CIAAG
CHRONIC ILLNESS ADVOCACY & AWARENESS GROUP

October 21, 2022

Honorable Senator Marsha Blackburn
United States Senate
Washington, D.C. 20510

Honorable Senator Ron Johnson
United States Senate
Washington, D.C. 20510

Honorable Senator Charles E. Grassley
United States Senate
Washington, D.C. 20510

Honorable Senator Roger Marshall, M.D.
United States Senate
Washington, D.C. 20510

Honorable Members of Senate,

Thank you for your leadership in penning a letter to the National Institutes of Health (NIH) addressing their failure to report the results of NIH-funded intramural and extramural clinical trials, as required by federal law.[1, 2, 3]

CIAAG is a national nonprofit organization and a civil society member at the UNODC working on issues related to public-health policy and its impact on the citizenry.

A major focus of our work is advocating for oversight, transparency and accountability with the public-private-partnership initiatives and the clinical trial work being conducted through National Institutes of Health (NIH), Agency Healthcare Research & Quality (AHRQ), the Veterans Association (VA) and the Patient-Centered Outcomes Research Institute (PCORI).

[1] Intramural clinical trials are carried out by NIH scientists in NIH laboratories. *See* U.S. Dept. of Health and Human Servs., Off. of Inspector Gen., *Report No. A-06-21-07000*: *The National Institutes of Health did not Ensure that All Clinical Trial Results were Reported in Accordance with Federal Requirements* 3-4 (2002), https://oig.hhs.gov/oas/reports/region6/62107000.pdf.

[2] Extramural clinical trials are carried out by scientists at universities, medical centers, hospitals, and research institutions and are supported by NIH grants and contracts. *See* U.S. Dept. of Health and Human Servs., Off. of Inspector Gen., *Report No. A-06-21-07000*: *The National Institutes of Health did not Ensure that All Clinical Trial Results were Reported in Accordance with Federal Requirements* 3-4 (2002),https://oig.hhs.gov/oas/reports/region6/62107000.pdf.

[3] 42 C.F.R. § 11.12. *See* U.S. Dept. of Health and Human Servs., Off. of Inspector Gen., *Report No. A-06-21-07000*: *The National Institutes of Health did not Ensure that All Clinical Trial Results were Reported in Accordance with Federal Requirements* 4 (2002), https://oig.hhs.gov/oas/reports/region6/62107000.pdf.

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The NIH is the United States' preeminent medical research institution and receives billions of dollars in federal appropriations each year. These appropriations are funded by American taxpayers and as such, we deserve accountability, transparency, and results. The NIH must do more to hold grant recipients accountable, so that the public, as well as lawmakers, are able to access timely clinical trial results. Lawmakers rely on accurate, ethical clinical trial results to make legislative decisions that impact millions of people every single day. Expedient results not only impact individual health, they impact the public-health of the entire nation.

Due to the vital importance clinical trials have in society, we ask you to look into the following concerns regarding the intramural and extramural clinical trials being funded at National Institutes of Health (NIH), Agency Healthcare Research & Quality (AHRQ), the Veterans Association (VA) and the Patient-Centered Outcomes Research Institute (PCORI).

1. NIH has expanded the use of "real-world" clinical trials. What guidance is in place to ensure the safety and the informed consent of the citizenry?
2. Is there a process to quantify negative outcomes and/or patient injury resulting from intramural and extramural trials being conducted?
3. When research outcomes state "more research needed" is there a review and/or audit conducted to justify the lack of outcome before awarding additional grants?
4. What mechanisms are in place to address misconduct by grant recipients?
5. NIH grantees are being permitted to run clinical trials in the "real-world" setting using the private citizenry without their knowledge or informed consent. Is there a tracking mechanism in place to quantify the harms, both physically and mentally, resulting from patients having proven effective treatments withheld and being forced into untested modalities to track the outcomes through the Electronic Medical Record? If not, why?

Thank you for your leadership and taking action on this important matter.

Sincerely,

Lauren Deluca
Executive Director