NPAC
NATIONAL PAIN ADVOCACY CENTER

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September 24, 2025

Suzanne Bakken, RN, PhD, FAAN, FACMI, FIAHSI
Alumni Professor of the School of Nursing
Professor of Biomedical Informatics
Vagelos College of Physicians & Surgeons
Columbia University
New York, NY 10032

Christin Veasley
Co-Founder and Director
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North Kingstown, RI 02852

Submitted via email to SciencePolicy@od.nih.gov

Re: Novel and Exceptional Technology and Research Advisory Committee, DRAFT Report of the Engaging the Public as Partners in Clinical Research (ENGAGE) Working Group

Dear Ms. Bakken, Ms. Veasley, and ENGAGE Working Group Members:

We write enthusiastically to endorse the DRAFT Report of the Engaging the Public as Partners in Clinical Research (ENGAGE) Working Group as a necessary and comprehensive framework for transforming clinical research toward public engagement. Engaging those most deeply affected by the outcomes of clinical research, including patients and caregivers living with the conditions being researched, clinicians managing care, and community groups supporting the advancement of health and well-being, is both paradigm shifting and essential to ensure that research is relevant, accountable, transparent, and capable of translation into positive health outcomes.

The **National Pain Advocacy Center (NPAC)** is a nonprofit organization comprised of researchers, clinicians, public health experts, and people living with pain, working to advance the health and rights of people with pain. As such, we represent several constituencies in the engagement ecosystem. NPAC envisions a world in which pain is treated effectively and people with pain have an opportunity to lead full, productive lives.

NPAC has been involved with clinical research at the National Institutes of Health at several stages. Our members have served on advisory councils for clinical studies, helped to set research priorities, and participated in strategic planning, most recently for the Helping to End Addiction Long-Term (HEAL) Initiative. We've served on Councils and coalitions of nonprofit groups supporting Centers and Institutes and we commented on the Request for Information for ENGAGE.

Our engagement hasn't always been seamless. Burdens fall disproportionately onto community groups to train, nominate and compensate people to serve on studies. While are happy to help advance clinical research, like many community groups, we have significantly smaller budgets than university partners or the NIH. We have also witnessed situations in which community members felt that their involvement was more about checking a box than being meaningfully welcomed or included as partners.

For these reasons, we welcome a comprehensive framework attuned to training, bi-directional learning, and compensation that is designed to be implemented consistently across NIH. We appreciate the framework's attention to the full life-cycle of research, from priority setting and design through delivery of results back into the community.

We fully endorse the core recommendations:

> -that NIH should require and support the integration of the Framework for Clinical Research Engagement into its funded clinical research by providing financial and training resources;
>
> -that NIH should actively foster an environment in which bi-directional researcher-community partnerships are standard practice;
>
> -that NIH should create a process to ensure robust community input on NIH initiatives from a broad range of community organizations and advocates; and
>
> -that NIH should invest in the continuous evolution and improvement of its clinical research engagement methods and processes.

In reviewing the details of the recommendations, we wish to underscore that NIH should take the lead in supporting the development of bi-directional training materials as an initial matter. Such initiative is needed to establish best practices and create "buy in" for training protocols that can be widely applied. The repository and ongoing technical assistance can then buttress this effort over time.

Given the kind of transformation ENGAGE envisions, we appreciate the DRAFT Report's attention to establishing metrics for evaluation, ongoing iteration and evolution.

A paradigm shift toward public engagement will require the cultivation of enduring relationships with a broad variety of community groups. The kind of broad community engagement envisioned will only be effective if infrastructures are established that are fully accessible, culturally competent, and include language translation.

We thank the Co-chairs and the Working Group for your extraordinary efforts. We very much hope that this DRAFT Report is approved and urge its full implementation at NIH.

Sincerely,

Kate M. Nicholson

Kate M. Nicholson

From: Greg Merritt
To: SciencePolicy
Subject: [EXTERNAL] Public Comment on ENGAGE NIH framework
Date: Wednesday, September 24, 2025 8:56:32 AM

Greetings:

Just wanted a note to highly endorse and support this report (and most importantly stress it's immediate implementation) for all research that is supported by NIH... As a patient partner with a number of studies and as a Sudden Cardiac Arrest and Heart attack survivor who has been gifted a second life... I have been stating for the past 7 years that my dream is that before my second life ends, I will hear researchers discussing with each other (and laughing at the thought) that there used to be a time that NIH and other funders would have done research WITHOUT patient and community partners highly engaged and authentically partnering with researchers at EVERY aspect of research lifecycle and we will look back at this time in astonishment for the blindspots this caused from question formulation to enrollment to dissemination and that by putting together a framework-- this can be changed from this day forward. I strongly endorse this report and plead with the decision makers to make this a reality as soon as possible. I thank the team for such incredible work and look forward to learning of how this will be implemented to make this second life partnering with researchers THE NORM-- not the exception... Thank you so much!

