

National Institutes of Health
Human Biospecimen Storage and Tracking Report
("Human Tissues Report")
FY 2024

Office of Intramural Research
National Institutes of Health
Department of Health and Human Services

January 2025

Background:

Human biospecimens are a valuable resource and are essential to biomedical research. The National Institutes of Health (NIH) is committed to the storage and tracking of human biospecimens according to the highest scientific and ethical standards to maintain the public's trust, to preserve and protect the specimens and the substantial investment these resources represent, and to facilitate research by maximizing use of human biospecimens.

Section 104 of the National Institutes of Health Reform Act of 2006 (Pub. L. 109-482), enacted on January 15, 2007, amends section 403A(c) of the Public Health Service Act to require the Director of the NIH to submit annually to Congress a report that describes how NIH and its Institutes and Centers (ICs) store and track human biospecimens.

NIH Human Biospecimen Collections:

To protect human biospecimens, they must be carefully stored and tracked, using a consistent process, which is specified in the NIH internal policy document, Manual Chapter 3008, "*NIH Human Biospecimen Program*" (Attachment 1). This Manual Chapter sets the NIH policy, delineates roles and responsibilities (including oversight), and establishes the expectation that certain NIH Intramural Research Program (IRP) employees, typically study principal investigators (PIs), or contractors track all IRP human biospecimens and report to NIH on an annual basis about the human biospecimens. It also facilitates compliance with the NIH Reform Act of 2006 (42 U.S.C. 283a.(c)). Throughout this report, we use the term "collection", which is defined in MC 3008 as "A set of similar types of human biospecimens taken from a human patient or research subject (such as blood samples, liver biopsy material, sputum samples), which are stored, tracked, and reported on together as like material." Also included in the Manual Chapter is the "NIH Intramural Research Program Human Biospecimen Guidelines," which operationalizes the administrative management of the annual reporting process in the IRP.

IRP storage and tracking of human biospecimens facilitates the ability to share these valuable resources. NIH intramural researchers obtain human biospecimens from a variety of sources, including directly from patients at the Clinical Center and other NIH clinical research sites and from external collaborators, contractors, commercial suppliers, or other partners who collect human biospecimens offsite and provide them to NIH.

In 2024, the IRP reports holding 3,109 collections of stored human biospecimens. These include 1,100 collections of blood/blood derivatives; 1,065 collections of human tissues; 580 collections of body fluids and substances; 142 collections of stem cells or transformed stem cells; 54

collections of malignant or benign tumors; and 168 collections of human-derived cell lines. The human biospecimens are held within 21 of NIH's Institutes and Centers, including the Clinical Center, the National Center for Advancing Translational Sciences, the National Center for Complementary Integrative Health, the National Cancer Institute, the National Eye Institute, the National Human Genome Research Institute, the National Heart, Lung, and Blood Institute, the National Institute on Aging, the National Institute on Alcohol Abuse and Alcoholism, National Institute of Allergy and Infectious Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Biomedical Imaging and Bioengineering, the National Institute of Child Health and Human Development, the National Institute on Drug Abuse, the National Institute on Deafness and Other Communication Disorders, the National Institute of Dental and Craniofacial Research, the National Institute of Diabetes and Digestive and Kidney Disease, the National Institute of Environmental Health Sciences, the National Institute of Mental Health, the National Institute of Neurological Disorders and Stroke, and the National Institute of Nursing Research. The annual Biospecimen Report demonstrates that the IRP routinely tracks all human biospecimens and is able to generate reports on all types of human biospecimens at any time.

Current Storage and Tracking Practices:

NIH is required by the NIH Reform Act of 2006 to report annually, through the Health and Human Services (HHS) Secretary, to Congress on how NIH human biospecimens are stored and tracked. Through Manual Chapter 3008, the NIH Director, through the Deputy Director for Intramural Research (DDIR) and Institutes/Centers/Offices leadership (ICO), sets requirements for NIH storage and tracking of IRP human biospecimens, oversight, and requires NIH staff and contractors to gather and report specific information about human biospecimens. The Office of Intramural Research (OIR), using Manual Chapter 3008, "*NIH Human Biospecimen Program*", is responsible for the administrative management of the annual reporting process in the IRP.

Summary:

Currently, there are 3,109 collections of human biospecimens being stored and tracked by NIH intramural researchers.



August 19, 2025

The Honorable Bill Cassidy
Chair
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

Dear Chair Cassidy:

I am pleased to provide you with the annual National Institutes of Health (NIH) Human Biospecimen Storage and Tracking Report covering FY 2024. This was prepared by NIH and is submitted in accordance with the reporting requirement in section 403A(c) of the Public Health Service Act (42 U.S.C. 283a(c)), as amended by the National Institutes of Health Reform Act of 2006 (Pub. L. 109-482).

The purpose of this report is to describe the NIH intramural human biospecimen collections as of August 30, 2024—held either directly in intramural facilities or by contractors to the Intramural Research Program—and how NIH stores and tracks the human biospecimens according to the highest scientific and ethical standards. The report does not include information about biospecimens not collected by NIH, e.g., biospecimens collected by NIH-funded grantees.

I hope you find this information helpful.

Sincerely,

A handwritten signature in black ink, reading "Gary Andres", is written over a horizontal line.

Gary Andres
Assistant Secretary for Legislation

Enclosure



August 19, 2025

The Honorable Bernie Sanders
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

Dear Senator Sanders:

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Gary Andres
Assistant Secretary for Legislation

Enclosure



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

August 19, 2025

The Honorable Brett Guthrie
Chair
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chair Guthrie:

I am pleased to provide you with the annual National Institutes of Health (NIH) Human Biospecimen Storage and Tracking Report covering FY 2024. This was prepared by NIH and is submitted in accordance with the reporting requirement in section 403A(c) of the Public Health Service Act (42 U.S.C. 283a(c)), as amended by the National Institutes of Health Reform Act of 2006 (Pub. L. 109-482).

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Gary Andres
Assistant Secretary for Legislation

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DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

August 19, 2025

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Representative Pallone:

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