's needs, and provides individuals with additional accommodations upon request.	Research organization designs engagement avenues to offer sufficient time and accessibility for the patient population's needs, ensures patients can easily request additional accommodations, and works with patients to co-design systemic updates in response to requests.	Patients co-create engagement avenues from the outset to ensure that full participation is accessible and minimally harmful across patient sub-populations.
Trauma-Informed Practices				
Research organization does not consider the trauma burden to patients. Patients may experience discrimination, hostility, new or recalled trauma, or other harms as a result of participation. No trauma-informed practices are in place, and patients receive no resources or support for the trauma caused by participation.	Research organization is aware of a possible trauma burden, but no systemic trauma-informed practices are in place, and patients receive no resources or support for their trauma.	Research organization recognizes the trauma burden, and some trauma-informed practices are in place. Resources and support are provided to patients upon request.	Research organization implements trauma-informed practices throughout the study, and collaborates with patients to co-design adjustments to those practices during the study. Requests for resources and support are honored at a systemic level for all patients.	A diverse array of patients, representative of the study's sub-populations, collaborates from the outset to co-create a safe, inclusive, mutually respectful environment; implement and adjust trauma-informed practices throughout the research process; and ensure all patients proactively receive sufficient, comprehensive resources and support.
Responsiveness to Patients				
No formal channels for patient input are established. Research organization does not address patient feedback, and may exclude or retaliate against patients who voice concerns.	Patients find channels for input to be unclear, difficult to access, or unsafe from retaliation. Patient feedback may be acknowledged, but rarely results in changes to the current study.	Research organization creates clear, accessible, safe channels for patient input only after the research process has begun. Patient feedback is acknowledged, resulting in changes to analysis, presentation, or communication; and ad-hoc changes to the current study.	Research organization creates clear, accessible, safe channels for patient input throughout the research process; acknowledges patient feedback; and establishes mechanisms for patients to co-design systemic changes to the current study.	Patients co-lead the study from end to end, including creating clear, accessible, safe channels for input, using that input to inform the research process, and acknowledging its impact. Members of the research organization are excited about and fully engaged in patient collaboration.
Compensation				
Patients are compensated below market rate for their domain expertise and experience level, with no or limited options for when and how they are paid. Expenses, harm, and risk assumed from participation are not compensated.	Patients are compensated at market rate for their expertise and experience, with no or limited payment options. Expenses, harm, and risk are not compensated.	Research organization sets patient compensation at market rate for their expertise and experience; and for anticipated expenses, harm, and risk. Multiple payment options are offered upfront. Requests for additional compensation and/or payment options are honored ad-hoc.	Research organization sets patient compensation at or above market rate for their expertise and experience; and for anticipated expenses, harm, and risk. Multiple payment options are offered upfront. Requests for additional compensation and/or payment options result in systemic changes that benefit all patients.	Patients have decision-making roles in setting and adjusting compensation. Patients are compensated at or above market rate for their expertise and experience; and for anticipated expenses, harm, and risk; in the method and timing of their choice. Requests benefit all patients. Patients receive non-monetary compensation in the form of visibility, professional development, authorship, and awareness of their impact.


Patient/Partner Governance
-2 Non-collaboration
-1 Minimal collaboration
0 Acceptable collaboration
1 Great collaboration
2 Ideal collaboration
Meaningful Decision-making between groups
Decision-making for significant decisions (funding, study design, publication, etc.) is not communicated transparently and/or the research organization decides the decision making process without patient input.
Decision-making process for significant decisions (funding, study design, publication, etc.) is not communicated and/or agreed upon. Patients have limited or not meaningful decision-making power.
Decision-making process for significant decisions (funding, study design, publication, etc.) is well communicated and agreed upon between patients and research organization.
Decision-making for significant decisions (funding, study design, publication, etc.) is well communicated and agreed upon between patient and partner group, with deference given to patient group.
Decision-making for significant decisions (funding, study design, publication, etc.) is well communicated and agreed upon between patient and partner group, with deference given to patient group with sufficient support to make the decisions.
Accountability between groups
There is a lack of understanding of the rules of engagement/culture between groups with no written agreement and no defined consequences for not following through.
There is an understanding of the rules of engagement/culture but no written agreement and/or defined consequences for not following through between groups.
There is a shared understanding and written agreement of the rules of engagement/culture with defined consequences for not following through between groups.
Shared understanding and written agreement of the rules of engagement/culture with defined consequences for not following through between groups. Deference is given to patient groups to define the engagement.
Shared understanding and written agreement of the rules of engagement/culture with defined consequences for not following through between groups. Deference is given to patient groups to define the engagement with sufficient support.

