Jaime Seltzer
Scientific Director
The Myalgic Encephalomyelitis Action Network (#MEAction)
Baltimore, Maryland
410-988-2083 | jaime@meaction.net | www.meaction.net

September 14, 2026

Katherine Beck, Ph.D.
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5601 Fishers Lane
Rockville, MD 20892
Via email: NIAIDExecutiveServices@mail.nih.gov

Re: Public Comment on the Proposed Reorganization of the Division of Clinical Research

Dear Dr. Beck:

I am writing on behalf of the Myalgic Encephalomyelitis Action Network (#MEAction) regarding the National Institute of Allergy and Infectious Diseases proposal to disestablish the Division of Clinical Research (DCR), redistribute its programs and functions, and establish or modify related offices and branches within the Office of the Director (OD), Division of Intramural Research (DIR), and Division of Microbiology and Infectious Diseases (DMID).

#MEAction supports efforts to improve coordination, scientific review, clinical research operations, and accountability. We also welcome the FY 2026-2030 Strategic Plan's express inclusion of myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS), Long COVID, and other infection-associated chronic conditions (IACCs). However, the information currently available does not permit the public to determine whether this reorganization will strengthen clinical research or instead fragment essential functions, disrupt active programs, and weaken continuity.

1. Fragmentation of DCR's integrated functions

DCR combines clinical operations, biostatistics, regulatory and policy support, domestic and international partnerships, specialized research capabilities, and rapid clinical research response. These functions are interdependent. Dividing them among OD, DIR, and DMID may create multiple chains of command, slower approvals and contracting, unclear accountability when problems span units, competition between division-specific priorities, and loss of specialized staff and institutional knowledge.

Centralizing some functions while dispersing others can succeed only with strong coordination mechanisms. The proposal does not describe a transition office, shared governance structure, service-level expectations, dispute-resolution process, or a single official accountable for functions that cross organizational boundaries.

2. Relationship to the FY 2026-2030 Strategic Plan

NIAID's strategic plan establishes three research goals: advancing foundational research; providing research tools and services; and promoting research transparency and accountability. Person-centered research, research technology and data science, and health across the lifespan are identified as crosscutting themes. The associated strategic vision organizes scientific priorities around infectious diseases that affect Americans and research in immunology, allergic disease, and autoimmune

disease. It expressly includes long-term post-infectious and inflammatory syndromes such as Long COVID and ME/CFS.

NIAID should explain how the strategic vision's two broad pillars map onto the formal plan's three goals and the proposed organizational structure. It should identify which programs, budgets, personnel, partnerships, and clinical research capabilities will be transferred, expanded, reduced, or discontinued. It should also state whether inclusion of IACCs will lead to dedicated funding, programs, and clinical infrastructure consistent with the NIH ME/CFS Research Roadmap.

The proposal states that the changes are intended to align with Presidential priorities. NIAID should identify the priorities that informed the reorganization, explain how they affected programmatic decisions, and describe safeguards that will preserve evidence-based priority-setting and scientific independence across administrations. It should also explain how an emphasis on diseases affecting Americans will influence global research and international clinical partnerships.

3. Scientific independence and concentration of authority

Locating the Clinical Director and the proposed Office of Biostatistics Research within OD could provide Institute-wide reach and influence. It could also concentrate control over protocol selection, trial design and continuation, safety and regulatory judgments, interpretation and release of results, and the clinical questions selected for rapid-response support.

The proposal should specify whether these offices will have protected scientific independence, transparent operating procedures, and authority to challenge program leadership. Statistical, regulatory, safety, and scientific judgments should be insulated from political or administrative pressure, and disagreements should have a documented escalation and resolution process.

4. Financial and operational costs

The statement that the reorganization requires no additional funding does not make it cost-neutral. Reorganization consumes staff time and requires systems changes, transfers of contracts and records, revised oversight processes, and possibly recruitment. If these costs must be absorbed within current allocations, the result may be reduced research activity, unfilled positions, loss of specialized personnel, or redirection of funds nominally transferred with a program.

The phrase "proportionally reallocated" requires definition. NIAID should state whether allocations will be based on historical spending, personnel, workload, program requirements, or leadership judgment. It should also explain how transferred funds will be tracked and protected during and after implementation.

5. Information required for meaningful evaluation

The organizational chart identifies proposed reporting relationships, but it does not show the practical effects on NIAID's research portfolio. Before final approval, NIAID should publish a crosswalk identifying every DCR program and function; its receiving office; associated staff and leadership; its FY 2026 and projected post-transfer budgets; affected grants, contracts, cohorts, trials, datasets, and collaborations; any planned consolidation, reduction, pause, or discontinuation; and transition milestones with responsible officials.

