

United States Senate

WASHINGTON, DC 20510

September 23, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Kennedy:

I am writing today to express serious concerns regarding the Real-World Data Platform pilot, being developed by the National Institutes of Health (NIH) and the Centers for Medicare and Medicaid Services (CMS). As you know, this initiative will be used to link Medicare and Medicaid claims for individuals with autism to other health data, including electronic medical records and consumer wearable-device data, in order to study causes of autism and outcomes.¹ While I agree that robust funding for autism research is needed, this program raises serious oversight issues related to privacy and scientific integrity that must be immediately addressed.

First, the privacy and data-governance safeguards for this platform appear inadequate or ill-defined. By design, this platform will aggregate unprecedented amounts of sensitive health information about autistic individuals. The official press release asserts that the system will be “fully compliant with privacy and security laws” and that it will protect “sensitive health information.”² However, it remains unclear what this means in practice and whether these protections will truly be sufficient. Experience shows that without strict oversight, large-scale data projects can lead to misuse of data or even re-identification of de-identified individuals. This is an unacceptable outcome that would undermine decades of work aimed at building public trust. Simply put, the public deserves clarity on how this program will protect individual privacy and who will oversee its execution. Detailed, public plans for how the data will be de-identified, audited, and secured is necessary. Furthermore, there are critical questions that remain unanswered: Will individuals be notified that their data are being collected? Will they be able to opt-in? How long will the data be kept? Who will have access? Without that transparency, the project risks unintended privacy harms and further eroding public trust.

Second, the autism and disability community itself has had little to no involvement in shaping this project, and this exclusion is deeply troubling. The autism community, which includes autistic people, their family members, clinicians, researchers, service providers, and advocates, has consistently emphasized the need for research to be conducted with them. NIH’s own materials highlight that “community-engaged research... involves the bidirectional relationship between community partners and the research team” as a means of improving relevance and

¹ <https://www.cms.gov/newsroom/press-releases/nih-cms-partner-advance-understanding-autism-through-secure-access-select-medicare-and-medicaid-data#:~:text=WASHINGTON%2C%20DC%E2%80%9494MAY%207%2C%202025%E2%80%9494The%20National,medical%20records%2C%20and%20consumer%20wearables>

² <https://www.cms.gov/newsroom/press-releases/nih-cms-partner-advance-understanding-autism-through-secure-access-select-medicare-and-medicaid-data>

transparency.³ Yet this platform was announced without formally consulting the very people it aims to serve. Neither people with autism nor various stakeholders were meaningfully included in the planning of this initiative. Additionally, NIH has yet to explain how community input will be integrated going forward. This top-down approach raises obvious questions about whose interests are being prioritized.

Third, it remains unclear how or whether individuals will have any choice or control over their inclusion in this database. The lack of stakeholder involvement heightens concerns about potential bias and misdirection in the project's research priorities. Autism is an extremely heterogeneous disorder, and historically many, including women and girls, people of color, individuals with more significant support needs, and adults, have been underrepresented in research and faced challenges in accessing critical. A data initiative intended to be cutting-edge that does not actively correct these gaps could inadvertently perpetuate scientific bias. Congress has made its expectations clear: the Autism CARES Act of 2024 highlights the "increased need for evidence-based treatments and interventions that have a more immediate impact on improving the lives of those living with autism." In other words, federally funded autism research should be measured by how it improves people's day-to-day lives, especially those who have historically been left behind, not solely by publications or abstract data analyses. ADSI's success must ultimately be judged by its real-world impact – whether it leads to better therapies, services, and outcomes for autistic individuals and their families across all demographics.

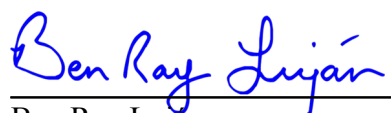
Without clear details and communication of your efforts, this has stoked fear in the lives of autistic people and their families. In light of these concerns, immediate steps are needed to strengthen the oversight, inclusivity, and transparency of the Autism Data Science Initiative. I therefore urge you to take the following actions and provide responses outlining your plans:

1. Establish an independent advisory board or committee that includes autistic individuals with lived experience, family advocates, privacy and ethics experts, and independent scientists to oversee the project's implementation. This board should be empowered to advise on data governance, review research priorities, and ensure community representation at every stage.
2. Publicly disclose all aspects of the platform's governance: data sources and partners, data use agreements, privacy and de-identification protocols, retention schedules, and any algorithms or AI tools to be used. Researchers and the public must be able to see who has access to the data and under what conditions.
3. The initiative should require affirmative consent from participants. No one's data should be included without their informed agreement. Federal health databases and registries are typically voluntary, and this project should be no different. Written patient notices and consent processes should be implemented before any data are drawn in, consistent with HIPAA's principle of patient autonomy.
4. Provide written assurance that data will be fully de-identified according to stringent standards, consistent with HIPAA and NIST guidance, and that no personally identifiable information will ever be shared or used without explicit consent. Deploy the strongest cybersecurity safeguards and audit controls to prevent breaches or unauthorized analysis

³ <https://dpcpsi.nih.gov/autism-data-science-initiative/funding-opportunities>

Thank you for your prompt attention to this matter. I look forward to your response and working together to ensure that federal science initiatives truly serve the people.

Sincerely,

A handwritten signature in blue ink that reads "Ben Ray Lujan". The signature is fluid and cursive, with the first letters of each name being capitalized and prominent.

Ben Ray Lujan
United States Senator

cc: Dr. Jay Bhattacharya, Director, National Institutes of Health
Dr. Mehmet Oz, Administrator, Centers for Medicare & Medicaid Services