



Mapping the terrain for data sharing

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Data sharing is conflicted at its core

- Data sharing can and often is essential to advance science
- Data used for biomedical research are known to be incomplete in a variety of ways
- Thus, much emphasis is placed on increasing access to data
- But data are assets that can be a source of value for those to whom the data pertains and to those who hold the data
- The ways that data are used can harm people, either accidentally or intentionally

The importance of governance

- Collecting data has ethical and legal implications
- Informed consent of the people to whom the data pertain is sometimes required under US law, but it is never sufficient, especially since funders increasingly require broad consent for data sharing

Increasing challenges to sharing across borders

- Some limits come from other countries
 - China
 - India
 - European Union – GDPR
- These must be addressed in data management and sharing plans
 - Policies related to data sharing vary across countries. Investigators from foreign institutions and U.S. investigators collecting data in other countries should familiarize themselves with the policies governing data sharing in the countries in which they plan to work and to address any specific limitations in the plan in their application. [Data Management & Sharing Policy Overview | Grants & Funding](#)

Gain of function research

[Improving the Safety and Security of Biological Research – The White House \(5/05/2025\)](#)

Rejected [United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential \(May 2024\)](#)

- Sec. 3. Stop Dangerous Gain-of-Function Research. (a) The Director of the Office of Science and Technology Policy (OSTP), in coordination . . shall establish guidance for the heads of relevant agencies, to the extent consistent with the terms and conditions of the funding, to immediately:
 - (i) end Federal funding of dangerous gain-of-function research conducted by foreign entities in countries of concern (e.g., China) pursuant to 42 U.S.C. 6627(c), or in other countries where there is not adequate oversight to ensure that the countries are compliant with United States oversight standards and policies; and
 - (ii) end Federal funding of other life-science research that is occurring in countries of concern or foreign countries where there is not adequate oversight to ensure that the countries are compliant with United States oversight standards and policies and that could reasonably pose a threat to public health, public safety, and economic or national security, as determined by the heads of relevant agencies.

Gain of function research

Executive order 5/2/2025

- Sec. 8. Definitions. For the purposes of this order, “dangerous gain-of-function research” means scientific research on an infectious agent or toxin with the potential to cause disease by enhancing its pathogenicity or increasing its transmissibility. Covered research activities are those that could result in significant societal consequences and that seek or achieve one or more of the following outcomes:
 - (a) enhancing the harmful consequences of the agent or toxin;
 - (b) disrupting beneficial immunological response or the effectiveness of an immunization against the agent or toxin;
 - (c) conferring to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitating their ability to evade detection methodologies;
 - (d) increasing the stability, transmissibility, or the ability to disseminate the agent or toxin;
 - (e) altering the host range or tropism of the agent or toxin;
 - (f) enhancing the susceptibility of a human host population to the agent or toxin; or
 - (g) generating or reconstituting an eradicated or extinct agent or toxin.

Increasing challenges to sharing across borders

- **Pertaining To Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons -- Department of Justice final rule 28 CFR Part 202**
- regulations . . . prohibit or otherwise restrict United States persons from engaging in any acquisition, holding, use, transfer, transportation, or exportation of, or dealing in, any property in which a foreign country or national thereof has any interest (“transaction”), where the transaction: involves United States Government-related data (“government-related data”) or bulk U.S. sensitive personal data, as defined by final rules implementing the Order; falls within a class of transactions that has been determined by the Attorney General to pose an unacceptable risk to the national security of the United States . . .

