**The University of Vermont Committees on Human Research**

**Biological Specimens/Data Repository Protocol**

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|  | **Protocol Version Date (required for each protocol modification):** |

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| **1.** | **Repository Name/Project**  |
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| **2.** | **Principal Investigator (PI):** |  | : |  |

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| **3.** | **Purpose of Repository:** *The information must include: (1) objectives or aims, (2) a brief but specific description of the procedure(s) involving the human subjects, their specimens and/or data, and (3) what types of research is hoped to be done utilizing the repository*  |
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| **4.** | SPECIMEN/DATA REPOSITORY INFORMATION |
|  |  |
| a. Location/Security/Contents |
| i. Identify the Repository Manager (provide name, email, fax and telephone) |
|  |
| ii. How and where will specimens/information be stored? |
|  |
| iii. Repository will include: (check all that apply) |
| Existing Specimens  |  | Existing Private Information  |  |  |
| Prospectively Collected Specimens |  | Prospectively Collected Private Information |  |  |
| iv. Who will have access to subject identities? |
|  |
| v. How will specimens/information stored by the repository be labeled? (For example, a unique identifier assigned by the repository) |
|  |
| vi. What are the security measures in place. (e.g., password protected computer (desktop or laptop), data on protected server, locked freezers, locked file cabinets) |
|  |
| vii. Describe the specimens & related information (blood, CSF, urine, etc. (fresh, sterile, formalin-fixed etc.) names, diagnoses) |
|  |
| viii. If collection of information only, describe information to be collected. |
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| ix. Duration that specimens/information will be kept. (if indefinite explain) |
|  |
| x. Will you conduct genetic testing as part of the repository activity? | Yes |  | No |  |
| If no, skip to section xi. If yes, respond to each of the following questions. |
| i. | Do your studies involve the analysis of genes known to be implicated in the disorder(s), syndrome(s), or conditions(s) you are studying? | Yes |  | No |  |
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|  | If yes, what genes will you study? |
|  |  |
| ii. | Alternatively, do your studies involve finding the gene(s) that may cause the condition, or genetic markers that co-segregate with this condition? | Yes |  | No |  |
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|  |  |
| iii. | Will you be collecting information from affected individuals only? | Yes |  |  No |  |
|  | If yes, will you also collect information from family members of affected individuals (whether affected or unaffected)? | Yes |  |  No |  |
|  |  |  |
| iv. | Are there effective treatments for the diseases/syndromes that you are studying? | Yes |  | No |  |
|  |  |
|  | Are the disease/syndromes treatable or curable? | Yes |  | No |  |
|  | What are the ages at onset? |
|  |  |
| v. | Is it possible that your testing will provide evidence of previously undiagnosed or unrecognized illness, or susceptibility to illness? | Yes |  | No |  |
|  |  |
|  | If no, skip to next question. |
|  | If yes, will you provide subjects with this information? | Yes |  | No |  |
|  | Will this information be provided by trained genetic counselors? | Yes |  | No |  |
|  | If no, explain who will provide this information and what training they have had |
|  |  |
|  | *NOTE: This research activity invokes the Genetic Information Nondiscrimination Act (GINA) because the protocol collects, stores and/or analyzes genetic materials. GINA requires that you provide information to subjects regarding protection of their genetic information. You may find template language for your consent form in our IRB consent form template (under risks).*  |
| vi. | Will you create or store cell lines as part of the repository activity? | Yes |  | No |  |

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| **b. Collection Procedures** |
| i. How will the cases be identified and collected? (e.g. medical records, hospital computer, pathology, directly from subjects) (obtaining specimens or private information prospectively almost always requires informed consent and (as applicable) HIPAA authorization from the subject) |
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| ii. List sites (hospitals, etc) collecting the specimens/information. |
|  |
| iii. For specimens collected in the course of 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 as a result of specimen banking? |
|  |
| iv. For specimens collected in non-clinical areas, explain procedures to be followed? |
|  |
| v. Explain how the specimens/information acquisition will be tracked. Attach gate-keeping forms used for this purpose. See example of database fields at end of form. |
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| vi. Explain how you will confirm that informed consent has been obtained for storage of the specimens/data. |
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| **c. Access to Repository** |
| i. 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 educational or non-profit research institutions *(list in 7.c.viii.)* |
|  | Researchers affiliated with industry or for-profit organizations *(list in 7.c.viii.)* |
|  | Others (specify) |
|  | **NOTE: UVM investigators sending data or specimens outside of the institution should contact the UVM Office of Technology Commercialization to determine if a Material Transfer Agreement or any other agreement defining the respective institutional responsibilities is warranted.** |
| ii. Explain how requests to use the specimens/information will be reviewed by the PI/study personnel:  |
|  |
| iii. Explain how you will track distribution (if any) of the specimens/information and attach any agreements or gate-keeping forms used for this purpose. |
|  |
| iv. Explain how secondary distribution of specimens/information will be controlled? |
|  |
| v. Confirm that you will require proof of IRB approval prior to release of specimen/information to a secondary person. |
| Confirm |  |  |  |
| vi. What mechanisms are in place to assure that future uses of subject specimens/information are consistent with the informed consent obtained at the time of initial specimen/information collection?  |
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| vii. List receiving sites not under UVM/UVM Medical Center IRB jurisdiction below |
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| **d. Identification of Specimens/Information** *(check one i, ii ,iii, or iv)* |
|  | i. With identifiers (e.g., names, patient numbers) attached. If you checked this box, explain what identifiers will be attached: |
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|  |
| 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 a definitive statement to this effect). |
|  |
| Will users, not listed as key personnel, be allowed access to specimens/data with identifiers? If yes, explain why this is necessary and how you will protect the use of this information. |
|  |
|  | ii. With a repository or study code, linked to identifiers on a master list. |
|  | Where will the master list be kept?  |
|  |  |
|  | Who will have access to the master list? Specify whether they will have access to specimens/information with identifiers or only to coded specimens/information with no access to identifiers. |
|  |  |
|  | iii. With a unique code that is not linked to any other code or identifiers |
|  | Explain the procedure by which the specimens/information is de-linked from subject identities. (e.g. when is the de-linking performed, what entity performs the de-linking, and what identifying information is removed and how) |
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|  | iv. With a study code for which the repository does not have access to the master list (attach data use agreement with other entity specifying no access to identifiers) |
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| **5.** | **HUMAN SUBJECT INFORMATION** |
|  | Number of subjects whose specimens or data will be collected1:

