COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD
POLICY ON RESEARCH REPOSITORIES

I. INTRODUCTION

Repositories (including registries, data banks and tissue banks) (**Repositories**) all involve the collection and storage over time of human biological specimens (**Biospecimens**) and/or data relating to humans or human biological materials, including genetic and genomic data (**Data)** (collectively, **Materials).** Some Repositories are created and maintained explicitly for research purposes. Others are created and maintained for non-research purposes, but Materials may be accessed for research uses. Rapid advances in clinical procedures have allowed Repositories to serve as important resources for investigators. Specifically, Repositories allow scientific questions to be addressed that may not have been envisioned at the time of the procurement of the Materials or the creation of the Repository.

Creation of a Repository for which research use is intended and research uses of Materials that are stored in Repositories, must conform to applicable regulations, including regulations of (a) the Department of Health and Human Services (**DHHS)** at 45 CFR 46, (b) the Food and Drug Administration (**FDA)** at 21 CFR 50 and 21 CFR 812 and (c) the Health Insurance Portability and Accountability Act (**HIPAA**) and the HIPAA Rules at 45 CFR 160 and 164 (collectively, the **Regulations**). The purpose of this Policy is to ensure that Materials in Repositories to be used for research are responsibly obtained, stored, distributed and used and that the rights of individuals who have contributed Materials or whose Materials have been deposited in a Repository are protected.

II. EFFECTIVE DATE: FEBRUARY 28, 2026

III. SCOPE

This Policy applies to Repositories established at or on behalf of Columbia University (**Columbia** or the **University),** including Columbia University Irving Medical Center (**CUIMC**), for the purpose of storing Materials for current or future research.

IV. DEFINITIONS

Terms used in this Policy are defined as follows:

Biospecimens: As defined in Section I.

Columbia or the **University:** As defined in Section II.

Covered Research: Research that:

- Meets the DHHS definition of Research with Human Subjects, i.e., if investigators can link the Materials to donors or were involved in the management, governance or oversight of the applicable Repository;
- Meets any of the FDA definitions of Research with Human Subjects, e.g., if the research is a clinical investigation of a medical device; or
- Involves Genetic Tests on Biological Samples (as each is defined in NYS 79-l).

CUIMC: As defined in Section II.

Data: As defined in Section I.

DHHS: As defined in Section I.

HIPAA: As defined in Section I.

HIPAA Authorization: As defined in Section IX.

HIPAA Rules: The Privacy, Security, Breach Notification and Enforcement Rules under HIPAA, as amended (45 CFR 160 and 164).

Honest Broker: An individual who collects and provides de-identified or coded Materials to a researcher or to a repository.

Human Subject (as defined by DHHS): A living individual about whom an investigator (a) obtains information or Biospecimens through intervention or interaction with such individual and uses, studies or analyzes the information or biospecimens or (b) obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

Human Subject (as defined by FDA): (a) An individual who is or becomes a participant in research, either as a recipient of a test article or as a control or (b) an individual participating in a clinical investigation or (c) an individual whose biological specimens are being used in a clinical investigation of a medical device.

HRPO: The Columbia University Human Research Protection Office.

Identifiable: With respect to any information or Biospecimens, when the identity of a subject is or may readily be ascertained by the investigator or associated with the information or Biospecimen (45 CFR 46.102; 21 CFR 50).

Materials: As defined in Section I.

Non-Research Repository: As defined in Section V.

NYS 79-1: New York State Civil Rights Law, Section 79-1

PHI: Protected Health Information, as defined in the HIPAA Rules.

Regulations: As defined in Section I.

Repository: As defined in Section I, including a Research Repository or a Non-Research Repository.

Research (as defined by DHHS): A systematic investigation designed to develop or contribute to generalizable knowledge.

Research or Clinical Investigation (as defined by the FDA): An experiment that involves a test article and one or more human subjects.

Research Participant: A donor of Materials for Research or an individual whose Materials are used for research purposes.

Research Repository: As defined in Section V.

Secondary Research: For purposes of this Policy, Research that uses the Materials from a Research Repository.

V. RESEARCH REPOSITORIES

A **Research Repository** is defined as a location where Materials have been collected and stored with the intention of using them for future research, either by the investigator who collected them or by other investigators.