Without this information, the public cannot evaluate continuity, accountability, or the likely effect on clinical research capacity. Public comment should be extended or reopened after the crosswalk and transition plan are released.

6. Implications for ME/CFS, Long COVID, and other IACCs

IACCs are especially vulnerable to organizational fragmentation because they do not fit neatly within a single pathogen, organ system, or traditional division. Long COVID spans infectious disease, immunology, neurology, cardiology, metabolism, rehabilitation, and clinical trial methodology. ME/CFS likewise falls across infectious, immune-mediated, neurological, metabolic, and multisystem portfolios. Rapid-response and special-project mechanisms may support emerging conditions precisely when they do not yet have a permanent organizational home.

Moving Special Projects to DMID could strengthen the connection to infectious disease expertise. It could also narrow the portfolio toward acute infection or pathogen-specific work. Programs focused on chronic post-infectious pathophysiology, symptom complexes, repurposed treatments, or cross-disease phenotyping could be divided among offices or left without clear ownership.

NIAID should therefore identify the receiving unit with primary responsibility for ME/CFS, Long COVID, and related infection-associated chronic conditions; confirm that Special Projects will retain authority to study chronic outcomes, including pathogen agnostic and cross-condition research; guarantee continuity of existing trials, cohorts, contracts, datasets, and community partnerships; transfer relevant staff and funding with the programs and protect them from redirection; and establish a cross-divisional structure that prevents multisystem conditions from being separated into incoherent components.

Patients and lived-experience experts should participate in priority setting, protocol design, safety oversight, and transition monitoring. Their participation is particularly important for conditions whose manifestations, risks, and meaningful outcomes are not adequately captured by conventional disease-specific structures.

7. Public notice and availability of materials

The Federal Register notice identified September 14 through September 18, 2026, as the period during which comments would be best assured of having their full effect. It also stated that the NIAID website would be active from September 14 through September 18. The NIAID webpage has also described the public comment period as beginning September 9. This discrepancy should be corrected and explained.

More importantly, the public could not meaningfully assess the proposal until NIAID posted its substantive description and reorganization chart. A technically accessible but empty or incomplete webpage does not provide a meaningful opportunity for review. NIAID should disclose when each element of the proposal was posted, publish the webpage's revision history, and extend or reopen the comment period for a reasonable period beginning when complete materials and a functional submission process are available.

Requested actions

1. Publish the full program, personnel, and budget crosswalk before final approval.
2. Disclose any activities expected to be reduced, paused, consolidated, or discontinued.
3. Guarantee continuity of active trials, cohorts, grants, contracts, data systems, and domestic and international partnerships.
4. Establish a transition management body with named accountability and transparent procedures.
5. Preserve independent statistical, regulatory, safety, and scientific judgment.
6. Specify an organizational home and cross-divisional strategy for ME/CFS, Long COVID, and other IACCs.
7. Include patients and community representatives in transition oversight.
8. Publish performance indicators and conduct public reviews at 6, 12, and 24 months.

9. Publish the webpage revision history and extend or reopen public comment after complete information is released.

At present, NIAID has not supplied enough operational, financial, and program-level information to determine whether disestablishing DCR will preserve clinical research capacity and scientific continuity. The proposal describes anticipated benefits but offers few measurable commitments by which the public can determine whether those benefits occur or whether the reorganization produces staff loss, portfolio narrowing, and disruption.

This ambiguity is especially serious for ME/CFS, Long COVID, and related IACCs. Crosscutting programs are often vulnerable when responsibilities are redistributed among conventional disease-specific structures. A clear organizational home, protected resources, patient involvement, and public accountability are necessary to ensure that the strategic plan's recognition of these conditions leads to sustained scientific progress.

#MEAction welcomes a meeting or further discussion and would be glad to provide additional information about the needs of people with ME/CFS, Long COVID, and related infection-associated chronic conditions.

Sincerely,

Jaime Seltzer
Scientific Director
The Myalgic Encephalomyelitis Action Network (#MEAction)
jaime@meaction.net
www.meaction.net

References

1. Federal Register, Notice of Public Hearing: NIAID Proposed Reorganization, 91 Fed. Reg. 55891-55892 (August 31, 2026). federalregister.gov/d/2026-17685

2. NIAID FY 2026-2030 Strategic Plan. niaid.nih.gov/sites/default/files/niaid-strategic-plan-2026.pdf