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## **Inspired by Successes of HIV Research, Patients with Long COVID, Affirm Importance of Deep, Meaningful Involvement in NIH's \$1.15 Billion RECOVER Initiative**

*In keeping with the accountable and ongoing involvement of people living with HIV in decades of successful research, leaders of patient-led groups for Long COVID press for greater integration into leadership and overdue answers on questions about the initiative's protocols and structures*

Over a year ago, in December 2020, Congress provided \$1.15 billion to the National Institutes of Health (NIH) for research on the long-term effects of SARS-CoV-2. This action by Congress still stands as a powerful signal of hope and encouragement to people living with the prolonged symptoms of a COVID-19 infection. These long-term effects, designated by NIH as Post-Acute Sequelae of SARS-CoV-2 Infection (PASC) and more generally referred to as Long COVID, are well-documented. The many millions now living with Long COVID are experiencing high rates of disability, post-viral conditions such as myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) and dysautonomia, and a wide range of debilitating neurological and cognitive disorders.

NIH further bolstered patient hopes for progress by promising significant patient engagement in the initiative. Patient leaders were eager to be a part of proven models of productive collaboration between investigators and those most affected, as seen in the HIV pandemic. But over a year later, the leaders of patient-led groups say they have been sidelined from meaningful involvement in the RECOVER Initiative, their [proposal for a meaningful patient engagement structure](#) has been ignored, and central questions vital for the conduct of the initiative and integrity of the data, [raised by dozens of groups](#), have not been answered. While they await word on the structure, scope and membership of a series of new task forces, they also stress the need for accountable, organized roles across the decision-making committees and core leadership of all Long COVID research, including the RECOVER Initiative.

However, advocates say they have still not seen an overall patient engagement strategy for RECOVER that outlines leadership, scope, or roles. There has been no promised meeting with Dr. Gary Gibbons, the director of NHLBI, which co-leads RECOVER with NINDS and NIAID. Parents and patients who were called on to give input remain blocked from even seeing the pediatric protocol, and have been told they have to wait until it is publicly released on the RECOVER website. Additionally, the definition of Long COVID deaths used in the autopsy study protocol shown to patient leaders would risk counting acute COVID and hospitalized deaths, in violation of the study's research opportunity announcement (ROA). *In these cases [and many more](#), say advocates, there's no sign that their input was heeded.*

"We're fenced off from the researchers making decisions, rather than being welcomed as valuable collaborators invested in the success of the RECOVER Initiative. I've seen the difference that active, consistent engagement can make, with decades of lived experience as a longtime HIV research advocate and external advisor to NIH," says **JD Davids of [Strategies for High Impact](#)** and its **National Network for Long COVID Justice**, who is living with Long COVID, ME/CFS, and other complex chronic conditions. "Meaningful involvement means deep, ongoing engagement with patient leaders accountable to their communities and each other, in specific, defined positions 'at the table' with investigators and staff. And that means we'd select

our own representatives to serve on the executive and steering committees and other core structures of RECOVER.”

“HIV established a new baseline for what patient engagement should look like, and we are nowhere near meeting that baseline,” adds **Alison Sbrana of [Body Politic](#)**, an international support and advocacy network for people with Long COVID. “As a person with post-viral conditions, it raises many red flags given the lack of accountability and missteps that have negatively affected ME/CFS patients, clinicians, and researchers desperate for answers. In that case, we see that ME/CFS is chronically underfunded -- but now we see a much more well-funded effort with the same lack of accountability.”

“We know there’s tremendous pressure for RECOVER to build a solid foundation for vital research on Long COVID -- our very lives depend upon it. That’s why we are puzzled why the Long COVID patient community is not being meaningfully involved in every step of the process, especially when we know the immense value of patient involvement given the kinds of breakthroughs we’ve achieved in the HIV pandemic, where deep collaboration between researchers and people with HIV turned the tide,” says **Lisa McCorkell**, a person living with Long COVID and co-leader of **[Patient-Led Research Collaborative \(PLRC\)](#)**. PLRC released the first in-depth report on Long COVID in May 2020 and now collaborates with researchers, public health officials, and health organizations worldwide.

“As patient representatives who have done successful patient involvement with dozens of research groups since the start of the pandemic, including a strong collaboration with RECOVER contractor the National Covid Cohort Collaborative (N3C), it is disappointing that the RECOVER program at large has not engaged patients earlier in the program and has not provided a clear definition or scope of patient engagement; moreover, RECOVER has not yet referenced the substantive body of meaningful patient engagement methods within or beyond the NIH,” she added.

“Sadly, people with myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) are all too familiar with the consequences that come from lack of meaningful engagement. We continue to see RECOVER investigators not heeding our urging to accurately and consistently identify ME/CFS cases or use validated instruments for measuring its cardinal symptom of post-exertional malaise (PEM),” explained **Ben HsuBorger of [#MEAction](#)**. “PEM can be challenging to capture since it is not a symptom that non-ME/CFS expert researchers typically know how to recognize. How can it be that we still have no idea how RECOVER investigators will define such important COVID-19 sequelae such as ME/CFS and PEM? Despite repeatedly raising this issue, we can’t get a clear answer. There are serious consequences for not getting this correct now.”

“Our members have many questions on RECOVER, and they deserve answers,” said **Karyn Bishof**, a first-wave longhailer, founder and president of the **[COVID-19 Longhailer Advocacy Project \(C19 LAP\)](#)**. “As we’ve raised with the Clinical Core leadership and staff numerous times, many of our members may not even be eligible by the time it’s fully enrolling: the protocol bans enrollment at 24 months past infection, which means we risk excluding the largest, longest-suffering group of longhailers struck in 2020. Imagine you’ve been profoundly ill for two years and told you’re excluded from a project *literally called RECOVER*, aimed to define PASC and its prevalence, that you helped advocate and secure the funding for. Is anything planned for us, or are we excluded entirely? If we fail to prioritize those most affected, we risk minimizing longhailers’ experiences and mischaracterizing the length of Long COVID’s effects. It honestly appears that despite numerous pleas for inclusion, no one is listening.”

