List of Concerns About the RECOVER Initiative
November 2021

PATIENT-LED RESEARCH COLLABORATIVE

The following lists of concerns is not exhaustive. However, they are ample evidence of the immediate need for two fundamental structural adjustments to the Initiative in order to safeguard the integrity and success of the initiative itself:

1) **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 that ensure empowered participation across all segments of RECOVER and include a collaborative of patients themselves. **A draft proposal** **can be found here.**

2) **Post-viral illness experts,** including researchers, clinicians, and patient advocates with expertise in conditions seen in Long COVID (including ME/CFS, postural orthostatic tachycardia syndrome [POTS] and other dysautonomias, and mast cell activation syndrome [MCAS]) **must be integrated into the Initiative**, as well as supported as a collective advisory panel in the RECOVER structure.

Our concerns include:

- **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.** Any structure that may have been developed lacks transparency, as multiple central groups of patients with Long COVID are unclear what that structure is. Patient involvement can include being informed of research opportunities, recruited for outreach, or invited to one-off listening sessions. However, ***meaningful*** involvement must include deep and ongoing engagement with patient leaders who are accountable to both their communities and each other, in specific, defined positions “at the table” with RECOVER investigators and staff.

  We have heard public statements on involvement of patients in the RECOVER steering and executive committees. Yet, despite the centrality of our groups in national networks of people with Long COVID, we have no clear information on what that involvement

consists of, and how it is or will be accountable to patient-led groups of people with Long COVID.

- **The patient engagement that has occurred is tokenizing and inadequate.** Some of us participated in initial listening sessions and several of the working groups, yet we have little to no evidence that our input was used, and several troubling instances where we see it was not incorporated into the protocol and not addressed in any visible way.

  The recruitment of patient representatives was rushed and only provided three days' notice with a requirement to attend daily, multi-hour meetings for the following two weeks. Rapid deadlines are also unreasonable when the population providing feedback is dealing with often debilitating symptoms. Patients were treated dismissively in conversation and often needed to say the same thing multiple times to be heard, if acknowledged at all. Patients' lived and past expertise have been ignored, even when they have medicine and healthcare backgrounds, or are among the most central and knowledgeable of Long COVID leaders in networks with thousands of people around the United States and world.

  As patient representatives who have done successful patient involvement with dozens of research groups since the start of the pandemic, when the RECOVER program has invited us into some rooms, it feels like it's purely to check a box.

  Patients are being asked to recruit other patients and that's counted as patient engagement. We have seen no clear definition or scope of patient engagement, nor reference to the substantive body of meaningful patient engagement methods within or beyond the NIH.

  In both structures, involvement of patients and post-viral illness experts must be *meaningful,* which includes transparency of membership and roles, distribution of membership across communities most affected by the COVID pandemic, decision-making power as authentic and essential collaborators with investigators, and accountability of patient representatives to patient groups.

  Both patient and post-viral illness expert collaborators must be seated and vested with the rights and responsibilities afforded to other RECOVER leaders at every level, including the executive committee and steering committee. They must be fully represented in the Cores, repositories, boards, panels, committees, studies and individual clinical sites, and on the teams for every current and future protocol.

- **In form and in content, the RECOVER Initiative shows a neglect of post-viral illness, and is not grounded in post-viral illness expertise or inquiry.** Seven months ago, Body Politic's open letter to the NIH urged NIH to build on prior myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) and related post-viral chronic illness research in the investigation of Long COVID. Patient-Led Research Collaborative

and other groups have provided recommended lists of longtime researchers and relevant study findings to build RECOVER on a foundation of existing knowledge and research, and we have taken precious time to educate the NYU and site leaders on these recommendations. Yet, in the clinical protocol, there is 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.

It is well-established that dysautonomia and ME/CFS can be triggered by infection. However, even the basic, most fundamental testing in dysautonomia and ME/CFS are absent; others are incomplete and improperly implemented, including the autonomic testing, which is a primary issue in Long COVID patients. In addition, upwards of 50% of Long COVID patients meet ME/CFS diagnostic criteria.

Yet the RECOVER protocol does not specify which diagnostic criteria will be used to identify and track ME/CFS cases.The set of diagnostic criteria used to identify and track study participants with ME/CFS must be clearly identified in the research protocol. Sets of criteria that require the cardinal symptom of post-exertional malaise include:

a. Canadian Consensus Criteria (CCC) (2003)
b. ME International Consensus Criteria (ICC) (2011)
c. National Academy of Medicine (NAM) (2015)

In some cases, researchers may choose to use more than one set of criteria in conjunction, such as NAM and CCC. Other sets of criteria are not recommended: older sets of criteria that do not require post-exertional malaise may capture a very different cohort of patients not in line with the way the disease is characterized today.

- While it is not the sole role of patient advocates to promote research participation or advise messaging, **the RECOVER Initiative is not managing patient and community expectations or providing adequate, basic information on the purpose and scope of the endeavor.** It is understandable that newly or more seriously ill and disabled people are looking to NIH for answers in a confusing time; thus it is exceptionally important that all involved set appropriate expectations for this Initiative, which is not currently a treatment study nor focused on delivering answers for clinical or self-management of Long COVID. Yet, from the very name of the Initiative itself, “recovery” is consistently laid out or 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 expansion of Long COVID research building on RECOVER’s initial findings. While it is not the job of RECOVER to address substantive gaps in public understanding in the scientific process or methodologies, it is incumbent upon us all to do all we can to appropriately explain the goals, methods, and potential outcomes of RECOVER, and to always ensure that we are not explicitly or

implicitly feeding into dominant narratives blaming ill people for their own suffering, as faced by so many with post-viral conditions.

- **The RECOVER Autopsy study component is not studying Long COVID, contradicting specific stipulations in the initial ROA.** While we look forward to a full discussion with you and your staff, as well as more authentic meaningful involvement of patients in RECOVER, we must give this specific and deeply disturbing situation, which has been repeatedly noted by patient advocates in the autopsy working group to no avail. **In the autopsy protocol, Long COVID deaths are defined as death at >30 days post-infection onset, with the control group being deaths before 30 days. Combined with the insistence on postmortem MRI imaging, this will likely result in more acute COVID and hospitalized deaths than Long COVID deaths.**

  This is despite the fact that the initial ROA for RECOVER specified that Long COVID deaths be defined as occurring 30 days or more *after* hospital discharge for hospitalized patients, which would have better captured Long COVID deaths. While patients provided this feedback during the protocol development, the input was ignored and the RECOVER team has moved forward with studying what will likely end up being acute COVID deaths.