Research Organization Readiness

-2 Non-collaboration	-1 Minimal collaboration	0 Acceptable collaboration	1 Great collaboration	2 Ideal collaboration
Recognition of Biases				
Research organization does not recognize bias and ignores feedback from patients	Research organization has limited awareness of own biases and listens to some feedback from patients.	Research organization is aware of own biases, is open to feedback from patients, and implements some of the feedback.	Research organization is aware of own biases and is open to feedback from patient group and actively iterates on feedback given	Research organization is aware of own biases and is open to listening to feedback from patient group. Actively iterates on feedback given. Other patient groups can attest to a positive working relationship. Research organization has a systemic process for accepting input from patients and patient groups.
Collaboration Process				
Research organization has no dedicated infrastructure for collaborating with patients.	Research organization has minimal resources/infrastructure for collaborating with patients.	Research organization has dedicated some resources and infrastructure for collaborating with patients (ie. patient panels); has at least one coordinating personnel focused on meeting the patient group's needs; conducts limited training to build skills to engage with patients.	Research organization has an established infrastructure and process for collaborating and codesigning with patients including at least one dedicated person focused on meeting the patient group's needs and advocating to the rest of the research organization; conducts routine training to build skills to engage with patients.	Research organization has an established infrastructure and process for collaborating with patients that has been vetted by other patients/patient groups; has at least one dedicated person who is focused on meeting the patient group's needs. The partner is recognized as a patient ally vetted by other patients and patient groups with background in disability justice. Conducts extensive training on meaningful engagement with patients.
Knowledge in Disease Subject				
Research organization has no knowledge/experience with the disease being researched	Research organization has minimal knowledge/experience (less than one year) with the disease being researched.	Research organization has at least one year worth of knowledge/experience with the disease being researched.	Research organization has more than one year worth of knowledge/experience of the disease being researched.	Research organization has extensive knowledge and direct experience with the disease being researched and those with knowledge are in decision-making roles. Research organization has a systemic way to keep on top of information from the patient community as well as the latest research.

Integration Into Research Process

-2 Non-collaboration	-1 Minimal collaboration	0 Acceptable collaboration	1 Great collaboration	2 Ideal collaboration
Hypothesis Generation				
Research goals are siloed from patients' priorities. Patients' questions and experiences are not included and/or are dismissed when generating research hypotheses.	Research goals attempt to involve patients' priorities, but limited by communication or collaboration. Patients' inquiries and lived experiences are rarely included when generating research hypotheses. Patients may have suggested the research question with no further involvement.	Research goals take into account patients' priorities. Patients' inquiries and lived experiences are included when generating research hypotheses.	Research goals proactively address patients' priorities with sufficient ongoing collaboration. Patient organization's inquiries and lived experiences are included when generating research hypotheses. Patient organizations work with patients to co-design research hypothesis.	Research goals are based on patients' priorities and co-written by patient organization or patient-researchers. Patient's inquiries and lived experiences share an equal weight with research organization's interests when generating research hypotheses.
Study Design				
Research organization does not include patients in the study design process. Patients do not have the opportunity to provide input on study design. Patient groups are utilized for recruitment purposes only, if at all.	Research organization does not include patients in the study design process. Patients may be invited to review study design but feedback is rarely incorporated and no functioning accountability system is in place.	Select patient voices are approached to inform the study design. Patients are invited to review study design and have an impact on the study design.	Patient organization and their community's input are proactively invited to help inform the study design. Patient organizations are invited to co-design and review study design and patient feedback changes the study design.	Study design is co-written and reviewed by a diverse array of patient-researchers representative of the study's sub-populations. If applicable, protocol testing is done by the patient community.
Analysis				
Patients do not have input in what data to prioritize for analysis and methods of analysis.	Patients are asked to review manuscript drafts but have little say in what data to prioritize for analysis and methods of analysis.	Patients are involved in interpreting data and carrying out analysis in some capacity.	Patients or patient organizations are invited and involved in interpreting data and carrying out analysis anywhere in the study.	Patient-researchers co-lead on the interpretation and analysis and/or work concurrently with partner organization's research team to carry out analysis.
Publication				
Study results are inaccessible to patients and/or behind an academic paywall. Findings are not communicated in lay terms.	Research organization summarizes findings in lay terms, but study results are inaccessible to patients and/or are behind an academic paywall.	Study results are freely accessible to patients and the public. Findings are summarized in lay terms in ways that are informative to the patient population.	Study results are freely accessible to patients and the public. Findings are summarized in lay terms and are actively disseminated to patient population. Patient-researchers co-write the interpretation and analysis.	Study results are freely accessible to patients and the public. Findings are summarized in lay terms and are actively disseminated to patient population. Patient organizations invite patients to co-write findings and reports. A channel of communication is available for patients to ask questions of the research organization.
Attribution				
Patients' work is attributed to others and/or patients are not attributed at all.	Patients are listed as being involved without a description of how they were involved. Patients were not consulted on how they prefer to be attributed.	Patients are acknowledged/ credited in major public facing communication (press, announcements, papers), to the extent that patients wish to be named. Patients were consulted on how they prefer to be attributed.	Patient group is credited in all public-facing communication and included as authors on papers, to the extent that the patient group wishes to be named. Patient group was consulted on how they prefer to be attributed.	Patients are acknowledged specifically for what they did throughout the engagement process, are credited in all public-facing communication, and included as authors on papers, to the extent that the patient group wishes to be named. Patient group was consulted on how they prefer to be attributed.