Other Repositories (**Non-Research Repositories)** are often created and maintained for purposes other than research. Such purposes may include, among others, diagnosis, treatment, billing, quality control and public health surveillance.

The creation and operation of a Non-Research Repository does not require IRB oversight. However, IRB oversight is required for use of Materials from a Non-Research Repository in Covered Research.

It is important to note that there are three separate points at which the need for a submission to the IRB and/or Research Participant consent must be considered:

- When the Research Repository is established;
- When Materials are collected for addition to the Repository; and
- When investigators wish to use Materials from a Repository in a research study.

VI. ESTABLISHMENT OF A RESEARCH REPOSITORY

A. IRB REVIEW AND APPROVAL

Investigators may create and maintain Research Repositories to make Materials available to multiple investigators and/or for multiple research projects, most of which cannot be specifically identified and described when the Repository is created. Any investigator at the University who intends to establish a Research Repository or who wishes to convert an existing database, collection of Biospecimens or a non-Research Repository into a Research Repository must obtain the approval of the IRB to do so prior to initiating any Repository-related activities. As with all research involving Human Subjects, the investigator must submit a protocol (**Repository Protocol)** to the IRB for its review and approval.

The Repository Protocol must specify the conditions under which Materials may be accepted into the Repository, how Materials will be securely stored and the procedures under which Materials will be shared to ensure that adequate measures will be employed to protect the privacy of Research Participants, maintain the confidentiality of the Materials, and ensure that the conditions under which the Materials were obtained are followed .

B. IRB PROTOCOL

In addition to the information generally required in any IRB protocol, a Repository Protocol should contain descriptions of the following:

- Background and rationale for the Repository;
- Management, governance and oversight of the Repository;
- That the Materials will be stored for future use in Secondary Research and the types of Secondary Research (e.g., specific disease area or broad unspecified use) for which the Materials will be used;
- That the research with the Materials will be conducted through separate protocols, some of which will require IRB approval;
- How consent will be obtained from Research Participants, if consent is required and was not obtained prior to the creation of the Repository;
- How HIPAA authorization (if required) will be obtained from Research Participants, if HIPAA authorization was not obtained prior to the creation of the Repository;
- Who will have access to the Materials, whether in de-identified or Identifiable form, the requirements for access and the application process for requesting and releasing Materials;
- Whether the managers of the Repository will have access to the Research Participants' medical or other nonpublic records;
- With whom the Materials will be shared (e.g., internally or externally), the conditions under which they will be shared, including whether large-scale data sharing will be undertaken, and the procedures for confirming IRB approval of the Secondary Research using such Materials when required;
- Any restrictions on use of the Materials;
- Whether the Materials will be used for genetic or genomic research;
- The procedures for protecting the confidentiality of the Materials and the privacy of the Research Participants, including security measures such as de-identification, encryption, coding, access control, or use of an Honest Broker;

- The procedures that will be used to track and verify the consent and authorization options selected by the Research Participants, e.g., future contact, future use of the Materials and when re-consent may be required;
- The procedures for verifying that Materials will be transferred using the appropriate institutional agreements (e.g., Data Use Agreements, Material Transfer Agreements);
- The length of time Materials will be kept and how Research Participants may withdraw their Materials from the Repository and the process for doing so;
- Whether Research Participants who have consented to the use of their Materials will be informed of the results of the Secondary Research by either the Repository or by recipient investigators; and
- Whether the Research Participants will or may be re-contacted for future research studies using their Materials.

VII. COLLECTION OF MATERIALS FOR ADDITION TO A RESEARCH REPOSITORY

Materials in a Research Repository may be collected from various sources and in various ways, including direct interaction with the donor, transfer of Materials from another Repository or other source or procurement of clinical samples that are no longer needed for diagnosis or treatment. The University imposes certain requirements on investigators who wish to collect Materials for inclusion in a Research Repository to be used for future research.

A. COLLECTION OF MATERIALS DIRECTLY FROM THE DONOR

Collection of Materials directly from a Donor for storage in a Research Repository and future use of Materials requires the consent of the donor.

