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

**Biological Specimens/Data Repository Protocol**

### 

###### A. Committee on Human Research, Clinical Research Center &/or Vermont Cancer Center

|  |  |  |
| --- | --- | --- |
| DATE STAMP | Shaded Sections | **PROTOCOL NUMBER** |
|  | **For Committee on Human Research Use Only** |  |

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| **1.** | **Repository Name/Project** |
|  |  | |

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| **2.** | **INVESTIGATOR INFORMATION** | | | |
|  | \*Principal Investigator (PI): | |  | | | | | | Degree: |  | |
|  | Dept. |  | | | | Phone |  | E-Mail | |  | |
|  | Campus/Office Address: | | |  | | | | | | Fax |  |
|  | PI’s Dept. Chair(s) | | |  | | | | | | | |

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|  | Is PI UVM Faculty?\* | | Yes | |  | | No |  | Is PI UVM Medical Center Employee?\* | | | | | | Yes |  | No |  |  | |
|  | Is PI UVM Employee only? | | | | | Yes | |  | No |  |  | |  | | | | | | | |
|  | Is the PI a Fellow |  | | Resident | | | |  | Or Student? | | |  | | If yes to any, complete #11 below. | | | | | |
|  | Check graduate status if applicable: | | | | | | |  | Graduate | | |  | | Undergraduate | | | | | |
|  | **\*NOTE:** Under normal circumstances only UVM or UVM Medical Center individuals can be PI. If you are not affiliated with either UVM nor UVM Medical Center, you must stop here and contact the RPO office for additional guidance. | | | | | | | | | | | | | | | | | | |

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|  | **DO YOU WANT TO APPOINT PRIMARY CONTACT OTHER THAN PI?:** | | | Yes | |  | No |  |  |
|  | *Investigators wishing to appoint a contact for* ***all*** *IRB communications should complete the contact information requested below.* ***Primary contacts are considered “key personnel” and must complete required human subjects training.*** | | | | | | | | |
|  | Contact Full Name |  | Email\* | |  | | | | |
|  | Department /Address |  | Fax Number | |  | | | | |
|  | Campus Phone Number/ Pager |  |

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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. Do not exceed one single-spaced 8 ½ X 11” page.* | | | | | | | | | | | | | | | | | | |
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| **4.** | | | | TYPE OF REVIEW | | | | | | | |
| **a. Which type of IRB review you are requesting?** | | | | | | | | Full |  | | Expedited | |  | | | Complete category. | | | | |
|  | | | | | | | | | | | | | | | | | | | | |
| Your research may be expeditable if the research activities (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories: (CHECK THE CATEGORY(IES) THAT APPLY. | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | (1) **Clinical studies of drugs and medical devices only when conditio**n **(a) or (b) is met.** | | | | | | | | | | | | | |
|  | | | | | | (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).  (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. | | | | | | | | | | | | | |
|  | | | | | | (2) **Collection of blood samples** by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh | | | | | | | | | | | | | |
|  | | | | | | at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week: or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. | | | | | | | | | | | | | |
|  | | | | | | (3) Prospective **collection of biological specimens** for research purposes by noninvasive means. | | | | | | | | | | | | | |
|  | | | | | | (4) **Collection of data through noninvasive procedures** (not involving general anesthesia or sedation) routinely employed | | | | | | | | | | | | | |
|  | | | | | | in clinical practice, excluding procedures involving x-rays or microwaves. | | | | | | | | | | | | | |
|  | | | | | | (5) Research involving **materials** (data, documents, records, or specimens) that have been collected, or will be **collected** | | | | | | | | | | | | | |
|  | | | | | | **solely for nonresearch purposes** (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 .CFR 46.101 (b)(4). This listing refers only to research that is not exempt.) | | | | | | | | | | | | | |
|  | | | | | | (6) **Collection of data from voice, video, digital, or image recordings** made for research purposes. | | | | | | | | | | | | | |
|  | | | | | | (7) **Research on individual or group characteristics or behavior or research employing survey, interview, oral** | | | | | | | | | | | | | |
|  | | | | | | **history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.** (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3)). | | | | | | | | | | | | | |
|  | | | |  | | | | | | | | | | | | | | | | |
| **b.** Is this research developed and written by industry? | | | | | | | | | | | | Yes | |  | | | No |  | |  |
| (drug or device company – industry sponsored) | | | | | | | | | | | | | | | |
| **c.** Is this research developed and written by a UVM/UVM Medical Center researcher? | | | | | | | | | | | | Yes | |  | | | No |  | |  |
| (investigator initiated) | | | | | | | | | | | | | | | |
| **d.** Does the research involve the study of cancer or is it cancer-related? | | | | | | | | | | | | Yes | |  | | | No |  | |  |
| **If yes,** this research is also subject to a separate review by the Vermont Cancer Center. Click here, [Protocol Review Committee](http://www.vermontcancer.org/getpage.php?pid=101) , for the requirements. | | | | | | | | | | | | | | |
| **e.** Does the research involve the use of any General Clinical Research Center (GCRC) facilities or resources? | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | Yes | | |  | | No | |  |  |
| **If yes,** research is subject to a separate review by the GCRC. Click here, [Scientific Advisory Committee](http://www.uvm.edu/~gcrc/), for the requirements. | | | | | | | | | | | | | | |

