



# Institute Policies

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## **I. Background/Mission**

The Fairbanks Institute for Healthy Communities (Fairbanks Institute) is a not-for-profit organization that is creating one of the nation's most comprehensive resources for research that will lead to new drugs, diagnostics and treatments for Indiana's and the nation's most common diseases. Formed with a gift from the Richard M. Fairbanks Foundation in collaboration with BioCrossroads, the Indiana University School of Medicine, the Regenstrief Institute and other Indianapolis community health leaders, the Fairbanks Institute's mission is to improve community and public health by facilitating breakthroughs in basic and translational research. To accomplish this goal, the Fairbanks Institute is integrating biological samples with longitudinal clinical and epidemiological information collected from the population of Indianapolis and other Indiana communities to support academic and commercial research.

## **II. Guiding Principles**

The Fairbanks Institute is committed to establishing and maintaining the highest professional and ethical standards in all aspects of its operations. The principles that guide the Fairbanks Institute's policies are to:

1. Engage Indiana communities in the formation of the Fairbanks Institute's research platforms.
2. Encourage participation of minority and other traditionally under-represented groups in the development of the research platform while protecting vulnerable populations.
3. Collect biological samples and information from the communities under protocols that adhere to all applicable laws and regulations governing the protection of human subjects and vulnerable populations.
4. Collect, process and store all biological samples under conditions that produce the highest quality samples.
5. Store all data associated with biological samples under conditions that meet or exceed industry standards for data security.
6. Employ practices that protect individual privacy.
7. Provide academic and commercial access to biological samples and information for research that advances the Fairbanks Institute's mission of improving community and public health.
8. Establish and maintain a fee structure for sample and information access that is consistent with the Fairbanks Institute's not-for-profit status.
9. Assess the ability of samples and information provided to academic and commercial researchers to produce knowledge that advances the Fairbanks Institute's mission.

### **III. Policies**

#### ***A. Informed Consent Policies***

1. Obtain Institutional Review Board (IRB) approval of all protocols for collecting biological samples and information for the Fairbanks Institute's research platform.
2. Only enroll individuals age 18 or older who can provide informed consent.
3. Exclude subjects deemed medically unsuitable for research donation by their treating physicians.
4. Only enroll individuals who have given consent to provide a biological sample and information that can be used for academic and commercial research purposes.
5. Only enroll individuals who have given consent for longitudinal follow-up.
6. Clearly state in the informed consent that the biological sample provided by the individual becomes the property of the Fairbanks Institute.
7. Allow individuals to withdraw from Fairbanks Institute collection studies at any time.
8. Collect no new information on individuals who withdraw.
9. Remove biological samples collected from individuals who withdraw from studies if the individual's samples have not already been distributed to researchers.

## ***B. Biological Sample Collection Policies***

1. Collect biological samples and information from the population of Indianapolis and other Indiana communities such that the collection is ethnically diverse and includes understudied populations.
2. Build a collection network of academic medical centers, community hospitals and community clinics to obtain sufficient high-quality samples and data for research that will advance the mission of the Fairbanks Institute.
3. Establish and maintain close working relationships with providers at the collection sites to facilitate efficient collection.
4. Use standardized protocols for the collection of biological samples and train collection personnel to insure the comparability of biological samples and information for research purposes.
5. For tumor samples, allow pathologists to determine what tissue is necessary for pathologic diagnosis and what is excess and can be given to the Fairbanks Institute for storage and research use.
6. Along with the biological sample, collect consistent, high-quality information using a minimal data set designed to meet the needs of researchers and fulfill the mission of the Fairbanks Institute.
7. Use an electronic tracking system to track biological samples and associated information from the time of collection through the time of distribution to researchers.

### ***C. Biological Sample Processing and Storage Policies***

1. Use standardized and carefully monitored shipping procedures with systems to track all shipments and expected receipts of samples to and from the sample processing site.
2. Process biological samples for storage according to detailed standardized protocols that are consistent with accepted standards for the type of sample.
3. Follow standard protocols for storage depending on the type of biological samples and preservation condition necessary to maintain sample integrity.
4. Monitor storage conditions to ensure that specimens are maintained at the necessary temperature and condition.