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Types of subjects (check all that apply): |
|  |  |  |  |  |
|  | Male |  |  |  | Pregnant Women |  |
|  | Female |  |  |  | Fetuses |  |
|  | Students |  |  |  | Prisoners |  |
|  | Employees |  |  |  | Diminished Capacity |  |
|  | Normal Volunteers |  |  |  | Non-English Speaking |  |
|  | Adults [Age Range: ] |  |  |  | Wards of State |  |
|  | Minors [Age Range: ] |  |  |  |  |  |
|  | Specific Disorder |  |  |
|  | Explain |  |
|  | Other Potentially Vulnerable |  |
|  | Do the subjects have rare diseases or are there characteristics of individuals or groups that would allow ready identification? Comment below. |
|  |  |
| 1 If you wish to receive approval for open-ended or unlimited numbers, please explain why this is necessary below. |
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| **6.** | CONSENT/AUTHORIZATION |  |
| a. Are you obtaining complete written consent and HIPAA authorization? (includes all elements) *If yes, skip to section c.* |  | Yes |  | No |
|  |  |
|  |
| b. Are you requesting a Waiver of Informed Consent and HIPAA authorization? |  | Yes |  | No |
|  |  |
| *This request means that you will not be obtaining verbal nor written consent.* If yes, complete the waiver form in UVMClick *and skip to section 10 in this form.* |
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| **c.** | **Consent Process/Required Elements** |
| i. | Once a prospective subject is identified, who initiates the informed consent discussion and answers questions presented by the subject or the subject’s family? *(provide names of all consenters)* |
|  |  |
| ii. | Where (in what setting) is the informed consent process initiated? How much time is the subject given to decide? |
|  |  |
| iii. | Is the principal investigator present for the initial and subsequent informed consent discussions with the subject? |
|  |  |
| iv. | What other method of documentation is used to record the informed consent process, in addition to the executed consent form? *See an example of documentation of the informed consent* ***process*** *on our website.* |
|  |  |
| v. | What policies and procedures are in place to protect privacy and confidentiality? Comment here and in consent form. |
|  |  |
| vi. | Will subjects be able to withdraw their specimen/information from the repository? If yes, explain the procedure for withdrawal and what happens to the specimen/information below and in the consent form. |
|  |  |
| vii. | 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) If yes, identify the information and explain why it could put the subject at risk below and in the consent form. |
|  |  |
| viii. | Is it possible that you might be obliged or compelled (for example, in response to a subpoena for evidence) to disclose specimens/information that could be linked with an individual or group? If yes, explain these circumstances below and in the consent form. If you have a federal Certificate of Confidentiality, then state so here and in consent form. |
|  |  |
| ix. | Will results of this research or future tests be communicated to the subjects?Comment below the information that will be provided and the process to evaluate the risk vs benefits associated with the return of individual research results. Include in the consent form. |
|  |  |
| x. | Are there plans to re-contact subjects to request additional samples/information? Explain below and explain in consent form. Subject should have the option to participate but not to be re-contacted. |
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| **7.** | **Research Data Management Plan** |
|  | The Research Data Management and Security Plan form must be completed. The form, along with guidance, can be found in our [forms library](https://www.uvm.edu/rpo/uvmclick-irb-forms-library) and must be submitted with your initial application.  |

Example of Acquisition Tracking

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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 |
| 8/4/01 | 1002 | Liver tissue | yes | no | yes | yes | no | 10/09/05 |
|  |  |  |  |  |  |  |  |  |
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Example of Distribution Tracking

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Subject Name and or code | Recipient IRB Approval or exemption? | Specimen sent to (name) | Location | Date Sent | What was sent? |
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