

University Rule 7-002A: Ownership, Access, and Use of Biospecimens and Associated Data. Revision 0. Effective date [TBD]

I. Purpose and Scope

Purpose: This Rule is intended to facilitate beneficial use of biospecimens in an effort to advance research. This Rule implements University Policy 7-002 by describing expectations, standards, and requirements governing ownership, access, and use of biospecimens and any associated data obtained or held under the auspices of the University.

Additionally, this Rule provides a framework to prevent and resolve disputes involving access to and use of biospecimens. Such disputes are routinely managed and resolved at the local level by University Researchers and the applicable academic and administrative units. This Rule is not intended to replace such management and resolution practices. Rather, this Rule specifies general expectations associated with biospecimens and outlines a process that will be utilized by the Vice President for Research to address biospecimen access and use issues that cannot be adequately resolved by the applicable University Researchers and academic and administrative unit(s).

Scope: This Rule applies to all University personnel (including faculty, staff, non-faculty academic employees, and students), and all academic and administrative units of the University.

II. Definitions

These definitions apply for the limited purposes of this Rule.

Associated data: Data that identifies or describes biospecimens and that were obtained or created in connection with a particular biospecimen acquisition and remain associated with a particular biospecimen. The types and extent of associated data may vary depending upon the circumstances associated with the collection and retention of biospecimens.

Biospecimens: Biological specimens, including solid tissues or body fluids or their derivatives (such as DNA or RNA) obtained or retained for potential research purposes.

Principal Investigator: The primary individual responsible for the preparation, conduct, and administration of a University Research project.

University clinical activities: University activities associated with the provision of health care services and related items to patients of the University.

University Research: The definition of University Research provided in Policy 7-002 applies for purposes of this Rule.

University Researcher: A University faculty member, non-faculty academic employee, staff employee, or student who has engaged or is engaged in any University Research.

III. Rule

- A. Biospecimens and associated data obtained in connection with University Research, as a result of University clinical activities, or that are otherwise acquired by the University are the property of the University except when ownership is otherwise expressly designated in a properly approved written agreement between the University and a third party, consistent with Policy 3-004: Processing and Signing Official Documents.
- B. Biospecimens and associated data obtained as a result of University clinical activities can only be released for potential research use only after the applicable clinical unit has determined that the biospecimens and associated data are no longer necessary for clinical purposes and that the release of such biospecimens and associated data will be consistent with biospecimen retention requirements imposed by applicable law or University Regulations.
- C. University Researchers and administrative units engaged in the collection of biospecimens and associated data are expected to comply with all applicable legal and contractual requirements associated with biospecimen and associated data collection, use, and sharing.
- D. University Researchers and administrative units engaged in the collection of biospecimens and associated data should make reasonable efforts to collect information regarding each biospecimen, including details about origin, collection, and processing.
- E. The Vice President for Research may require University Researchers to document and supply information about biospecimens and associated data to better enable communication and coordination among University Researchers and research partners.
- F. The Vice President for Research may prohibit University Researchers from discarding biospecimens and associated data deemed to have value in promoting the University's research mission. In such cases, the University should provide resources for the continued storage of the biospecimens and associated data.

