



University of Pittsburgh
Human Data and Biological Samples Sharing Policy Committee Charter

I. Preamble

This body is called the Human Data and Biological Samples Sharing Policy Committee (“Committee”). It is authorized by the Chancellor and will serve at the Chancellor’s discretion. The Chancellor has authorized the Senior Vice Chancellor for Research (“SVC-R”) and the Senior Vice Chancellor for the Health Sciences (“SVC-HS”) to direct the operations of this Committee, consistent with the terms of this Charter. This Charter outlines the purpose, relevant background, scope, responsibilities, composition, and operations of the Committee, as well as the review process for any proposals generated by this Committee.

This document should be read in conjunction with Policy AO 01, Establishing University Policies, and all other applicable University policies, protocols, and procedures.

II. Purpose

The Committee is created for the purpose of proposing a new University Policy, as well as documents that support its implementation, which will govern how the University of Pittsburgh (“University”) shares data and biological materials from humans that is generated or gathered by researchers on behalf of the University.

III. Background

The extensive and wide-ranging human subject research programs at the University conducted by investigators, including those dually employed by the University and UPMC, generate considerable human data and biological samples that are valuable to academic and government collaborators, as well as the research industry. Currently, there is no formal University Policy regarding the sharing and licensing of human data and biological samples. Without an overarching University-level Policy and without any central oversight, varying practices for sharing these types of materials may not be following consistent best practices. Additionally, the immense scientific value of human data and biological samples collected by the University is counterbalanced by potential ethical concerns in transferring these materials, particularly to non-academic or non-government entities. The lack of a formal University-level Policy on human data and biological samples sharing thereby limits collaborative opportunities, while raising the potential for criticism that the University lacks apt ethical standards. A policy designed to create a formal set of rules, principles, and procedures on sharing this information would potentially remove this limitation.

IV. Scope and Authority

The Committee will recommend a University Policy on Human Data and Biological Samples Sharing, and supporting documents (e.g., guidelines and procedures). In doing so, the Committee's deliberations must address the following topics:

- **Definitions and Terms.** Identify and define terms necessary for the Policy's scope and implementation. Specifically, the Committee should define what constitutes "human data" and "biological samples" and whether such definitions should include the sharing of cell lines derived from human subjects, including synthetic cells with human cell components.
- **Scope.** Determine what materials are within the scope of the Policy, including whether the Policy should be limited to research materials (in the health sciences and other fields such as social sciences) only or whether clinical materials and data collected outside of these research contexts are also within scope. Additionally, if the scope of the Policy permits third party sharing of materials, it should further determine if such entities can commercialize any of those materials.
- **Alignment.** Align the proposed Policy and Procedure with any applicable UPMC policies and/or protocols on sharing human data and biological samples, to the extent possible.
- **Sharing and Costs/Profits.** Consider which entities (e.g., academic, government, non-profit, commercial, University-licensed startups) with whom the University should share human data and biological samples and whether there should be any level of sharing priority. If third party sharing is recommended, that recommendation should include the scope of a third party's use of human data and biological samples (e.g., commercial applications). If such a sharing priority is recommended, that recommendation should include how that priority is determined (e.g., criteria). Additionally, if such materials are shared with a commercial entity, the Committee should consider if a net profit can be earned by the University, and if so, how that profit would be distributed.
- **Ownership.** Determine who retains ownership of the human data and biological samples when those materials are transferred (i.e., shared) with a third party.
- **Compliance.** Ensure the proposed Policy complies with any relevant local, state, and federal laws and regulations, including those governing informed consent language for human data and biological samples sharing. Additionally, ensure the proposed Policy complies with and does not conflict with any other relevant University Policies, including but not limited to, University Policy CS 30, HIPAA, and University Policy RI 10, Intellectual Property.

- **Guidelines and Implementation.** Establish a consistent and uniform process for the implementation of the proposed Policy (e.g., an associated Procedure) at the University. In doing so, the Committee should consider and propose which office(s) at the University are responsible for the Policy's implementation (e.g., Governance and Responsibilities). Additionally, any proposed guidelines should address procedures for the prospective sharing of human data and biological samples.

