Cleveland Clinic BioRepository (CC-BioR) General Governance Principles

Mission: To accelerate biomedical discovery, innovation, and therapies by leveraging biospecimens and associated data.

Vision: We will learn from a million patients to better care for each one.

Strategy: The CC-BioR is specimen- and data-rich; its exponential growth will enhance and facilitate quality and quantity of biomedical research, permitting alignment with clinical care processes and priorities.

Execution: The CC-BioR team offers biospecimen and data services to Cleveland Clinic Caregivers ranging from subject involvement, specimen collection, storage, processing for subsequent analyses and phenotyping.

These guidelines were developed by the Cleveland Clinic BioRepository Governance Committee and will be reviewed periodically and amended as required.

General principles:

- Governance decisions are guided in alignment with Cleveland Clinic's mission, vision, and strategy.
- Specimens and their corresponding data, both housed in CC-BioR must adhere to the FAIR principles:
  - **F**indable – defined by a persistent identifier and detailed metadata
  - **A**ccessible – well-defined license and access conditions
  - **I**nteroperable – ready to be combined with other data by humans and machines: standardized formats and vocabulary
  - **R**eusable – ready to be reused in future research and processed using computational methods
- Cleveland Clinic owns and/or holds a proprietary interest in any research materials generated at the Cleveland Clinic, including all BioRepository samples and data.

Specific recommendations:

A- Application and review process:

1. All biospecimen requests must be approved by the requester's Institute Chair or designee. For biospecimens obtained by a specific institute, the request must be approved by the donating Institute Chair or designee and a Co-Investigator assigned to the research.
2. A CC-BioR Review Committee will review all requests for biospecimen and/or data "withdrawal." This review committee prioritizes projects in consultation with Enterprise Data Governance when needed, according to these metrics:

Quality • Scientific Excellence • Robust Methodology • Ethical Soundness	Value • Complementary to existing projects • Potential impact on public health • Potential to improve patient care • Alignment with Enterprise goals
Quantity • Number of subjects/specimens • Number and type of sample requested • Volume of data	Funding Status • Obtained or pending? • Public, private, or both?

3. Biospecimen requests that meet the following criteria will be reviewed first at the CC-BioR Review Committee level:
    a. Federally funded projects or projects funded by a not-for-profit sponsor
    b. IRB-approved projects
    c. Projects designed to generate pilot data
4. The CC-BioR Committee refers biospecimen requests intended for data sharing with a for-profit entity or with the intent of commercialization to Enterprise Data Governance.
5. A Cleveland Clinic collaborator must be included in any proposal submitted by an external investigator(s). Samples will be analyzed locally unless explicitly approved by the CC-BioR Review Committee or Enterprise Data Governance as needed.
6. Access to samples that are limited and/or will be depleted with the current request require extra review by the CC-BioR Executive Committee and will be prioritized against the quality and value of the proposed research project, consulting appropriate experts as required.
7. The final research project, analysis plan, and publication must be approved by the donating Institute Chair or designee. If appropriate, a co-author will be assigned from the donating institute.

B- <u>Governance of data generated from CC-BioR samples:</u>

8. Samples and/or data are provided for specific uses. Any change in the scope of the project must be approved by the CC-BioR Review Committee. Resources are not provided for unspecified use.
9. Data generated from BioRepository samples must be returned to the CC-BioR database for potential use by other investigators. Exceptions to this guideline should be rare and must be justified and approved by the BioRepository Review Committee.
10. Individuals requesting BioRepository sample data must consult with content experts to ensure appropriate interpretation of the data can be executed. Note that appropriate credit must be given to original data generator in any/all presentations/publications.
11. Publications using CC-BioR samples must include the acknowledgement, “The author(s) would like to thank the Cleveland Clinic BioRepository for its kind support and permission to use data and samples.” OR “This research has been conducted using the Cleveland Clinic BioRepository Resource.” When possible, this should be linked to reference search tools such as PUBMED.

C- <u>Cost Recovery:</u>

12. CC-BioR will award services in the context of competitive yearly RFPs.
13. CC-BioR will offer services on a cost-recovery basis with a fixed charge for application review and a variable charge depending on the number of samples and/or data requested.