- G. University Researchers, prior to the external transfer of biospecimens and associated data that have potential commercial value or when such a transfer would restrict or eliminate access by other University Researchers, must seek approval from the Vice President for Research through a Material Transfer Agreement or similar agreement addressing expectations regarding the use, privacy, and security of biospecimens and associated data.. University Researchers initiate this process by contacting Technology and Venture Commercialization. University Researchers with questions about the scope of this obligation should contact Technology and Venture Commercialization for guidance.
- H. University Researchers who collaborate to collect biospecimens and associated data or to create a pooled resource of biospecimens and associated data should document expectations and processes concerning access to and use of such biospecimens and associated data.
- I. University Researchers are authorized and encouraged to transfer or share biospecimens and associated data within the University. In such circumstances, the University units and University Researchers involved in the sharing or transfer arrangement are encouraged to prepare an Internal Material Transfer Agreement (IMTA) to document requirements and expectations. Technology and Venture Commercialization can assist with this process. Each IMTA should document:
 - 1. a detailed description of the biospecimens and associated data, including the number of biospecimens to be shared and how that number relates to the total number of biospecimens;
 - 2. the nature and scope of permissible research;
 - 3. management of residual biospecimens and associated data following the research;
 - 4. intellectual property rights resulting from discoveries; and
 - 5. authorship rights related to any resulting publications.
- J. The Vice President for Research has ultimate authority over the utilization of biospecimens and associated data banked or retained for potential research use. If a Principal Investigator oversaw collection of the biospecimens and associated data, use of the biospecimens and associated data will generally require the approval of that Principal Investigator; provided that the Principal Investigator has adhered to the approved protocol associated with the research and complied with applicable law and University Regulations.
- K. Dispute Resolution:
 - 1. In the event of a dispute over access to or use of biospecimens and associated data, and when any applicable local efforts at dispute resolution have failed, the Vice President for Research may authorize

access to or use of biospecimens and associated data without the approval of a Principal Investigator who oversaw collection of the biospecimens and associated data if the Vice President for Research determines that:

- a. the Principle Investigator is not reasonably available,
 - b. the Principal Investigator has relinquished decision-making authority about access to or use of biospecimens and associated data to the Vice President for Research or another designated individual(s) acceptable to the Vice President for Research, or
 - c. the Principal Investigator is denying access to other University Researchers without sufficient justification.
2. In making a determination that a University Researcher is denying access to other University Researchers without sufficient justification, the Vice President for Research should make use of an internal dispute resolution process. Such process will involve the formation of a dispute resolution panel including representatives from the office of the Vice President for Research, the academic or administrative units the involved Researchers are most closely associated with in connection with the subject matter of the dispute, and the cognizant Senior Vice President(s) or their designee(s). The Vice President for Research shall determine the makeup of the dispute resolution panel consistent with this Rule; provided that at least half of the members of the dispute resolution panel must be Tenure-line faculty members who are not involved in the dispute. The dispute resolution panel will gather relevant facts, consider the views of each involved University Researcher, and recommend a course of action to the Vice President for Research, who will make the final decision on the matter.
3. To the extent a final decision of the Vice President for Research requires a University Researcher to make biospecimens and associated data available to another University Researcher, the access or use provided should be confined to an amount reasonably necessary to meet the needs of the University Researcher requesting such access or use.

[Note: Parts IV -VII of this Regulation (and all other University Regulations) are Regulations Resource Information—the contents of which are not approved by the Academic Senate or Board of Trustees, and are to be updated from time to time as determined appropriate by the cognizant Policy Officer and the Institutional Policy Committee, as per Policy 1-001 and Rule 1-001.]

IV. Procedures, Guidelines, Forms and other Related Resources [reserved]

V. References: [reserved]

VI. Contacts:

The designated contact officials for this Rule are:

- A. Policy Owner: Director of Technology & Venture Commercialization
- B. Policy Officer: Vice President for Research

These officials are designated by the University President or delegee, with assistance of the Institutional Policy Committee, to have the following roles and authority, as provided in University Rule 1-001:

"A 'Policy Officer' will be assigned by the President for each University Policy, and will typically be someone at the executive level of the University (i.e., the President and his/her Cabinet Officers). The assigned Policy Officer is authorized to allow exceptions to the Policy in appropriate cases"

"The Policy Officer will identify an 'Owner' for each Policy. The Policy Owner is an expert on the Policy topic who may respond to questions about, and provide interpretation of the Policy; and will typically be someone reporting to an executive level position (as defined above), but may be any other person to whom the President or a Vice President has delegated such authority for a specified area of University operations. The Owner has primary responsibility for maintaining the relevant portions of the Regulations Library [and] bears the responsibility for determining -requirements of particular Policies"

University Rule 1-001-III-B & E

VII. History:

Renumbering: Not applicable.

Revision History:

Current Version Revision 0.

Approved by the Academic Senate [_____]

Effective Date: [_____]

Legislative history of Revision 0 {link to history file}.