**THE UNIVERSITY OF VERMONT COMMITTEES ON HUMAN RESEARCH**

**Biological Specimens/Data Repository Protocol**

Protocol Version Date:

(Required for each

protocol modification)

1. **REPOSITORY NAME:**

|  |
| --- |
|  |

1. **PRINCIPAL INVESTIGATOR:**

|  |
| --- |
|  |

1. **PURPOSE OF REPOSITORY:** The information must include: 1) objectives/aims, 2) a brief but specific description of the procedures(s) involving human subjects, their specimens and/or data, and 3) what types of future research is hoped to be done utilizing the repository.

|  |
| --- |
|  |

1. **SPECIMEN INFORMATION**
	1. Identify the Repository Manager (provide name, email, and telephone number).

|  |
| --- |
|  |

* 1. Describe the specimens and related information (tissue, blood, CSF, urine, etc., [fresh, sterile, formalin-fixed], names, diagnoses).

|  |
| --- |
|  |

* 1. Repository will include: (check all that apply)

Existing Personally Identifiable Information (PII) [ ]

Existing Protected Health Information (PHI) [ ]

Prospectively collected PII [ ]

Prospectively collected PHI [ ]

Existing Specimens [ ]

Prospectively Collected Specimens [ ]

* 1. If you wish to receive approval for open-ended or unlimited numbers, please explain why this is necessary.

|  |
| --- |
|  |

1. **SPECIMEN COLLECTION PROCEDURES**
	1. How will the cases be identified and collected? (e.g., medical records, hospital computer, pathology, directly from subject). Obtaining specimens or private information prospectively almost always requires informed consent and (as applicable) HIPAA authorization from the subject.

|  |
| --- |
|  |

* 1. For specimens collected during routine medical care, what procedures are in place to ensure that adequate material is available for patient care and that patient care will not be compromised because of specimen banking?

|  |
| --- |
|  |

* 1. For specimens collected in non-clinical areas, explain the procedures to be followed.

|  |
| --- |
|  |

* 1. Explain how the specimens/information acquisition will be tracked. Attach gate-keeping forms used for that purpose. See examples of acquisition template in the Appendix. You may also use your own templates.

|  |
| --- |
|  |

* 1. Explain how you will confirm that informed consent has been obtained for storage of the specimens/data.

|  |
| --- |
|  |

1. **ACCESS TO REPOSITORY:**
	1. Who will have access to the specimens/information? (Check all that apply)

[ ]  Only key personnel listed on this repository form.

[ ]  Only researchers affiliated with UVM/UVM Medical Center

[ ]  Researchers at other institutions.

[ ]  Researchers affiliated with industry or for-profit organizations.

[ ]  Others (specify):

|  |
| --- |
|  |

**NOTE: UVM investigators sending specimens outside of the institution should contact the UVM Office of Technology Commercialization to determine if a** [**Material Transfer Agreement**](https://www.uvm.edu/uvminnovations/material-transfer-agreements-mtas) **is needed. Sharing data with an individual or entity outside of UVM and/or UVMHN (as applicable) will require a data use agreement by either UVM Sponsored Project Administration (**[**SPA**](https://www.uvm.edu/spa)**) or the UVM Medical Center’s Office of Clinical Trials Research (**[**OCTR**](https://www.med.uvm.edu/clinicaltrials/regulatoryinfo)**).**

* 1. Explain how requests to use the specimens/information will be reviewed by the PI/study personnel:

|  |
| --- |
|  |

* 1. Explain how you will track distribution (if any) of the specimens/information and attach any agreements or gate-keeping forms used for this purpose. See example of distribution template in the Appendix.

|  |
| --- |
|  |

* 1. Explain how secondary distribution of specimens/information will be controlled.

|  |
| --- |
|  |

* 1. Confirm that you will require proof of IRB approval prior to release of specimen/information to a secondary person.

 Confirm [ ]

* 1. What mechanisms are in place to assure future uses of subject specimens/information are consistent with the informed consent obtained at the time of initial specimen/information collection?

|  |
| --- |
|  |

1. **IDENTIFICATION OF SPECIMENS/INFORMATION**
	1. How will specimen be identified (check one):

[ ]  With identifiers (e.g., names, patient numbers) attached. If you check this box, explain what identifiers will be attached.

|  |
| --- |
|  |

Explain why it is necessary to retain these identifiers.

|  |
| --- |
|  |

How long will identifiers be kept? If indefinitely, explain why this is necessary (for example, you intend to follow the course of treatment or disease, or you want to contact or re-contact subjects).

|  |
| --- |
|  |

Under no circumstances should subjects be contacted without explicit prior approval by the IRB (make definitive statement to this effect).

|  |
| --- |
|  |

[ ]  With repository or study code, linked to identifiers on a master list.

[ ]  With a unique code that is not linked to any other code or identifiers.

* 1. Do the subjects have rare diseases or are there characteristics of individuals or groups that would allow ready identification? Comment below.

|  |
| --- |
|  |

1. **CONSENT/AUTHORIZATION**
	1. Are you obtaining complete written consent and/or HIPAA authorization (as applicable)?

 Yes [ ]  No [ ]

If no, please explain:

|  |
| --- |
|  |

* 1. Are you requesting a waiver of informed consent and HIPAA authorization?

This means you will not be obtaining verbal or written consent/authorization. If yes, complete the consent and HIPAA authorization waiver forms in Click and skip to section 10 in this form.

 Yes [ ]  No [ ]

* 1. Will subjects be able to withdraw their specimen/information from the repository?

 Yes [ ]  No [ ]

If yes, please explain the procedure for withdrawal and what happens to the specimen/information below and in the consent form.

|  |
| --- |
|  |

* 1. Will you retain any specimens/information that could reasonably place the subjects at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, or reputation? For example, use of illegal drugs, underage drinking, child or elder abuse, sexual behavior, disease condition, genetic test results, etc.

 Yes [ ]  No [ ]

If yes, identify the information and explain why it could put the subject at risk below and in the consent form.

|  |
| --- |
|  |

* 1. Is it possible that you might be obliged or compelled to disclose specimens/information that could be linked to an individual or group, for example, in response to a subpoena for evidence?

 Yes [ ]  No [ ]

If yes, explain these circumstances below and in the consent form. If you have a federal [Certificate of Confidentiality](https://www.uvm.edu/rpo/irb-policies-and-procedures#coc_II), then state this here and in the consent form.

|  |
| --- |
|  |

* 1. Are there plans to re-contact subjects to request additional samples/information?

 Yes [ ]  No [ ]

Explain below and in the consent form. The subject should have the option to participate but not to be re-contacted.

|  |
| --- |
|  |

**Data Management and Security Plan (DMSP)**

The [DMSP](https://www.uvm.edu/sites/default/files/Research-Protections-Office/Data_Management_and_Security_Plan_.docx) must be completed. This form, along with guidance can be found in our forms library and must be submitted with your initial IRB application.

**Appendix**

Examples for tracking acquisition and distribution of samples. You may also provide your own template.

Template for Acquisition Tracking

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date of Collection | Subject Name and/or Code | Description | Informed Consent Obtained? | Future Research Requires Consent? | Future Research for (Disease Only?) | Future Research for any Conditions? | Can be Contacted for Future Research? | Date of Withdrawal of Specimen and/or Information |
| 8/4/2022 | 1002 | Liver tissue | Yes | No | Yes | Yes | No | 10/31/2022 |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

Template for Distribution Tracking

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Subject Name or Code | Recipient IRB Approval or Exemption? | Data/Specimen sent to (Name) | Location | Date Sent | What was Sent? |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |