

October 13, 2022

**VIA ELECTRONIC TRANSMISSION**

Lawrence A. Tabak, D.D.S., Ph.D.  
Acting Director  
National Institutes of Health  
Bethesda, M.D. 20892

Acting Director Dr. Tabak:

We write to you today regarding the Department of Health and Human Services (HHS), Office of Inspector General's (OIG) recent report finding that the National Institutes of Health (NIH) failed to ensure that the results of NIH-funded intramural and extramural clinical trials are submitted to ClinicalTrials.gov, as required by federal law.<sup>1, 2, 3</sup> For example, HHS OIG found that, of 72 NIH-funded intramural and extramural clinical trials required to report findings in 2019 and 2020, only 37 studies complied with federal reporting requirements.<sup>4</sup> Moreover, NIH allowed 21 researchers who failed to comply with federal reporting requirements to begin new NIH-funded trials before submitting the results of their previous clinical trials.<sup>5</sup> According to HHS OIG, providers, patients, and researchers benefit the most when clinical trial results are posted online because it gives them more information on patient outcomes including adverse side-effects and other related events.<sup>6</sup>

Federal law and NIH policy requires the sponsor(s) of a clinical trial to report the results of its clinical trial to ClinicalTrials.gov within one year of the trial completion date.<sup>7</sup> NIH policy establishes an exception for NIH-funded clinical trials, which requires the sponsor to submit the results of the clinical trial to the National Library of Medicine staff.<sup>8</sup> NIH policy then requires the National Library of Medicine to report these findings to ClinicalTrials.gov.<sup>9</sup> HHS OIG found that

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<sup>1</sup> 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>.

<sup>2</sup> 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>.

<sup>3</sup> 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>.

<sup>4</sup> 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>.

<sup>5</sup> *Id.* at 8.

<sup>6</sup> *Id.*

<sup>7</sup> *Id.* at 5.

<sup>8</sup> *Id.* at 2.

<sup>9</sup> *Id.*

NIH did not have adequate internal policies and procedures in place to notify parties prior to non-compliance, and took limited enforcement actions after the fact.<sup>10</sup>

HHS OIG made a number of recommendations to NIH to improve its internal processes and procedures regarding clinical trials.<sup>11</sup> NIH concurred with HHS OIG, and outlined a series of steps it planned to implement including the establishment of an integrated electronic system that will allow NIH staff to monitor ClinicalTrials.gov and alert them of instances of non-compliance.<sup>12</sup> According to NIH, this integrated electronic system will “provide a robust and automated system for centralized tracking of registration and reporting information.”<sup>13</sup>

The NIH is the United States’ preeminent medical research institution and receives billions of dollars in federal appropriations each year. For example, in FY2022, NIH received \$46.183 billion in federal appropriations.<sup>14</sup> When American taxpayers spend billions of dollars on federal programs, they expect accountability, transparency, and results. HHS OIG’s report makes clear that the NIH must do more to hold grant recipients accountable, so that the public is able to access timely clinical trial results.

In light of these concerns, please respond to the following questions by November 3, 2022:

1. What steps, including those noted in NIH’s response to the OIG report, is the NIH taking to increase accountability for grant recipients? What types of enforcement measures will be put in place?
2. Please provide the status and implementation timeline of those improvements referenced in the NIH’s response to the OIG’s recommendations including NIH’s development of a centralized workflow and the establishment of an integrated electronic system to facilitate non-compliance alerts.
3. Since 2007, how many NIH-funded trials have failed to comply with federal and NIH reporting requirements? Will NIH commit to making these results public? If not, why not?
4. Please provide a list of the 37 grant recipients that failed to comply with federal and NIH reporting requirements in 2019 and 2020.
  - a. How much taxpayer funding did NIH grant to the 37 recipients that failed to comply with reporting requirements?
  - b. How much funding did NIH give to the grant recipients that have failed to comply with reporting requirements since 2007?

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<sup>10</sup> *Id.* at 5.

<sup>11</sup> *Id.* at 8-9.

<sup>12</sup> *Id.* at 12-14.

<sup>13</sup> *Id.* at 12-13.

<sup>14</sup> Congressional Rsch. Serv., *Report No. 43341: National Institutes of Health (NIH) Funding: FY1996-FY2023* (2022).

5. What actions has NIH taken to remove oversight responsibilities from employees who intentionally opted to ignore the enforcement requirements?
6. How will NIH ensure that staff follows their enforcement obligations??

Thank you for your attention to this important matter. We look forward to your reply.

Sincerely,



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Marsha Blackburn  
United States Senator



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Charles E. Grassley  
United States Senator



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Ron Johnson  
United States Senator



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Roger Marshall, M.D.  
United States Senator