Patient Group Readiness

-2 Non-collaboration	-1 Minimal collaboration	0 Acceptable collaboration	1 Great collaboration	2 Ideal collaboration
Expertise				
Patient group is not versed in research on condition or speaks on only a narrow representation of the condition. Patient group promotes research that is harmful to the community.	Patient group is not versed in research on condition or speaks on only a narrow representation of the condition.	Patient group is up-to-date on research associated with condition and speaks on the diversity of the condition.	Patient group is up-to-date on research and has existing expertise (doing research, disability justice background) and includes diverse patient experts of the illness.	Patient group has done research on condition, is up-to-date on research, and has existing expertise (doing research, disability justice background) and includes diverse patient experts of the illness.
Bias and Representativeness				
The majority of the patient group is not patients or caregivers who can speak on behalf of patients. Patient diversity isn't prioritized or intentionally planned for, as such, participation in collaboration is severely limited and patient group leaders may be gatekeepers of research opportunities.	The leadership of the patient group is not patients or caregivers who can speak on behalf of patients. The leadership is not demographically representative of the group they are representing. Participation in collaboration is limited to a select few members of the group.	Leadership of patient group are patients themselves or caregivers who can speak on behalf of patients. Leadership is demographically representative of the patient group they are representing. Patient diversity is prioritized and their participation is planned for.	The majority of the patient group are patients themselves or caregivers who can speak on behalf of patients. The majority of the patient group are representative of the group they are representing. Patient group prioritizes and surfaces views brought by on diverse patient population into research collaboration.	The entire patient group are patients or caregivers who can speak on behalf of patients. The group is completely representative of the group they are representing. Patient group is well versed on own biases and centers the views of underrepresented patient population.
Accountability				
Patient group has explicit conflicts of interest with greater community good. Patient group gaslights or bullies the patient population.	Patient group does not seek out or respond to feedback from the patient population. Patient group is opaque in their involvement of the collaboration.	Patient group responds to the broader patient population and other patient groups of related illnesses. Patient group advocates for sharing research outputs and is transparent in their involvement of the collaboration.	Patient group proactively seeks feedback from the patient population and other patient groups of related illnesses. Patient group advocates for sharing research outputs and is transparent in their involvement of the collaboration.	Patient group proactively seeks feedback from the patient population and other patient groups of related illnesses. Patient group is transparent in sharing research outputs as well as decision-making that affect the patient population.
Accommodation				
Patient group doesn't acknowledge or accommodate access needs of the illness.	Patient group acknowledges access needs of the illness but does not accommodate them.	Patient group acknowledges access needs of the illness. Patient group accommodates most of the access needs of the illness when able.	Patient group acknowledges access needs of the illness. Patient group accommodates most of access needs of the illness when able. Patient group advocates for access needs of its members.	Patient group acknowledges access needs of the illness. Patient group accommodates all of the access needs of the illness when able. Patient group advocates for access needs of its members and the wider patient population.
Culture of Collaboration				
There are unsolvable disagreements within the group and/or the group often is in disagreement with other patient groups. Patient group has no agreed upon code of conduct and/or rules of engagement.	There are concerning disagreements on core values and/or inequitable practices within the group and/or with other patient groups that have caused tension. Patient group has code of conduct and/or rules of engagement that is not followed.	Patient group is able to work through any disagreement within the group and with other groups. Patient group has code of conduct and/or rules of engagement that is followed.	Patient group has productive relationships with each other and with other groups. In the event of disagreements, patient group has a process to work through any disagreement within the group and with other groups. Patient group has code of conduct and/or rules of engagement that is followed.	Patient group has aligned values and practices and seamlessly collaborates with each other and with other groups. Patient group has policies developed to address collaboration dynamics with the group and with other groups. Patient group has code of conduct and/or rules of engagement that is followed.