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## Long COVID Advocates' Background on the RECOVER Initiative:

The RECOVER Initiative (Researching COVID to Enhance Recovery) was launched by the National Institutes of Health in February 2021. Its purpose is “to understand, prevent, and treat PASC [post-acute sequelae of SARS-CoV-2], including Long COVID,” and it is funded through a \$1.15 billion appropriation provided in December 2020.

Patient-led groups recognize that the RECOVER Initiative has raised the hopes of the millions who are struggling with the myriad challenges of Long COVID. Unfortunately, we believe it is in grave danger of failing to realize its goals. **At this particular moment, with the RECOVER Initiative just beginning its full-scale implementation, it is vital that NIH establish a productive and constructive role for patients and the Long COVID community in this effort.** Our sharing of [these issues and concerns](#) is meant to signal our commitment to working together toward the success of the Initiative and the progress that people with Long COVID so desperately need.

NIH and NYU have not recently held a meeting with organized, accountable patient-led groups, despite the promise of Dr. Gary Gibbons, director of the National Heart, Lung, and Blood Institute (NHLBI) in November, and there's been no official reply to the [open letter](#) from patient advocates. There have been vague commitments to patient engagement, but ongoing, substantive, and meaningful patient involvement has been lacking. We have identified these primary concerns, shared in hopes of constructively engagement:

- **Building on Established Expertise in Post-viral Illness:** The Initiative to date has lacked a solid grounding (in both form and content) in post-viral illness expertise and inquiry. Specifically, in the clinical protocol, there has been no mention of the term "post-viral illness," key researchers have been overlooked, and Initiative leads and site leads appear to have a shallow understanding of the field of post-viral illness.

**Post-viral illness experts**, including researchers, clinicians, and patient advocates with expertise in conditions seen in Long COVID (including myalgic encephalomyelitis/chronic fatigue syndrome [ME/CFS], postural orthostatic tachycardia syndrome [POTS] and other dysautonomias, and mast cell activation syndrome [MCAS]) **must be integrated into the top leadership of RECOVER.** *While we recognize there is now a task force on Commonalities with Other Post Viral Syndromes, its power and scope have not been revealed, and we know of no major post-viral illness researcher who is in the central leadership of the Initiative.*

Further, the NIH RECOVER Initiative presents **a singular opportunity to validate previous post-viral illness research findings and establish [meaningful clinical subgroups of chronic post-acute COVID illnesses](#)**, including ME/CFS. Inaction on these issues will only waste taxpayer dollars and further impede research progress, resulting in a series of cascading negative impacts.

- **Patient Engagement.** To date, there has not been a systematic and accountable integration of people living with Long COVID and Long COVID community advocates into the Initiative. To our knowledge,

there is no central, comprehensive, accountable, ongoing, and staffed community/patient advocacy or engagement structure ensuring meaningful involvement of people with Long COVID. *Patients have been polled about task forces, but assignments have not been released and it is unclear what their structure/scopes will look like. An initial onboarding meeting for the task forces on February 11 excluded patient representatives.*

**A comprehensive and adequately resourced patient engagement structure** must be rapidly created and sustained using existing best practices such as those in the NIAID HIV research structure. This will ensure **empowered participation across all segments of RECOVER and include a distinct, supported panel of patients themselves** who select their own leaders to serve on the Initiative's executive and steering committees. *An ongoing structure that seats accountable patient leaders from patient-led groups as fully-vested, ongoing representatives in key leadership positions is categorically distinct from selective consultation with Initiative-selected patient leaders, and has been vital to successful research collaboration in the HIV pandemic.*

- **Transparency:** Activities associated with the Initiative have fallen well short of even minimal expectations for transparency. Information that is customarily made public has not been shared. The planned allocation of the funds appropriated for the Initiative has never been presented publicly, and neither have the management frameworks for the Initiative and for the national network led by NYU.

**In addition, NIH has publicly stated that the \$1.15 billion provided by Congress in December 2020 for Long COVID research has been used for other purposes. While the agency has provided assurances that the Initiative will be funded in full, no substantive information has been provided to back up those assurances.**

- **Credibility:** Public statements are not reflected in official actions. For example, in recent presentations, NIH officials have overstated the status of a number of activities, such as patient engagement on key committees and the enrollment of patients at RECOVER sites.
- **Patient Resources and Messaging:** The RECOVER Initiative isn't managing patient and community expectations or providing adequate, basic information on the purpose and scope of the endeavor. The Initiative lacks a mechanism for sharing resources with patients in a manner that is structured, coordinated, and easily accessible. The [website](#) for RECOVER lacks basic information about the Initiative itself, and navigation is confusing.

Newly or more seriously ill and disabled people are looking to NIH for answers in a confusing time; we must set appropriate expectations for the Initiative, which doesn't currently offer treatment studies nor is focused on delivering answers for clinical or self-management of Long COVID. Yet, from the very name of the Initiative itself, "recovery" is consistently implied as a central goal.

*Overemphasis of "recovery" not only stigmatizes those who don't recover; it sets up patients for thinking that this first meta-cohort study will give answers on how to recover, not just identifying factors that can shed light on who recovers.* It also jeopardizes public and Congressional support for vitally-needed research to build on RECOVER's initial findings. It's vital to explain the goals, methods, and potential outcomes of RECOVER, and to not explicitly or implicitly feed into dominant narratives blaming chronically-ill people for our own suffering.

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