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AVAC Statement/Comment to the NIAID Council and the AIDS Research Advisory Committee (ARAC) on the proposed NIAID reorganization

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To the esteemed members of the NIAID Council and the AIDS Research Advisory Committee: on behalf of all of us at AVAC, we thank you for the opportunity to submit this comment. We are focusing this statement on the proposed reorganization currently being considered by NIH leadership and its potential effects on HIV research under NIAID. AVAC is an international non-profit organization that leverages its independent voice and global partnerships to accelerate ethical development and equitable delivery of effective HIV prevention options, as part of a comprehensive and integrated pathway to global health equity.

As you all know, NIAID has for decades supported and advanced prevention and treatment research that has improved the lives of people living with HIV and affected by HIV. Organizations such as ours have stood side-by-side with NIH and NIAID researchers and leadership through numerous Presidential administrations and Congressional turnover to focus this institution's energy and expertise to end HIV globally in the way that only well-funded, ethical, apolitical, data-driven science, policy, and programs can deliver. Today, we are dismayed and concerned that NIH's hasty actions to reorganize NIAID are threatening the incredible progress that has been achieved toward HIV treatment and prevention as well as potentially putting lives at risk.

The reorganization of NIAID has raised alarm and questions among the HIV and larger R&D community in regard to the outlook of HIV/AIDS and other infectious diseases research at this institution. Even with the scant detail available publicly, AVAC is concerned by several proposed changes to the support and oversight structures within NIAID. For example, the complete elimination of the Division of Clinical Research (DCR), removes a critical, unified trial and oversight support system. Redistributing these functions across multiple offices and divisions is not only less efficient but will also likely: generate siloes and fragment support functions, increase administrative friction, and create inconsistent standards for managing already complex HIV clinical trials.

Moreover, managing specialized research partnerships with international institutions requires both technical expertise and relationships across a complex network of parties and entities. Shifting global research functions into the Division of Intramural Research (DIR) risks disrupting both ongoing and future trials. Proper community

engagement and, more specifically, Good Participatory Practice (GPP) are essential for HIV research. The proposed reorganization does not provide sufficient detail to understand if DIR has the necessary personnel or expertise to manage these activities.

This reorganization also occurs in the face of major delays in the release of the notice of funding opportunities (NOFOs) for NIAID's flagship HIV clinical trials networks and the Centers for AIDS Research (CFARs). Collectively, these programs have saved millions of lives over the last several decades and advanced some of the most important scientific discoveries and implementation science advances. Delays in the release of the NOFOs are forcing clinical trial sites to prepare for lapses in funding that could harm study participants, halt promising clinical trials, and erode the scientific workforce and infrastructure that has taken decades to develop.

Lastly, we wanted to note that the public comment window for this restructure was remarkably narrow, coupled with minimal detail or discussion provided beyond the DCR reorganization chart. At AVAC, we strongly believe and advocate for meaningful engagement of communities in all aspects of publicly-funded research and decision-making to ensure success through all stages of clinical research into implementation. The decision to forgo comprehensive community consultation with researchers, research advocates, and people living with and vulnerable to HIV, runs antithetical to the deep history of community engagement that has been central to the development of biomedical innovations in the treatment and prevention in HIV.

To that end, we urge NIH leadership to withdraw the NIAID organization proposal, provide more details and allow sufficient time to offer meaningful opportunities for community engagement, to glean better understanding of the implications and justifications taken into account for this proposed reorganization to proceed. We also respectfully urge NIH to resolve ongoing issues and ensure the immediate release of the NOFOs for the HIV Clinical Trial Networks and the CFARs to further mitigate the destabilization of the HIV research enterprise, especially with these changes happening at NIAID.

We look forward to further discussions with ARAC and the NIAID Council to shape the future of HIV/AIDS research at NIH, together. Thank you.

For any questions related to this statement, please contact: Jennifer Maple, Senior Advisor: Federal Policy at jmaple@avac.org or Suraj Madoori, Director: Policy Advocacy at suraj@avac.org