V. Responsibilities

As provided above, the Committee is created to propose a Human Data and Biological Samples Sharing Policy. To perform this function, the Committee has the responsibility to:

- Review and consider terms and procedures used in other University Policies that could inform the drafting of the proposed Policy, including but not limited to, University Policy CS 30, HIPAA, and University Policy RI 10, Intellectual Property.
- Research and discuss best practices that govern human data and biological samples sharing at peer and aspirant institutions, including a benchmarking of relevant policies.
- Consult with relevant University and UPMC stakeholders, including those dually employed by the University and UPMC.
- Research and discuss relevant federal, state, and local guidance on the sharing of human data and biological samples.
- Incorporate or address any applicable requirements imposed by local, state, and federal laws and regulations.
- Recommend a draft Policy for review pursuant to the process described in Section VIII below and consider feedback received during that review; and
- Recommend a draft procedure or other supporting documents for review pursuant to Section VIII below that is needed for the effective and efficient implementation of the proposed Policy.

It is expected that the Committee will work in confidence to have full and frank discussion of all options. Individual members should maintain the deliberations of the Committee as confidential and are expected to not discuss the content of the Committee's deliberations outside of the Committee, unless authorized to do so by the Committee. The broader community will have an opportunity to consider the Committee's proposals pursuant to the Process described in Section VIII below.

VI. Composition

This Committee, at the direction of the SVC-R and the SVC-HS, will be co-chaired by **Bill Yates**, Vice Chancellor for Research Protections, and **Leeanna McKibben**, Chief of Staff and Vice Chancellor for Health Sciences Administration. The Committee will include the following members:

1. **Heather Bachman**, Associate Professor, School of Education

2. **Jean Barone:** Director of Human Research Protection Division, Office of Research Protections
3. **Joe Havrilla:** Associate Vice Chancellor for Innovation and Entrepreneurship
4. **Matthias Kleinz:** Senior Vice President, UPMC Enterprises
5. **Adrian Lee:** Professor of Pharmacology and Chemical Biology and Pittsburgh Foundation Chair in Precision Medicine
6. **Yu-Ru Lin,** Associate Professor, School of Computing and Information
7. **Oscar Marroquin:** Chief Health Care Data and Analytics Officer, UPMC; Associate Professor of Medicine, Epidemiology and Clinical and Translational Science
8. **Uduak Ndoh:** Vice Chancellor and Deputy Chief Information Officer, Health Sciences
9. **Lisa Parker:** Professor of Human Genetics; Director, Center for Bioethics & Health Law
10. **Felix Proessel:** Director of Sports Science
11. **Steve Reis:** Director, Clinical and Translational Science Institute; Associate Senior Vice Chancellor for Clinical and Translational Research, Health Sciences; Distinguished Service Professor of Medicine
12. **William Wagner:** Distinguished Professor of Surgery; Professor of Bioengineering and Chemical Engineering; Director, McGowan Institute for Regenerative Medicine
13. **Katherine Wood,** Research Assistant Professor; Co-chair of the Senate Research Committee
14. **Jennifer Woodward:** Vice Chancellor for Sponsored Programs and Research Operations; Professor of Surgery and Immunology

Brittany Conner, Policy Specialist, will help facilitate and support the Committee on behalf of the Office of Policy Development and Management.

Andrew Eisman, Associate Legal Counsel, will support the Committee on behalf of the Office of University Counsel.

Michele Jegasothy, UPMC Corporate Secretary & Senior Associate Counsel, will support the Committee.

VII. Operations

The Committee will meet weekly or more frequently as circumstances dictate, until the work set forth above is complete. The Committee's proposed Policy on Human Data and Biological Samples Sharing will be submitted to the SVC-R and SVC-HS by the end of the Fall Semester 2022. The SVC-R and the SVC-HS may ask for interim status reports.

After the SVC-R's and the SVC-HS's review is complete, the draft Policy will be submitted to the Policy Office to coordinate its review consistent with Policy AO 01.

VIII. Proposed Policy Review Process

The review process for the Committee's recommended Policy is as follows:

- University comment period;

- Council of Deans;
- University Senate Research Committee;
- Faculty Assembly;
- University Senate Council; and
- Administration Leadership.

The Committee will coordinate with the Policy Office to consider feedback provided throughout this process.

Once this review process is complete, the proposed Policy will be sent to the Policy Office for review and submission to the Chancellor in accordance with Policy AO 01.

IX. Amendment

Any amendments to this Charter must be made in accordance with Policy AO 01 and receive the approval of the Chancellor or designee.

The Committee shall expire on the publication of a new University Policy that governs how the University shares data and biological materials from humans that is generated or gathered by researchers on behalf of the University, unless otherwise directed by the Chancellor.