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| **5.** | OTHER KEY PERSONNEL – Complete Section 10. |

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| **6. UVMMC Compliance Coverage Analysis and Billing Plan Approval** | | | | | |
| **j.** Will this study involve any UVM Medical Center patients (including data and or specimens) or any equipment, facilities, supplies or personnel of UVM Medical Center, whether standard of care or protocol-driven, such as laboratory, pharmacy, imaging, EKGs, or other diagnostic or therapeutic items or staff? | | | | | |
|  | Yes |  | No |  |  |
| If the answer to any part of the above question is Yes, the UVM Medical Center Compliance Office will need to approve a billing plan prior to the release of IRB approval. For more information, please reference [“Research Billing Compliance”](http://www.fletcherallen.org/services/administrative/integrity_compliance/research_billing_compliance.html) on the Fletcher Allen Health Care website. For additional questions, call Denise Quint in the Fletcher Allen Integrity and Compliance department at 847-9482. | | | | | |

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| **7.** | | **SOURCE OF SUPPORT, CONTRACT/AGREEMENTS, AND FEES** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | **a. Source of Funding - *Check all that apply.*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | |  | | **UVM/UVM Medical Center Department** | | | | | | | | | | | Specify Dept(s): | | | | | | |  | | | | | | | | | |
|  | | | |  | | **UVM Grant processed by SPA Pre-Award Services –** Non-Industry | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | |  | | *(e.g. NIH, DOD, cooperative groups, other state or local ,private foundations, etc.)* | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | |  | | Name of Funding Agency | | | | | | | | |  | | | | | | | | | | | | | | | | | | |
|  | | | |  | | InfoEd Proposal # | | | | | | | | |  | | | | | | | | | | | | | | | | | | |
|  | | | |  | | Funding Agency Grant Number | | | | | | | | |  | | | | | | | | | | | | | | | | | | |
|  | | | |  | | Is this a Program Project grant? | | | | | | | | | | | |  | | Yes | | |  | | No | | | | | | | | |
|  | | | |  | | If yes, list PI on the Program Project grant | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
|  | | | |  | | What is the status of the grant? | | | | | | | |  | Awarded | | | | |  | | Pending | | | |  | Just in Time Request | | | | | | |
|  | | | |  | | If the award is pending or Just-In-Time, do you intend to begin research activities prior to obtaining the funding? | | | | | | | | | | | | | | | | | | | | | |  | | Yes |  | No | |
|  | |  |  |  | |
|  | | | |  | | | | *If yes, the consent form, if applicable, cannot include the funding agency. Once the funding has been received, you must submit an amendment to provide the final awarded grant document and to update the consent form with the funding agency’s name.* | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | |  | | Attach corresponding grant proposal. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | |  | | **Industry Supported Research processed through UVM SPA Pre-Award Services** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | |  | | InfoEd Proposal # | | | | | | | | |  | | | | | | | | | | | | | | | | | | |
|  | | | |  | | Name of Company | | | | | | | | |  | | | | | | | | | | | | | | | | | | |
|  | | | |  | | **Industry Supported Research processed through UVM Medical Center Office of Clinical Trials Research** | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | | |  | | Name of Company | | | | | | |  | | | | | | | | | | | | | | | | | | | | |
|  | | | |  | | What support is the Company providing? | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | |  | | |  | | Monetary reimbursement to UVM Medical Center for patient enrollment. | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | |  | | |  | | Test Drug\* | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | |  | | |  | | Test Device\* | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | |  | | |  | | Other List: | |  | | | | | | | | | | | | | | | | | |  | | | | |
|  | | | |  | | \*If the Company is providing only the drug or device, it is not subject to IRB fees. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | **b.** | | | | **Contracts/Agreements** - ***Contracts are required for any industry supported protocol.*** | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | | | | If this is an industry supported protocol, what is the status of the contract/agreement? | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | | | |  | | Complete |  | | Pending | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | | | | If complete attach a copy.  If it is pending, which institution is assisting you with its completion? | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | | | |  | | UVM Medical Center - Office of Clinical Trials Research or | | | | | | | | | | | | |  | | UVM - SPA Pre-Award Services | | | | | | | | | |
|  | **c.** | | | | **Protocols Subject to IRB Fees** | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | | | | | | *“The University’s Institutional Review Boards (IRBs) charge fees for initial and annual continuing review for all UVM Medical Center studies sponsored by pharmaceutical firms and other for-profit entities, and to review protocols for outside organizations. Fees are not charged for University or UVM Medical Center federal, non-profit foundation, or departmentally-funded studies. The fee schedule is reviewed each year by the IRB and is subject to change.”* | | | | | | | | | | | | | | | | | | | | | | | | | | |
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|  | | | | | | | **Does the protocol meet the above criteria?** | | | | | | | | | | | |  | | Yes | | | |  | No | | | | | | | |
|  | | | | | | | **If yes, provide the Company’s billing information below.** | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | Name | | | | | | | | |  | | | | | | | | | | | | | | | | | |
|  | | | | | | | Contact Person Name for the Invoice | | | | | | | | |  | | | | | | | | | | | | | | | | | |
|  | | | | | | | Contact Person E-mail address | | | | | | | | |  | | | | | | | | | | | | | | | | | |
|  | | | | | | | Street Address | | | | | | | | |  | | | | | | | | | | | | | | | | | |
|  | | | | | | | City, State, Zip | | | | | | | | |  | | | | | | | | | | | | | | | | | |

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| **8.** | | 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) | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| ix. Duration that specimens/information will be kept. (if indefinite explain) | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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? | | | | | | | | | | | | | | | | | | | |
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| 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 | |  | |
|  | | | |  | |
|  | | | |  | |
| 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 | | | | | | | | | | | | | | | | | | |
|  | | |  | | | | | | | | | | | | | | | | | | |
| vi. | | | 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). | | | | | | | | | | | | | | | | | | |
|  | | |  | | | | | | | | | | | | | | | | | | |
| xi. | | | | | 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) | | |
|  |
| 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. | | |
|  |
| 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? | | | | | |
|  | | | | |
| 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: | | |
|  |
|  | |
| 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) | |
|  | |  | |
|  | 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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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **9.** | | **HUMAN SUBJECT INFORMATION** | | | | | | | | | | | | | | | | | |
| **a.** | | | | Type and Number of Specimens/Subject Data (check all that apply): | | | | | | | | | | | | | | |
| Subjects | | | | | | # of Subjects1 | | | |  | Subjects | | | | # of Subjects1 |
|  | | | 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. | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| **b. Will subjects be compensated?** | | | | | | | | Yes |  | No | | |  | |
| If yes, explain which subjects in your pool will be compensated and how. *(e.g. subjects with or without disease/condition, monetary or other)* | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | |
| If you are providing monetary compensation, explain how you will be obtaining the subjects’ social security number? (e.g., on paper, verbally) *(UVM and UVM Medical Center require subject social security numbers for payment.)* | | | | | | | | | | | | | | |
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| **10.** | | | | | 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 form *Request for a Waiver of Informed Consent/Authorization/Documentation Section I and skip to section 10 in this form.* | | | | | | | | |
|  | | | |  | | | | | | | | |
| **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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| **11.** | **PERSONNEL ROSTER** | |  | |  | |
|  | **All personnel with access to subjects or their data are required to have completed human subjects protection training within the last three years. To check completions go to** [**http://www.uvm.edu/~irb/education/TutorialCOMPLETION.htm**](http://www.uvm.edu/~irb/education/TutorialCOMPLETION.htm)**.**  Note: A UVM NetID is required to complete the training. \*To request a UVM NetID, complete and submit the [“Request for UVM Net ID for Required Training”](http://www.uvm.edu/irb/tutorial/uvm_net_id_form.doc) form. Training completion for all key personnel is not required prior to submission of this form, however it is required prior to final protocol approval. If you have someone in need of a UVM NetID to complete this requirement, complete the column “Date of Request for UVM NetID” in lieu of the Date of Tutorial Completion. Attach additional sheets if necessary. | | | | | |
|  |  |  | |  | |  |
|  | **Personnel Name** | **Email Address** | | **Date of Tutorial Completion** (within last three years) | | **Date of Request for UVM NetID** (only necessary if you can’t complete training for lack of a UVM NetID) |
| 1. | PI: |  | |  | |  |
| 2. | Contact Person: |  | |  | |  |
| 3. | Faculty Sponsor: |  | |  | |  |
| 4. |  |  | |  | |  |
| 5. |  |  | |  | |  |
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| **12. AGREEMENTS** | | | | | | | | | | | | | | | | | | |
