

Department of Health and Human Services  
*National Institutes of Health*

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# NIH Controlled-Access Data Policy and Proposed Revisions to NIH Genomic Data Sharing Policy

## AUTHORS

**Jack Burnham**

*Senior Research Analyst, FDD's China Program*

**Craig Singleton**

*Senior Director and Senior Fellow, FDD's  
China Program*

Washington, DC  
March 18, 2026

## **Introduction**

China increasingly sees biology as an emerging battlefield — putting the National Institutes of Health (NIH), the world’s foremost funder of biomedical research, directly on the front line. Having identified advanced biotechnology, particularly genetic therapies, as a key strategic market and a potential accelerator of military innovation, Beijing has poured resources into its biomedical sector and engaged in strategic outreach to key sectoral leaders, including those within the United States. In pursuit of a strategy of military-civil fusion — pulling together all facets of commercial and military innovation into a singular effort to modernize its armed forces — Chinese state-linked scholars have targeted federal agencies and federally funded projects as a source of basic research, high-quality data, and advanced capabilities.

NIH has steadily worked to prevent foreign adversaries, namely China, from relying on federally funded repositories of genomic data to further their economic and dual-use ambitions. Along with cutting off access to specific databases, NIH has worked to implement the BIOSECURE Act by enforcing supply chain audit requirements for researchers seeking agency grant funding. These efforts have complemented other federal agency actions to prevent China from acquiring dual-use capabilities, including the Food and Drug Administration (FDA) banning the transfer of Americans’ genetic material for clinical trial research conducted by foreign adversaries and the Bureau of Industry and Security (BIS) enacting export controls on key scientific equipment used in both clinical genomic research and the production of biological weapons.

As NIH updates the application of its Controlled-Access Data (CAD) Policy and revises its Genomic Data Sharing (GDS) Policy, it must prioritize two goals: strengthening American biomedical innovation and protecting genomic repositories from Beijing’s efforts to steal and leverage American data. The former requires easing compliance costs while modernizing data storage practices. The latter demands strict cybersecurity controls and standardized and enforced access policies.

## **China Relies on NIH and Other Federal Biomedical Resources To Fuel Its Biotechnology Sector**

China’s biotechnology industry, including segments connected to the People’s Liberation Army (PLA), has increasingly focused on producing genetic-based therapies. Having been the first country globally to approve a commercially available genetic therapy, Chinese firms have emerged as industry leaders in applying gene-editing technologies in clinical settings.<sup>1</sup> This growth has translated into China holding a leading position across a range of treatments; nearly

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<sup>1</sup> Sue Pearson, Hepeng Jia, and Keiko Kandachi, “China approves first gene therapy,” *Nature Biotechnology*, January 2004. (<https://pmc.ncbi.nlm.nih.gov/articles/PMC7097065>)

half of all new drug molecules that began human trials in the first half of 2025 originated in Chinese biopharma companies.<sup>2</sup>

This surge has also been the result of significant state investment in the country's biotechnology sector. Identifying biotechnology as an emerging strategic industry, Beijing has continuously increased funding for basic and applied research with the aim of building a sustainable research pipeline to develop first-in-class genetic treatments.<sup>3</sup> This funding has supported a growing stream of academic biomedical research; a strong biotechnology manufacturing base capable of producing the necessary raw materials, such as nucleotides, reagents, and genetic samples; and next-generation capabilities such as medical-specific artificial intelligence (AI).<sup>4</sup> It also attracted a growing share of Western investment, with the value of China-to-West licensing agreements growing 66 percent from 2023 to 2024, reaching a record \$41.5 billion — a trend partially driven by China's strong genetic therapy pipeline.<sup>5</sup>

China's progress has also been accelerated by its exploitation of the United States, including its access to federally funded research programs. Chinese scholars have increasingly collaborated with American partners in the life science sector over the past decade, driven in part by both the availability of federal science funding and the high quality of U.S. academic research.<sup>6</sup>

The Centers for Disease Control and Prevention and the NIH awarded \$28.9 million between FY 2015 and 2021 to Chinese academics and research institutions for drug development and clinical studies.<sup>7</sup> These partnerships also extended throughout the NIH-funded academic ecosystem, with

