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Dr. Grail Sipes

Assistant Director for Biomedical Regulatory Policy
Office of Science and Technology Policy
Re: Emergency Clinical Trials RFI

Dear Dr. Grail Sipes,

Thank you for the opportunity to respond to the RFI: *Strengthening Capacity for Emergency Clinical Trials*. I write on behalf of the Federation of Associations in Behavioral and Brain Sciences (FABBS), a coalition of 29 scientific societies and 60 academic departments that come together to equitably advance the rigor, impact, and accessibility of our disciplines. We are grateful to see this OSTP effort.

Broadly, and specific to the RFI, FABBS would like to underscore the critical role of the behavioral sciences to mitigate and address the COVID-19 pandemic. Our members contribute a wide range of expertise critical to pandemic preparedness that were regrettably overlooked and underutilized in the U.S. response to COVID-19. This administration could learn from this enormously consequential mistake by investing in behavioral science to prepare for the next pandemic. FABBS scientists address critical questions at the core of understanding vaccine uptake and resistance, including science communication, threat and risk perception, social norms, stress and coping, leadership styles, individual vs. collective interests, decision making and cognitive processing. Collectively, our expertise comes together to answer fundamental questions about how and why people, organizations, and groups behave in the way they do within wider societal and economic contexts.

In the early days of the pandemic, policymakers relied completely on behavioral interventions to reduce the spread of the virus – mask wearing, hand washing, and physical distancing. Even after effective vaccines were widely available, human behavior continued to play a large role due to many people being hesitant to get vaccinated. Former NIH Director Dr. Francis Collins has said that, according to a Kaiser Family Foundation study, as of December 2022, roughly 330,000 people had died in the United States because they had chosen to forgo the vaccine. (<https://www.washingtonpost.com/washington-post-live/2022/12/07/transcript-trust-science/>) While many of these behavioral interventions are extremely low risk, some are classified as clinical trials, triggering all of the cumbersome reporting requirements, needlessly delaying effective implementation.



These comments reflect input from FABBS scientists and the challenges that they faced and opportunities for streamlining clinical trials processes to accelerate implementation of effective interventions.

1. **Governance for Emergency Clinical Trials Response.** While an invaluable tool, behavioral interventions often have far fewer risks than biological ones – and should be treated accordingly. FABBS recommends aligning complexity of clinical trials approval with the level of risk to health. The current NIH definition of clinical trials, which includes behavioral interventions, can needlessly delay approval for extremely effective and very low risk behavioral research. FABBS recommends revisiting the NIH definition of clinical trials. Given that behavioral interventions are currently considered to be clinical trials, these interventions should be explicitly included in efforts to facilitate emergency approval. Specifically, our scientists have lamented the heavy burden of complying with the additional review of the NIH Data Safety Monitoring Board as one example.
2. **Identifying and Incentivizing Research Institutions and Networks: Building Diversity and Equity.** Clinical trials compliance requires considerable time and specific knowledge and is, reportedly, a significant burden to researchers and health care professionals who are not affiliated with well-resourced infrastructure. FABBS encourages OSTP to consider the unintended barriers of clinical trials compliance to diverse and underserved communities and networks. Furthermore, engaging diverse institutions and networks through more affordable and manageable interventions, has the potential to lay the groundwork for growing the capacity.

By way of illustration, the Behavior Change for Good Initiative (BCFG at the University of Pennsylvania (<https://bcfg.wharton.upenn.edu/vaccination/>) partnered with two regional health systems to test messaging techniques, ultimately increasing vaccination rates by as much as 11 percent. This critical work was supported by two NIH Roybal Centers. BCFG has dedicated research staff who made it possible, with support from the Roybal Centers, to navigate the complexity of clinical trial compliance in a short timeframe. It would have been far more difficult for an individual research team to accomplish this without this level of infrastructure. Even with this team of professionals in place managing BCFG's project, there were delays to the intended launch date because the NIH was unable to convene a necessary DSMB in a timely manner.



3. **“Warm Base” Research.** While waiting for the FDA approval of the COVID vaccine, BCFG scientists anticipated the potential challenges around vaccine uptake and worked to identify effective practices for increasing vaccination rates. In addition to their study with health systems, BCFG partnered with Walmart pharmacies to test 22 text reminders of differently worded and timed text reminders to patients to nudge flu vaccination. The experiment demonstrated the effectiveness of behaviorally informed reminder messages for increasing vaccination rates and the benefits of testing such reminders at scale to identify the key features that added value. The results are captured in this important article: A 680,000-person mega study of nudges to encourage vaccination in pharmacies (<https://www.pnas.org/doi/10.1073/pnas.2115126119>).

FABBS also encourages OSTP to recognize the devastating mental health consequences of the pandemic as our country works to prepare for future pandemics. Thanks to previous research, largely funded by the National Science Foundation (NSF), researchers have identified characteristics of communities at the greatest risk of disproportionate negative consequences. Accordingly, researchers have the opportunity to work in at-risk communities in advance of future outbreaks or crises to both establish a baseline understanding and develop ‘warm bases’. NSF has continued to lay the groundwork for warm bases. In Fall 2021, in partnership with foundations, Social Science Research Council (SSRC) launched the Mercury Project, mobilizing social and behavioral scientists in a search for cost-effective and scalable solutions to build vaccination demand and healthier information environments.

<https://www.ssrc.org/programs/the-mercury-project/call-for-proposals/>

Looking at the experience of FABBS scientists, the National Institutes of Health (NIH) has not prioritized this sort of research.

As the pandemic played out and FABBS researchers turned to federal agencies to support investigations of pressing questions from the behavioral sciences, our members reported very different experiences at NSF and NIH. NSF was quick and nimble, awarding RAPID grants to investigators across disciplines. This meant that researchers with the potential to help answer key questions were able to turn to NSF for new funding. NIH, on the other hand, was initially limited to providing additional funding only to active investigators. As a result, relevant experts with warm bases, unless currently receiving NIH funds for a separate purpose, were unable to receive support, even if they had the



warm base and expertise to conduct critical research during the rapidly evolving COVID-19 pandemic.

4. **Emergency Master Agreement.** The COVID-19 pandemic shined a bright light on the need to invest in the behavioral sciences and develop pathways for incorporating these sciences into practice and policy. FABBS recommends preemptively developing interdisciplinary research teams with clear and streamlined approval processes. UK Research and Innovation (UKRI) offers a useful example, developing a leadership team to create a ‘hub’ that will connect stakeholders and drive interdisciplinary innovation in behavioral research to mobilize research into policy and practice. Without existing teams with established practices for clinical trial approval, researchers risk losing precious time navigating clinical trial processes developed with purely biological models in mind.

In summary, FABBS urges OSTP to explicitly include consideration of the behavioral sciences in all efforts to prepare for future pandemics. In their 2021 update to their strategic plan, the NIH clarified their mission to explicitly include behavioral – in addition to biomedical – research. We recommend that OSTP recognize and reflect this evolution.

Thank you,

Juliane Baron

Executive Director