| **PRINCIPAL INVESTIGATOR**  **As Principal Investigator of this study, I assure the Committees on Human Research that the following statements are true**:  The information that is provided in this form is correct. I will seek and obtain prior written approval from the IRB for any modifications in the proposal, including changes in procedures, co-investigators, etc. All of the members of the research team have completed the applicable institutional credentialing processes required to conduct this research. I will promptly forward any reportable adverse events and unanticipated problems to subjects or others that may occur in the course of this study. I will report in writing any significant new findings that develop during the course of this study that may affect the risks and benefits to participation. I will not begin my research until I have received written notification of IRB approval. I will comply with all IRB requests to report on the status of the study. I certify that the research team will collect only information essential to the study in accord with the HIPAA Minimum Necessary Standard and I will limit, to the greatest extent possible, access to the information. I assure that the information I obtain as part of this research including PHI will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law or for authorized oversight of the research project. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entities, I will seek prior IRB approval. I will maintain records of this research according to applicable guidelines. If I am seeking IRB approval for a sponsored project, I hereby certify that the application that I have submitted to my funding agency accurately and completely reflects what is contained in this application. Agreement allows invoicing and collection of IRB review fees. | | | | | | | | | | | | | | | | | | |
| x | | | | |  | |  | | | | | | | | | |  | |
| Original Signature of PI | | | | |  | | Date | | | | | | | | | | | |
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|  | | | | |  | |  | | | | | | | | | | | |
| **FACULTY SPONSOR (if applicable and referenced on page one, section 2, of this form)** | | | | | | | | | | | | | | | | | | |
|  | | | | |  | |  | | | | | | | | | | | |
| Advisor’s Name: |  | | | | | Telephone Number: | | | | | | | | |  | | | |
|  | | | | | |  | |  | | | | | | | | | | |
| Department/Address: | |  | | | | E-mail: | | | | |  | | | | | | | |
|  | | | | | | | | | | | | | | | | | | |
| Date of Human Subjects Tutorial Completion | | | | |  | | | | | | | | |  | | | | |
| ***Policy Statement from the Research Manual:*** *“As the responsible investigator, the faculty sponsor or course instructor is required to complete the Human Subjects in Research tutorial. Protocol approvals will not be released until that requirement has been met.” Completion of this requirement is every three years. The training can be found at* [*http://www.uvm.edu/irb/tutorial/index.html*](http://www.uvm.edu/irb/tutorial/index.html) | | | | | | | | | | | | | | | | | | |
| Is there is a thesis or dissertation committee reviewing this research? | | | | | | | | | | Yes | |  | No | | |  | |  |
| If yes, date of approval: | | |  |  | | | | | | | | | | | | | | |
| **As the faculty sponsor for this protocol,** I certify that the student will conduct this research under my supervision and guidance. I further certify that I will assume final responsibility for the conduct of this protocol in accordance with all University of Vermont and Federal Regulations relating to human research as outlined above and in the Human Subjects Research Manual. | | | | | | | | | | | | | | | | | | |
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|  | | | | |  | | | |  | | | | | | | | | |
| x | | | | |  | | | |  | | | | | | | | | |
| Original Signature of Faculty Sponsor | | | | |  | | | | Date | | | | | | | | | |
|  | | | | |  | | | |  | | | | | | | | | |
| Printed Name | | | | |  | | | |  | | | | | | | | | |

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| **13. Attachments** This checklist is optional. | | | |
|  |  | If applicable | |
|  | Item | Version # | Dated |
|  | Complete copy of grant proposal with budget (if applicable) |  |  |
|  | Consent Form/HIPAA Authorization |  |  |
|  | Child Assent Form (if applicable) |  |  |
|  | Request for Waiver of Consent/HIPAA Authorization |  |  |
|  |  |  |  |
|  | Agreements with Other Collaborators |  |  |
|  |  |  |  |
|  | Surveys/Questionnaires |  |  |
|  | Other: |  |  |

Example of 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 |
| 8/4/01 | 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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