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<sup>2</sup> "China Is Increasing Its Share of Global Drug Development," *Goldman Sachs*, December 17, 2025. (<https://www.goldmansachs.com/insights/articles/china-is-increasing-its-share-of-global-drug-development>)

<sup>3</sup> Craig Singleton, "Biotech Battlefield," *Foundation for Defense of Democracies*, January 15, 2025. (<https://www.fdd.org/analysis/2025/01/15/biotech-battlefield>); Jeroen Groenewegen-Lau, "How China's Biotech Is Changing Global Ecosystems," *Testimony before the U.S.-China Economic and Security Review Commission*, June 5, 2025. ([https://www.uscc.gov/sites/default/files/2025-06/Jeroen\\_Groenewegen-Lau\\_Testimony.pdf](https://www.uscc.gov/sites/default/files/2025-06/Jeroen_Groenewegen-Lau_Testimony.pdf))

<sup>4</sup> Jack Burnham and Johanna Yang, "U.S. at Risk of Falling Behind China in Biotechnology," *Foundation for Defense of Democracies*, April 15, 2025. ([https://www.fdd.org/analysis/policy\\_briefs/2025/04/15/u-s-at-risk-of-falling-behind-china-in-biotechnology](https://www.fdd.org/analysis/policy_briefs/2025/04/15/u-s-at-risk-of-falling-behind-china-in-biotechnology)); "Chinese pharma is on the cusp of going global," *The Economist* (UK), November 23, 2025. (<https://www.economist.com/china/2025/11/23/chinese-pharma-is-on-the-cusp-of-going-global>); Caroline Schuerger, Vikram Venkatram, and Katherine Quinn, "China and Medical AI: Implications of Big Biodata for the Bioeconomy," *Center for Security and Emerging Technology*, May 2024. (<https://cset.georgetown.edu/publication/china-and-medical-ai>)

<sup>5</sup> Ben Fidler, "China's edge in early-stage drugmaking 'likely to persist,' Pitchbook says," *BioPharmaDive*, January 26, 2026. (<https://www.biopharmadive.com/news/china-biotech-drug-licensing-trends-pitchbook-cell-gene-therapy/810478>)

<sup>6</sup> Ruixue Jia, Margaret E. Roberts, Ye Wang, and Eddie Yang, "The impact of US-China tensions on US science: Evidence from the NIH investigations," *Proceedings of the National Academy of Sciences*, April 30, 2024. (<https://pmc.ncbi.nlm.nih.gov/articles/PMC11087765/#s15>)

<sup>7</sup> Government Accountability Office, "Federal Research: Information on Funding for U.S.-China Research Collaboration and Other International Activities," September 29, 2022. (<https://www.gao.gov/products/gao-22-105313>)

Chinese firms such as BGI Group offering low-cost genomic sequencing while simultaneously building out China’s state-funded collection of genetic samples.<sup>8</sup>

While advancing certain aspects of NIH-funded genetic research, these programs pose significant national security risks, contributing to China’s potential biological warfare. Given that China’s overall basic research pipeline still lags behind the United States’s due to a legacy of state underinvestment and regulatory barriers, federal funding — either directly in the form of federal grants or indirectly in the form of federally funded resources — offers relatively more benefit to Chinese institutions than their American counterparts.<sup>9</sup> This trend is particularly relevant within life sciences, as NIH remains the premier repository of databases used as standard-setting instruments, allowing Chinese scholars to advance their research at a far lower cost than having to rely on home-grown alternatives.<sup>10</sup>

As China’s biotech economy is inextricably linked to the PLA, joint research projects between U.S. and Chinese institutions have often inadvertently accelerated military-civil fusion. Along with being a principal funder of genetic research, the PLA has cited interest in gene-editing tools such as CRISPR (clustered regularly interspaced short palindromic repeats) technology while senior PLA officials have voiced concern over the possible deployment of ethnically linked biological weapons.<sup>11</sup> Moreover, while Beijing is a state party to the Biological Weapons Convention, the U.S. State Department has accused China of failing to uphold the treaty’s commitments to abandon biological warfare-related research and fully eliminate its assessed historical biological warfare program.<sup>12</sup>

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<sup>8</sup> Craig Singleton, “Biotech Battlefield,” *Foundation for Defense of Democracies*, January 15, 2025. (<https://www.fdd.org/analysis/2025/01/15/biotech-battlefield>); Antonio Regalado, “China’s BGI says it can sequence a genome for just \$100,” *MIT Technology Review*, February 26, 2020.