The Informed Consent form for collection of Materials from Donors for inclusion in a Research Repository should include, in addition to the elements of consent required by the applicable Regulations and the Columbia University Policy on Informed Consent (the **IC Policy**), the following information:

- That the Materials will be stored for future use and the types of research that may be conducted with them;
- Who will have access to the Materials, either in de-identified or Identifiable form;
- Whether the research that will be conducted with the Materials will involve genetic or genomic research;
- With whom the Materials may be shared (e.g., internally or externally) and the conditions under which they may be shared;
- The procedures for protecting the confidentiality of the Materials and privacy of the Research Participants, including security measures such as de-identification, encryption, coding, access control, or use of an Honest Broker;
- The potential benefits and risks of participating in the Research Repository;
- Whether the Research Participants may withdraw their Materials from the Repository and the process for doing so;

- Whether Research Participants may be informed of the results of research conducted with the Materials;
- Whether Research Participants may be contacted by the Repository or by recipient investigators for future research studies; and
- Statements that Research Participants' Materials may be used in research that may result in new discoveries and that the Research Participant will not retain any property rights therein and will not receive any financial benefits therefrom.

B. COLLECTION OF MATERIALS OTHER THAN DIRECTLY FROM A DONOR

Materials that have already been collected and deposited in another Repository or that are residual clinical samples may be added to a Research Repository (the **Recipient Repository)** if the following confirmations have been received from the originating Repository or collector:

- Confirmation that consent was obtained from the original donors that is consistent with the proposed collection of Materials for the Recipient Repository or, if such consent was not obtained, whether amended consents will be obtained or waivers of consent will be sought from the IRB;
- Confirmation that appropriate institutional agreements covering the Materials to be collected (such as Material Transfer Agreements or Data Use Agreements) have been or will be executed; and
- Confirmation that procedures have been or will be established to track and verify compliance with the consent and authorization options selected by Research Participants, e.g., future contact, future use of Materials and when re-consent may be required.

VIII. USE OF MATERIALS FROM A RESEARCH REPOSITORY FOR RESEARCH

A. IRB REVIEW

Materials stored in a Research Repository may be used by Columbia investigators or by investigators outside of Columbia for Secondary Research studies. Materials that have been de-identified or coded may be used in many situations without the approval of the IRB or the consent of the applicable Research Participant. However, prior IRB approval must be obtained and consent received from Participants, unless waived by the IRB, when the research is Covered Research.

The recipient investigator's protocol should identify the Repository from which materials will be obtained and, if the Repository is located at Columbia or was established by Columbia investigators, the Rascal protocol number relating to such Repository. Documentation of IRB approval for Covered Research must be provided to the Repository.

B. INFORMED CONSENT

Use for Covered Research of Materials previously collected by a Research Repository requires confirmation by the Repository that (a) such use is permitted by the terms of the initial consent and that any donor did not elect to "opt out" of permitting such Materials to be used in the manner contemplated by the subsequent research protocol or (b) the investigator planning to use such Materials has obtained or will obtain consent from the donors or will provide justification to the IRB that a waiver of informed consent is appropriate. If informed consent that meets the regulatory requirements for research was not obtained from the donors, such as for residual clinical samples because standard consent forms for treatment rarely meet such regulatory requirements, obtaining consent before use for Secondary Research may be necessary.

Consent for the use of Materials whenever obtained must include the elements described in Section VII(A) above. If the IRB approves a waiver of consent, use of the Materials will generally be limited, due, for example, to requirements of certain federal policies (such as the NIH Genomic Data Sharing Policy) or institutional policies.

IX. HIPAA AUTHORIZATION

Any investigator at the University who wishes to include PHI of a Research Participant with Materials to be collected in a Research Repository or use such PHI in a research study must obtain written authorization from the Research Participant to whom the PHI refers (a **HIPAA Authorization**) or obtain a waiver of authorization from the IRB, acting as the Privacy Board. In either case, the authorization or waiver must specifically permit the inclusion of the PHI in the Research Repository or the disclosure and use of PHI in a subsequent research study.

See the Columbia University Institutional Review Policy on The Privacy Rule and the Use of Health Information in Research for requirements for obtaining authorization to use or disclose PHI for research purposes.

X. OWNERSHIP OF MATERIALS

All Materials deposited in a University Research Repository remain the property of the University and may not be taken from a Research Repository, e.g., transferred to another institution upon transfer of the principal investigator of the repository protocol, without the explicit approval of the appropriate University official.