Solve M.E. Public Comment on Proposed Reorganization of NIAID

Solve M.E. submits this comment on NIAID's proposed reorganization, which would disestablish the Division of Clinical Research (DCR) and realign its clinical operations, oversight, biostatistics, and rapid-response clinical trial functions.

Solve M.E. is a national nonprofit representing people with myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) and Long COVID. These are infection-associated chronic diseases that fall squarely within NIAID's mission to understand and treat infectious and immune-mediated illness. We offer this comment in that spirit: we share NIAID's stated interest in a clinical research enterprise that is well-coordinated, accountable, and able to move discoveries forward to the point that they become treatments patients can access.

Consolidated clinical research infrastructure is the connective tissue that carries a discovery from the laboratory, through rigorous and well-overseen trials, and into treatments patients can actually access. A dedicated division concentrates the specialized expertise, creates a sense of continuity, and ensures coordinated oversight of clinical trial design, biostatistics, and data and safety monitoring. This coordination is the bedrock of well-run multi-site trials. We are concerned that dispersing these functions across several divisions and offices risks fragmenting that coordination, diffusing accountability, and creating communication gaps between departments.

This is not an abstract concern for our community. NIAID leads RECOVER-TLC, the current generation of NIH-supported Long COVID treatment trials. After years of development, many of these trials are only now reaching enrollment, with several more in protocol development for the coming year. These are precisely the kind of coordinated, statistically rigorous, safety-monitored trials that a dedicated clinical research division exists to support. Restructuring the home of that infrastructure while trials are mid-stride carries a risk of disruption for the millions of Americans with Long COVID, along with the millions more with ME/CFS, a condition NIH's own research shows frequently follows COVID-19. Our community has already waited far too long for clinical trials to begin, and further disruption now would be devastating.

We also raise procedural concern. The public comment period is exceptionally brief, and the information describing the proposal has been made available only as that window opens. A restructuring of this magnitude cannot be meaningfully studied, understood, and responded to on a timeline that leaves the public little opportunity to review the proposal before comments close. A window this short does not afford patients, families, researchers, and clinicians a genuine opportunity to participate.

We therefore respectfully urge NIAID to (1) extend the public comment period to allow for adequate review, and (2) preserve the coordinated clinical research oversight the Division of Clinical Research provides. Alternatively, if realignment proceeds, we request that NIAID publicly detail how the continuity, specialized expertise, and integrated oversight of clinical trials, including the Long COVID treatment trials now underway, will be protected without interruption. We also request that (3) NIAID provide assurance that funds appropriated by Congress will not be diverted to other agencies due to this restructuring process.

We thank NIAID for its longstanding investment in infection-associated chronic disease, and for the opportunity to comment.

Respectfully,
Monique Wike
Director of Advocacy
Solve M.E.