Specimen and Data Repository Guidance

This guidance was written for NSLIJ Health System investigators who want to establish a biological specimen and/or data repository. Investigators should have adequate repository management procedures and adhere to appropriate policies and best practices.

When IRB Approval is Required

All specimen and data repositories that qualify as human subject research require IRB review and approval. IRB review and approval is also needed when identifiable samples are provided to internal or external investigators for research purposes. If you are releasing anonymous samples to an investigator-user, you do not need prior IRB review and approval.

Developing a Protocol and SOPs

A protocol and/or Standard Operating Procedure (SOP) should be submitted along with the IRB application for establishing a specimen and/or data repository. SOPs are a good way to standardize processes, especially for large teams that may have different functions or are located at multiple sites.

When you develop your process you should include the following sections as appropriate:

1) **General Purpose of the Repository** – Provide information on the general purpose for gathering types of specimens and/or data (usually to further research about a disease or condition), the departments, sites, or other protocols involved, and the intent to share specimens and data with internal and external investigators. If you have a repository program you can describe the roles and responsibilities of the various key personnel and departments or sites involved.

2) **Subject Recruitment and Consent** – Outline the general characteristics of subjects that you intend to recruit (e.g. adult, minor, affected, non-affected, etc.), eligibility criteria, and methods of how and where subjects are recruited to provide specimens and data. Include information about the consent process and instances of when re-consent may be necessary (e.g. when minors turn 18). If waivers of consent/authorization are to be sought from the IRB (such as in the use of discard specimens) you should outline this process as well.

   If subjects are required to select certain choices for the use or limitations to the use of their samples and/or data within the consent form, you will need to have a centralized process to track this information. Maintaining this information in a centralized database would provide research teams with quick access to this information.

3) **Confidentiality and Security** – Outline the methods used to secure data and ensure subject privacy and confidentiality, including security measures and/or systems. Identify who will have access to subject information and the key to the identification code(s). Security measures should also be in place for maintaining data on computers and databases and during transfer of data and specimens. If you are working with repository services that process, store, and distribute your samples, ensure that samples are properly coded without personal identifiers and you have a process for maintaining and protecting
the key to the identification code(s). If a Certificate of Confidentiality (COC) has been obtained or will be sought for this study for the protection of sensitive information, you should indicate this as well.

4) Banking Procedures*

a) Sample/Data Collection – Include information about the sources and process by which specimens are obtained, labeled, and tracked with associated data. Information should be included about how the various types of samples are labeled and coded (or bar-coded) with non-PHI derived unique identifiers, and how they will be tracked along with associated data, which can be through an electronic information management system or database.

* Suggested Form: Initial Specimen Collection Sheet - Provides information about when the specimen was collected by whom.

b) Deposit of Samples and Data – Detail how samples and data are deposited into the repository by internal and external investigators. This should also include a review and approval process by the PI or committee of the repository for donors from internal and external investigators. Include required conditions for specimen and/data to be deposited into the repository.

* Suggested Form: Sample/Data Deposit Form - Provides information about the investigator (and their affiliation) depositing the samples, description of the samples, storage requirements, and processing details.

* Suggested Form: Submittal Agreement – Where the investigator provides an attestation that the samples and/or data were obtained through appropriate methods. If applicable, documentation of IRB approval for the collection of the specimens should accompany this agreement.

c) Sample Storage and Maintenance – Describe where samples are stored and how they are maintained. You should include information about back up storage and notification procedures in the case of power failures and the use of temperature recording systems to ensure the integrity of samples are maintained.

d) Sample Processing – Describe how samples are processed and by what general group, site or department.

e) Sample/Data Requests – Provide information about the process for which samples and/or data are requested by internal and external investigator-users. You should also detail how you will handle further requests for information on a sample that was distributed.

* Suggested Form: Sample/Data Withdrawal Request Form – Requests are documented that detail the name of the requestor, the quantity and type of samples/data requested, when the request was made, and how the samples will be distributed.

f) Sample/Data Retrieval and Transfer – Provide information about how samples/data are retrieved from storage and then transferred and shared with the investigator-user.
g) Sample/Data Destruction – Detail the process by which samples and/or data are destroyed and documented.

- **Suggested Form**: Sample/Data destruction Form – Documents the reason for destruction, who destroyed the sample/data, when, and witnesses, if any.

*If you are using a repository service for any of these functions, ensure that they have SOPs and you can just refer to them within your own for these sections.

5) **Subject Withdrawal Procedures** – Outline how you will handle requests from subjects who withdraw their consent for further use of their samples and/or data. If it is not possible to withdraw their samples and/or data from the repository (because they have already been placed in batched plates, for example) you should have a process where the subject’s samples are flagged in the system that will prevent further use.

6) **Sub-Protocol Initiation** – Describe the procedure for investigators interested in initiating a sub-protocol using identifiable or coded specimens in the repository, and approval by the PI or an assigned committee.

**Agreements for the Release and Transfer of Samples and Data**

When you provide samples and/or data to an investigator, you should have a signed agreement; the type of agreement may depend on whether the investigator is internal or external to our Health System. A usage agreement is typically used for samples and/or data that are provided to internal investigators. This type of agreement outlines the conditions for receipt and use of samples and/or data and prohibits the investigator from seeking the identity of the subject (if applicable).

Any **biological** samples transferred to an entity outside of the Health System require a signed agreement between the Health System and the receiving entity in the form of a Material Transfer Agreement (MTA) or a Uniform Biological MTA, which are drafted by the Office of Technology Transfer (OTT). Please contact the OTT at (516) 562-3404 for assistance.

Refer to the Health System Research Policies on Intellectual Property and MTAs for more information. All executed agreements must be maintained by the PI of the repository and available for inspection.

**Documentation of Sample and Data Accountability and Tracking**

Make sure that your documentation provides a clear chain of custody for the samples and data from initial acquisition to the final release to the end recipient that reflects an appropriate process. There should also be centralized management systems to track samples and sample numbers. If multiple numbers are assigned to a subject’s samples, you should have a process to maintain this information so that you can identify who the samples belong to. If you are using a repository service, you should maintain documentation of the types of samples/data that were sent to the repository and when they were submitted. There should be personnel with assigned roles that track and manage samples and data
or who are designated as the overall gatekeeper of the repository system and process. Documentation and electronic information should be available or readily accessible in the event of an audit.

Note: Maintain documentation of training and certification for anyone involved in packing and shipping biological specimens (e.g. Saf-T Pak or equivalent program) as well as the shipping manifests and records.

Termination of a Repository

If a repository will no longer be used you should maintain documentation of the final disposition (e.g. transfer, donation, or destruction) of samples and data and associated documents.

Repository Best Practice Resources