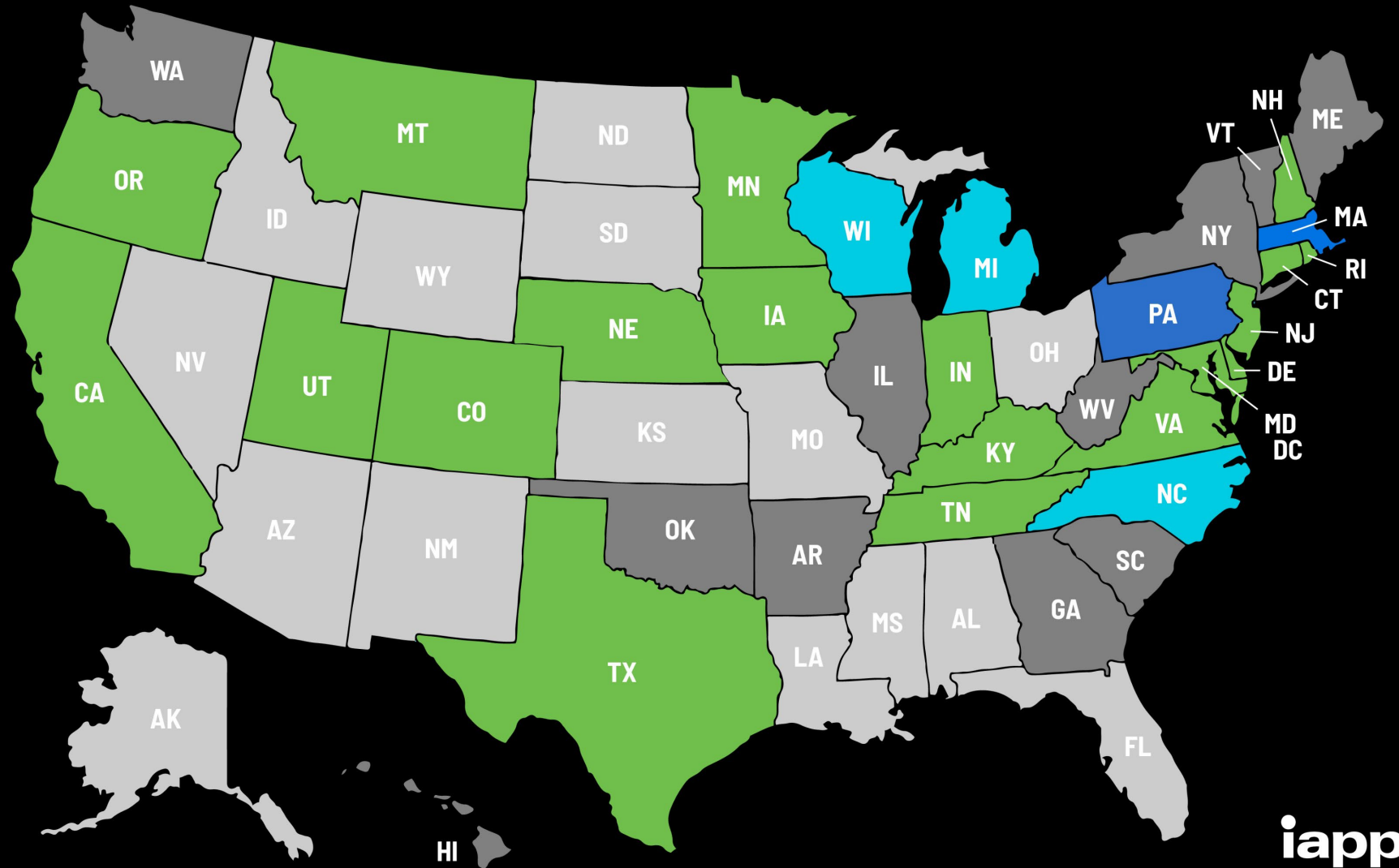
§ 202.209 Country of concern.

- The term *country of concern* means any foreign government that, as determined by the Attorney General with the concurrence of the Secretary of State and the Secretary of Commerce:
- (a) Has engaged in a long-term pattern or serious instances of conduct significantly adverse to the national security of the United States or security and safety of United States persons; and
- (b) Poses a significant risk of exploiting government-related data or bulk U.S. sensitive personal data to the detriment of the national security of the United States or security and safety of U.S. persons.
- Currently includes China, Russia, North Korea, Venezuela, Cuba, Iran

US State Privacy Legislation Tracker 2025



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