Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2025–22609 Filed 12–11–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH Policy on Enhancing Security Measures for Human Biospecimens

AGENCY: National Institutes of Health, HHS.

ACTION: Notice of policy.

SUMMARY: This Policy establishes expectations for ensuring the security of human biospecimens whose collection, obtainment, storage, use, or distribution are supported by NIH funds. The policy ensures protections for human participants and vital national security interests, consistent with Executive Order 14117 (see: *https://www.govinfo.gov/content/pkg/FR-2024-03-01/pdf/2024-04573.pdf*) and 28 CFR 202 ''Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons'' (see: *https://www.federalregister.gov/documents/2025/01/08/2024-31486/preventing-access-to-us-sensitive-personal-data-and-government-related-data-by-countries-of-concern*).

DATES: This policy became effective as of October 24, 2025.

FOR FURTHER INFORMATION CONTACT: Further information about this policy notice may be directed to Dr. Adam Berger at 301–496–9838 or *SCIENCEPOLICY@OD.NIH.GOV.*

SUPPLEMENTARY INFORMATION: On April 8, 2025, the Department of Justice (DoJ) implemented a final rule (28 CFR 202) to ''address a national emergency declared by the President in Executive Order 13873 (see: *https://www.federalregister.gov/documents/2019/05/17/2019-10538/securing-the-information-and-communications-technology-and-services-supply-chain*) of May 15, 2019, to deal with the 'unusual and extraordinary threat . . . to the national security and foreign policy of the United States' posed by foreign adversaries' access to Americans' ''vast amounts of sensitive information.'' 28 CFR 202 specifically exempts transactions that are for the conduct of the official business of the United States Government by its employees, grantees, or contractors, any authorized activity of any United States Government department or agency, or transactions conducted pursuant to a grant, contract, or other agreement entered into with the United States Government. Recognizing the need for Departments and Agencies to implement appropriate security policies tailored to the risks posed by their supported or conducted activities, E.O. 14117 (see: *https://www.govinfo.gov/content/pkg/FR-2024-03-01/pdf/2024-04573.pdf*) directs the Secretary of Health and Human Services to ''consider taking steps . . . to prohibit the provision of assistance that enables access by countries of concern or covered persons to United States [U.S.] persons' bulk sensitive personal data, including personal health data and human genomic data, . . . on the recipients of Federal assistance to address this threat.''

NIH Policy on Enhancing Security Measures for Human Biospecimens

Purpose

NIH is implementing additional policies and standard practices to protect Americans' sensitive and personal health-related data from foreign adversary misuse. This NIH Policy on Enhancing Security Measures for Human Biospecimens (herein referred to as NIH Biospecimens Security Policy) establishes expectations for ensuring the security of human biospecimens whose collection, obtainment, storage, use, or distribution are supported by NIH funds. The policy ensures protections for human participants and vital national security interests, consistent with E.O. 14117 (see: *https://www.govinfo.gov/content/pkg/FR-2024-03-01/pdf/2024-04573.pdf*) and 28 CFR 202 ''Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons'' (see: *https://www.federalregister.gov/documents/2025/01/08/2024-31486/preventing-access-to-us-sensitive-personal-data-and-government-related-data-by-countries-of-concern*).

NIH funds and supports the collection, obtainment, storage, use, or distribution of a wide variety of human biospecimens of U.S. persons and is therefore accountable to those individuals from whom the biospecimens were obtained. NIH takes seriously the privacy and security of these individuals and recognizes that human biospecimens may be used to derive sensitive information, such as an individuals' genome sequence.

On April 8, 2025, the Department of Justice (DoJ) implemented a final rule (28 CFR 202) to address a national emergency declared by the President in Executive Order 13873 (see: *https://www.federalregister.gov/documents/2019/05/17/2019-10538/securing-the-information-and-communications-technology-and-services-supply-chain*) of May 15, 2019 to deal with the 'unusual and extraordinary threat . . . to the national security and foreign policy of the United States' posed by foreign adversaries' access to Americans' ''vast amounts of sensitive information.'' The final rule exempts specific types of transactions conducted and authorized by United States Government employees, grantees, or contractors, acknowledging the need for Departments and Agencies to implement appropriate security policies tailored to the risks posed by their supported or conducted activities. Additionally, E.O. 14117 (see: *https://www.govinfo.gov/content/pkg/FR-2024-03-01/pdf/2024-04573.pdf*) directs the Secretary of Health and Human Services to ''consider taking steps . . . to prohibit the provision of assistance that enables access by countries of concern or covered persons to United States [U.S.] persons' bulk sensitive personal data, including personal health data and human genomic data, . . . on the recipients of Federal assistance to address this threat.''

Recent security directives, including E.O. 14117 (*https://www.govinfo.gov/content/pkg/FR-2024-03-01/pdf/2024-04573.pdf*) and 28 CFR 202 ''Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons'' (see: *https://www.federalregister.gov/documents/2025/01/08/2024-31486/preventing-access-to-us-sensitive-personal-data-and-government-related-data-by-countries-of-concern*), have increased the need to set expectations for securing human biospecimens to address national security and related concerns. NIH is enacting the NIH Biospecimens Security Policy in support of these directives to secure Americans' sensitive personal health-related data from exploitation, ensure America's leadership in scientific research and technology development, and protect the privacy and rights of Americans.