#### ***D. Quality Assurance Policies***

1. Employ, or enter into contracts with organizations that employ, personnel trained in the collection, processing, annotation, storage and distribution of human biological materials.
2. Perform quality control testing on biological samples as specified in the collection study protocol.
3. Obtain feedback from researchers or their institution on the quality of biological samples and information they receive to identify specific problems, inconsistencies, or shortcomings of the samples or information in the Fairbanks Institute's research platform or in samples collected in a certain way or from a certain collection site.
4. Require all researchers to provide feedback on the quality of the data that resulted from studies which used samples and information from the Fairbanks Institute's research platform.

### ***E. Data Management Policies***

1. Utilize an information system that is searchable.
2. Utilize methods that ensure the accuracy of data entry.
3. Employ independent checks of manually entered data.
4. Have a system for capturing and tracking information system requirements, defects and feature requests.
5. Employ network security systems and access control to ensure that privacy is protected and that information in the Fairbanks Institute's research platform is secure.
6. Link all results and annotations gathered from any assays or tests performed on the biological samples at the processing site to the biological samples for at least as long as these samples are in the Fairbanks Institute's research platform.

## ***F. Biological Sample and Data Distribution Policies***

1. Require researchers to pay a fee to access data and biological samples that is consistent with the cost of collecting, processing and maintaining the samples and data, the scarcity of the samples requested, the likelihood that resulting data will be entered into the public domain and the Fairbanks Institute's status as a not-for-profit organization.
2. Evaluate research proposals requesting no cost or reduced cost distribution of biological samples and data on a case by case basis according to criteria established by the Fairbanks Institute Science and Policy Committee that include:
  - a. Academic credentials and demonstrated competence of the requesting researcher
  - b. Scientific merit of the proposed research
  - c. Validity of proposed study design
  - d. Potential for clinical or scientific impact of the proposed research
  - e. Practicality and feasibility (amount of tissue/samples required)
  - f. Potential for the research to advance the mission of the Fairbanks Institute
  - g. Affiliation of requesting researcher with a Fairbanks Institute partner organization
  - h. Potential for publication of the research findings
3. Release biological samples and data only to institutions and researchers considered by the Fairbanks Science and Policy Committee to be reputable and possessing the appropriate scientific experience and credentials to extract the maximum scientific value from the samples and data.
4. Release biological samples and data only to researchers who have agreed to the Fairbanks Institute's Terms and Conditions of Use Agreement and paid applicable fees.

## ***G. Conditions of Use Policies***

1. Use a Terms and Conditions of Use Agreement for release of biological samples and information that requires researchers to agree that:
  - a. The biological samples and data supplied to them by the Fairbanks Institute will be used only for the purposes cited in the application.
  - b. No attempt to obtain identifying information will be made.
  - c. No biological samples will be sold or shared with a third party without the prior written permission of the Fairbanks Institute.
  - d. All biological samples will be treated as potentially infectious.
  - e. There is no implied warranty on the biological samples.
  - f. The researcher/institution using the biological samples assumes responsibility for all risks associated with the receipt, handling, storage and use of the samples.
  - g. The researcher will comply with all applicable laws and regulations relating to the use of human biological materials.
  - h. Any publications or presentations in a public setting resulting from the use of the Fairbanks Institute's biological samples and information will acknowledge the Fairbanks Institute for Healthy Communities.
  - i. The Fairbanks Institute may disclose the name of institutions that have accessed biological samples and information from the Fairbanks Institute's research platform and the general purpose for which the samples and information were accessed.
  - j. Researchers or their respective institutions will report improvements to community health arising from research performed using samples and information obtained from the Fairbanks Institute.

## ***H. Privacy and Confidentiality Policies***

1. Do not release information to researchers that may identify an individual.
2. Release only the minimum amount of information necessary to perform the research.
3. Explicitly prohibit researchers from attempting to identify individuals.
4. Protect information systems from security risks and breaches of privacy by appropriate technical and management policies.