**University of Michigan**

**Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)**

**Template for Repository Protocol**

A research repository is defined as a collection of data and/or biospecimens that have been collected and stored with the intention of using the materials for future research, either by the investigator who collected them or by sharing the materials with other investigators.

The Repository Protocol is designed to supplement the basic information collected in the eResearch Repository Application.

The IRB must review and approve the following procedures associated with repositories:

* Intake of data and/or biospecimens for inclusion in the repository
* Distribution of data and/or specimens to other investigators
* Data security plans

Consistence with institutional policy, the protocol should also include information regarding

* Physical storage and maintenance
* Governance and oversight of the repository

**REP#:**

**NAME:**

**REPOSITORY DIRECTOR:**

1. **Intake Procedures for Acceptance of Data into the Repository**

Describe conditions under which data are accepted into the repository:

* 1. Identify source of data and describe the data elements.
	2. Describe the application process for submitting materials to the repository.
	3. In order to accept research data, the repository must obtain documentation from the depositor that materials were collected with IRB approval and that the informed consent permits the future use planned by the repository (or that the research did not require IRB oversight). How will your repository do this?
1. For projects collecting materials that were not obtained under research informed consent (e.g. administrative records such as medical records, student records, etc.), the IRB must approve a waiver of informed consent to accept the data. Please respond to the following questions:
	1. The research involves no more than minimal risk to subjects.
	2. The waiver of informed consent will not adversely affect the rights and welfare of subjects.
	3. The research could not practicably be carried out without the waiver or alteration; and
	4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
2. **Distribution and Dissemination**

Describe process for releasing data and/or biospecimens

* 1. Describe application process, if any
	2. Ensure that recipient has obtained IRB approval for use of identifiable data and/or specimens
	3. Describe procedures for verifying that that proposed use is consistent with the informed consent under which materials were collected
	4. Verify that data will be transferred only using the appropriate institutional agreements (Data Use Agreements for data)

**NOTE:** For repositories that hold [Protected Health Information (PHI) subject to HIPAA](http://privacyruleandresearch.nih.gov/research_repositories.asp) , the repository is NOT directly responsible for tracking additional disclosures made BY secondary users, HOWEVER, the repository is responsible for ensuring via Data Use Agreements or Memoranda of Understanding that secondary users agree to appropriate privacy and confidentiality protections, including appropriate limits on re-disclosure.

* 1. Describe methods for ensuring security and confidentiality of data and/or biospecimens during transfer/release.
1. **Data security plan**
	1. Access plan and controls
		1. Who may access data
		2. Describe requirements for access
	2. Data security procedures
	3. Subject identifiers
		1. Describe the plan to protect identifiers from improper use or disclosure
		2. For coded materials, indicate who holds the key and where it is stored in relation to the materials.
		3. Include information regarding when and how direct identifiers or the code (if any) will be destroyed
2. **Governance and oversight**
	1. Describe the role of the repository director.
	2. Describe the role of the governance committee for your repository, if appropriate.
	3. Describe plan for sustaining repository over time, including
		1. Expectations for continuing funding
		2. Data destruction