Effective Date

This policy became effective as of October 24, 2025.

Definitions

The following definitions are used for the purpose of the NIH Biospecimens Security Policy:

Countries of concern—Those countries as determined under 28 CFR 202.601 (Subpart F: Determination of Countries of Concern)(see: *https://*

www.federalregister.gov/documents/2025/01/08/2024-31486/preventing-access-to-us-sensitive-personal-data-and-government-related-data-by-countries-of-concern#sectno-reference-202.601).

Human biospecimens—A quantity of tissue, blood, urine, or other human-derived material. A single biopsy may generate several human biospecimens, including multiple paraffin blocks or frozen sample. A human biospecimen can comprise subcellular structures, cells, tissue (*e.g.,* bone, muscle, connective tissue, and skin), organs (*e.g.,* liver, bladder, heart, and kidney), blood, gametes (sperm and ova), embryos, fetal tissue, and waste (urine, feces, sweat, hair and nail clippings, shed epithelial cells, and placenta). Human biospecimens include those that are isolated and propagated into new cell lines. The term also includes cell lines for which an agreement is in place to commercially or publicly make them available, but for which the cell lines have not yet been made commercially or publicly available on or after the effective date of this policy.

U.S. person—As defined under 28 CFR 202.256 (see: *https://www.ecfr.gov/current/title-28/section-202.256*) any United States citizen, national, or lawful permanent resident; any individual admitted to the United States as a refugee under 8 U.S.C. 1157 (see: *https://www.govinfo.gov/link/uscode/8/1157*) or granted asylum under 8 U.S.C. 1158; (see: *https://www.govinfo.gov/link/uscode/8/1158*) any entity organized solely under the laws of the United States or any jurisdiction within the United States (including foreign branches); or any person in the United States.

Scope and Applicability

The NIH Biospecimens Security Policy applies to all human clinical and research biospecimens obtained from U.S. persons (regardless of identifiability) that are collected, obtained, stored, used, or distributed and that are supported or funded by any on-going or new NIH funding mechanisms (grants, cooperative agreements, contracts, Other Transactions, and intramural support) regardless of NIH funding level.

This Policy does not apply to cell derivative products or cell lines derived from human biospecimens of U.S. persons collected, obtained, stored, used, or distributed using on-going or new NIH funds that are commercially or publicly available prior to the effective date of this policy.

Requirements

NIH expects the research community to recognize the risks posed by the sharing or distribution of U.S. persons biospecimens that were collected, obtained, stored, used, or distributed with previous NIH funds or support with countries of concern.

The entity (*e.g.,* biorepository, institution, investigator) that holds human biospecimens of U.S. persons collected, obtained, stored, used, or distributed using on-going or new NIH funds are prohibited from directly or indirectly distributing the human biospecimens to institutions or parties located in countries of concern (see: *https://www.federalregister.gov/documents/2025/01/08/2024-31486/preventing-access-to-us-sensitive-personal-data-and-government-related-data-by-countries-of-concern#sectno-reference-202.601*).

In limited circumstances, the human biospecimens may be shared or distributed to countries of concern only if use of the human biospecimens is:

1. to meet transactions required or authorized by Federal law or international agreements, (see: *https://www.federalregister.gov/documents/2025/01/08/2024-31486/preventing-access-to-us-sensitive-personal-data-and-government-related-data-by-countries-of-concern#sectno-reference-202.507*) including Global health, or necessary for compliance with Federal law; or

2. needed in rare and compelling circumstances where the facility and personnel in the country of concern possess needed capabilities and/or expertise not available elsewhere, the use of the biospecimen cannot be delayed to a time when capability and/or expertise is available elsewhere, and done with the consent of the individual from whom the biospecimen was collected; or

3. at the request of the individual whose biospecimen was collected, obtained, or stored using NIH-funds; for purposes of diagnosis, prevention or treatment of that individual; and in compliance with applicable Federal laws, regulations, and policies.

As a reminder, the export of human biospecimens must follow all applicable export administration regulations (see: *https://www.ecfr.gov/current/title-15/subtitle-B/chapter-VII/subchapter-C*).

NIH requires all entities retain documentation related to sharing or distributing biospecimens to countries of concern under one of the allowable limited circumstances and further document the quantity and content of the biospecimen material that was shared or distributed. Documentation must be retained and provided to NIH upon request.

Matthew J. Memoli,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2025–22618 Filed 12–11–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neurotoxicology and Alcohol Study Section.

Date: January 20–21, 2026.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Eileen Marie Moore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–8928, *eileen.moore@nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neurobiology of Pain and Itch Study Section.

Date: January 28–29, 2026.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Natalia Strunnikova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–0288, *natalia.strunnikova@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333,