(<https://www.technologyreview.com/2020/02/26/905658/china-bgi-100-dollar-genome>)

<sup>9</sup> Jack Burnham, Georgianna Shea, Mark Montgomery, and Craig Singleton, “Accelerating the American Scientific Enterprise,” *Foundation for Defense of Democracies*, December 22, 2025.

(<https://www.fdd.org/analysis/2025/12/22/accelerating-the-american-scientific-enterprise>)

<sup>10</sup> Richard Stone, “Researchers from China and five other ‘countries of concern’ barred from NIH databases,” *Science*, April 10, 2025. (<https://www.science.org/content/article/researchers-china-and-five-other-countries-concern-barred-nih-databases>)

<sup>11</sup> Alexis Dale-Huang and Nathan Beauchamp-Mustafaga, “Chinese Military Thinking at the Crossroads of Biological Security, Biotechnology, and Global Health,” *The National Bureau of Asian Research*, December 4, 2024.

(<https://www.nbr.org/publication/chinese-military-thinking-at-the-crossroads-of-biological-security-biotechnology-and-global-health>); Craig Singleton, “Biotech Battlefield,” *Foundation for Defense of Democracies*, January 15, 2025.

(<https://www.fdd.org/analysis/2025/01/15/biotech-battlefield>); Jack Burnham, “Reimagining and Improving Student Education,” *Foundation for Defense of Democracies*, March 2, 2026.

(<https://www.fdd.org/analysis/2026/03/02/reimagining-and-improving-student-education>)

<sup>12</sup> Jack Burnham, “Reimagining and Improving Student Education,” *Foundation for Defense of Democracies*, March 2, 2026. (<https://www.fdd.org/analysis/2026/03/02/reimagining-and-improving-student-education>); U.S. Department of State, “Adherence to and Compliance With Arms Control, Nonproliferation, and Disarmament Agreements and Commitments,” April 2025.

([https://www.state.gov/wp-content/uploads/2025/04/2025-Arms-Control-Treaty-Compliance-Report\\_Final-Accessible.pdf](https://www.state.gov/wp-content/uploads/2025/04/2025-Arms-Control-Treaty-Compliance-Report_Final-Accessible.pdf))

## **NIH Should Strengthen Data Protection Rules for Genomic Research Projects**

NIH has made significant progress in preventing China and other foreign adversaries from using U.S. genetic research and databases to advance their own scientific and commercial efforts. While the Biden administration sporadically denied foreign adversaries access to certain data sets, including the Adolescent Brain Cognitive Development (ABCD) Study database, the Trump administration introduced broader restrictions in April 2025 that covered 21 biomedical databases containing information related to genetic variations, cancer cases, and other diseases.<sup>13</sup> This measure will prevent Chinese academics from accessing critical datasets necessary to advance dual-use genetic research and accessing American genetic information.

This action complemented other efforts by both regulatory agencies and Congress to cut off China from accessing American genetic research material. The FDA has pushed to end cross-border clinical trials and commercial work with contract research organizations that involve the transfer of American genetic data to China and other foreign adversaries.<sup>14</sup> BIS has also introduced export controls on technologies critical to genetic research, including industrial-grade high-parameter flow cytometers and liquid chromatography mass spectrometers, both of which may be used to collect high-quality data for training AI systems in the production of biological weapons.<sup>15</sup> Congress has further strengthened these protections with the passage of the BIOSECURE Act, which prohibits entities that receive federal fundings from using biotechnologies produced by a foreign adversary.<sup>16</sup>

However, NIH should update its policies both in light of China's growing interest in dominating genetic-based biotechnology and several recent security lapses within other federal grant-writing agencies. In January, a congressional investigation revealed that Chinese military institutions, including the "Seven Sons of National Defense," maintained standing access to National Science Foundation supercomputing resources via the agency's Advanced Cyberinfrastructure Coordination Ecosystem: Services & Support (ACCESS) program.<sup>17</sup> Other congressional investigations have identified repeated instances of federally funded research projects and other

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<sup>13</sup> Richard Stone, "Researchers from China and five other 'countries of concern' barred from NIH databases," *Science*, April 10, 2025. (<https://www.science.org/content/article/researchers-china-and-five-other-countries-concern-barred-nih-databases>)