Greg Merritt (GP) Grateful Patient
Founder, Patient is Partner, LLC

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J Greg Merritt, PhD
CEO/Founder Patient is Partner, LLC & Informational Interviewing, LLC
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From: Sharon Waldrop
To: SciencePolicy
Subject: [EXTERNAL] Public Comment: ENGAGE Working Group
Date: Wednesday, September 24, 2025 4:42:41 PM

I strongly support NIH's recognition of the importance of clinical research engagement. Studies are most impactful when patients, caregivers, and communities are partners in planning, design, and dissemination. As stated, engagement improves efficiency, builds trust, increases relevance, and supports broader dissemination of results. From my professional and lived experience working with individuals living with chronic pain and complex conditions, I have seen firsthand how patient and community involvement leads to studies that are not only scientifically rigorous but also practically meaningful. This greatly increases the likelihood that findings will translate into real-world improvements in care, adherence, and health outcomes.

I urge NIH to develop a centralized engagement framework across all Institutes and Centers; provide training and resources for researchers and community partners; require high-quality engagement plans in grant applications; and support evaluation metrics to measure impact. Genuine engagement is not a formality—it is an essential element of rigorous science that advances equity, accelerates discovery, and builds trust.

Respectfully submitted,
A person with chronic pain, advocate, educator, and coach with nearly three decades of experience partnering with patients, clinicians, researchers, and policymakers.

Sharon Waldrop, NBC-HWC
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From: Brittany Knight
To: SciencePolicy
Subject: [EXTERNAL] NExTRAC: ENGAGE Comments from USASP
Date: Thursday, September 25, 2025 4:07:36 PM
Attachments: img-2590333b-c270-495e-88d2-6134055ef845
img-fd55b663-0d41-4e4d-bff6-993ccdabd4a0

To whom it may concern,

On behalf of the more than 900 members of the United States Association for the Study of Pain (USASP), I am writing to express our strong support for the DRAFT Report of the Engaging the Public as Partners in Clinical Research (ENGAGE) Working Group. USASP is a non-profit professional society comprised of individuals interested in reducing the burden of pain through scientific discovery, clinical care, and advocacy. Our members come from numerous disciplines, including medicine, nursing, psychology, physical therapy, pharmacy, neuroscience, and other fields of science. Many are clinical researchers who value the involvement of people with lived experience of pain in their work, yet struggle to find the resources required to pursue the ideas presented in this draft report. Some of our members are people with lived experience of pain and have been guiding us in helping our members develop partnerships to understand the lived reality of people in pain and to collaborate on research that has a meaningful impact on people's lives.

This report is timely and well developed, providing a useful framework that guides the process of engagement within a single clinical research study and across studies over time. We have a few comments to add to the ongoing discussion:

1. We are concerned that resources are not currently available to efficiently provide either investigators or the public with training in engagement best practices. If training is to be required, NIH will have to identify - or even develop - the materials that meet the best practices standard. Once this is done, the fourth recommendation that proposes continuous evolution and improvement is critically important as best practices evolve.
2. The burden and cost of training has not been operationalized by the working group, yet required training will have a substantial impact on both the public and the clinical research community, as it will affect all potential NIH clinical research applicants, many grant reviewers, and ultimately thousands of community members. Some public discussion about the burden (cost and time), as well as how NIH can mitigate this burden, is needed.
3. We applaud the recommendation that NIH integrate community input into all strategic planning and clinical research initiatives and that this is implemented agency-wide. We recommend the community representatives selected for these roles be required to have training in clinical research methods so as to maximize their preparation and contribution to the process.

And finally, we note that key groups were not included in the community conversations. Ideally the continued work of this group will invite participation of indigenous people, individuals living in rural communities with few healthcare resources, and children/adolescents/parents/caretakers. As men and women differ in their risk and experience of many illnesses and health conditions, it is ideal that the sex of attendees at the public meetings also be reported.

Warm regards,

Burel R. Goodin, PhD
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President, U.S. Association for the Study of Pain (USASP)

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