<sup>14</sup> "FDA crackdown on cells across borders," *Nature Biotechnology*, August 12, 2025. (<https://www.nature.com/articles/s41587-025-02789-4>)

<sup>15</sup> Jack Burnham and Johanna Yang, "New U.S. Export Controls Seek to Prevent China From Weaponizing Biotech," *Foundation for Defense of Democracies*, January 21, 2025. (<https://www.fdd.org/analysis/2025/01/21/new-u-s-export-controls-seek-to-prevent-china-from-weaponizing-biotech>)

<sup>16</sup> Eric Sagonowsky and Fraiser Kansteiner, "Biosecure Act heads to Trump's desk with defense spending bill after Senate vote," *Fierce Pharma*, December 17, 2025. (<https://www.fiercepharma.com/pharma/biosecure-act-heads-trumps-desk-defense-spending-bill-after-senate-vote>)

<sup>17</sup> Jack Burnham, "China May Have Accessed U.S. Supercomputing Resources To Fuel Its Military Modernization Efforts," *Foundation for Defense of Democracies*, January 21, 2026. (<https://www.fdd.org/analysis/2026/01/21/china-may-have-accessed-u-s-supercomputing-resources-to-fuel-its-military-modernization-efforts>)

resources aiding Beijing, including joint research collaboration between American and Chinese scholars with direct military implications.<sup>18</sup>

## **Recommendations**

As China looks to penetrate the U.S. science ecosystem, NIH should balance the need to promote efficiency within cross-center collaborative efforts while ensuring security in reforming its CAD and GDS policies. These efforts should include promoting a uniform controlled-access data policy to ease compliance costs while strengthening cybersecurity protections for sharing genomic data.

- **The CAD policy should govern the sharing of all genomic and other omics data.** Chinese state-aligned actors have previously penetrated federally funded research programs due to gaps within data security regimes, allowing Beijing to exploit compliance gaps to further its military modernization efforts. At the same time, differences with data-sharing agreements raise compliance costs for grantees and agency personnel, slowing research and potentially leading to costly errors. As such, NIH should ensure that all NIH-funded research projects involving the sharing of genomic data (and other related information) comply with CAD.
- **NIH Institutes, Centers, and Offices (ICOs) should be flexible in modifying genomic data practices for specific projects.** While NIH ICOs should preferably adhere to the same policy to minimize gaps between privacy standards, certain projects will likely require stronger protection standards due to specific sensitivities. As such, individual NIH offices and centers should be capable of requesting additional data protection policies upon submitting data to NIH controlled-access repositories — this measure would maintain the efficiency gains of a single policy while adding greater protective measures in response to specific circumstances.
- **Simplify thresholds for what is considered “large scale” genomic data and reform timelines for data processing.** While ensuring the security of Americans’ genomic data remains paramount, NIH must also prioritize the effectiveness of the American scientific enterprise to deliver cutting-edge clinical results to build on a strong foundation of basic research. To that end, NIH should establish a sensible benchmark for applying data security policies: data gathered from more than 100 individuals should be subject to the stricter GDS policy, while samples from fewer than 100 should be subject to the CAD policy. Moreover, NIH should ensure that data is released immediately into its repositories by eliminating timing requirements from its GDS guidelines.

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<sup>18</sup> Craig Singleton, “The Middle Kingdom Meets Higher Education,” *Foundation for Defense of Democracies*, December 9, 2021. (<https://www.fdd.org/analysis/2021/12/09/the-middle-kingdom-meets-higher-education>)

- **NIH should ensure strict cybersecurity standards for new imputation servers.** While introducing more imputation servers to allow scientists and researchers to uphold their genomic datasets will benefit American scientists and their international colleagues, this expansion effort also poses a new range of cybersecurity challenges. As such, NIH should ensure that any effort to expand access to imputation servers includes measures to protect against cyber and physical espionage, comply with NIH security practices, and are funded and operated by NIH or another federal agency.

### **Conclusion**

By strengthening data access policies to accelerate innovation while maintaining stringent security measures, the National Institutes of Health can bolster U.S. national security while supporting investment in the American health care sector.

Thank you for considering our comments. We look forward to seeing how our input is incorporated into the agency's ongoing policy work.