### The University of Vermont Committees on Human Research

### Common Protocol Cover Form

###### A. Committee on Human Research, Clinical Research Center and/or University of Vermont Cancer Center

|  |  |
| --- | --- |
| **1.** | **PROTOCOL/PROJECT TITLE** |
|  |  |

|  |  |
| --- | --- |
| **2.** | **INVESTIGATOR INFORMATION** |
|  | \*Principal Investigator (PI): |  | Degree: |  |
|  | Department |  | Subspecialty |  |
|  | Phone |  | E-Mail: |  |
|  | Campus/Office Address: |  |
|  | PI’s Dept. Chair(s) |  |
|  | Is PI UVM faculty?\* | Yes |  | No |  | UVM Medical Center employee?\* | Yes |  | No |  |
|  | Is PI UVM Employee only? | Yes |  | No |  |  |  |
|  | Is the PI a Student in Training? (if yes, check applicable status) |
|  |  |  | Fellow |  | Resident |  | Graduate |  | Undergraduate |
|  | Faculty Sponsor Name |  |
|  | Faculty Sponsor Department |  |
|  | Faculty Sponsor Email |  |
|  | **\*NOTE:** Under normal circumstances only UVM or UVM Medical Center individuals can be PI. If you are not affiliated with either UVM or UVM Medical Center, you must stop here and contact the RPO office for additional guidance.  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **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 |  |
|   | Campus Phone Number/ Pager |  |

|  |  |
| --- | --- |
| **3.** | **BRIEF LAY LANGUAGE SUMMARY:** *(Use non-technical language that would be understood by nonscientific IRB members to summarize the proposed research project. The information must include: (1) objectives or aims, and (2) a brief but specific description of the procedure(s) involving the human subjects. Do not exceed one single-spaced 8 ½ X 11” page.* |
|  |  |

|  |  |
| --- | --- |
| **4.**  | TYPE OF REVIEW  |
| **a. Which type of IRB review are you 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) |
| If available, please attach a copy of the data security requirements the sponsor may have specified. |
| **c.** Is this research developed 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 may also be subject to a separate review by the [Vermont Cancer Center Protocol Review and Monitoring Committee (PRMC).](http://www.uvm.edu/medicine/vtcancercenter/?Page=protocol.html&SM=protocolsubmenu.html)List here the date the protocol was submitted to PRMC \_\_\_\_\_\_\_\_\_\_\_. |
| **e.1.** Does the research involve the application of radioactive materials for example, radioisotopes, and/or radiation treatment to humans? |
|  | Yes |  | No |  |  |
| **e.2.** Does the research involve application of imaging, excluding MRI and ultrasounds, for non-standard of care purposes *(not used for treatment or diagnosis, e.g. on UVM equipment or x-rays required for protocol purposes only)?* |
|  | Yes |  | No |  |  |
|  **e.3.** If yes to either e.1. or e.2. above, where is the radiation equipment and/or research procedures taking place? *(if using CRC DEXA, check UVM)* |
|  | UVM, contact UVM’s [Radiation Safety Committee](http://www.uvm.edu/~radsafe/?Page=rso.personnel.html) for review. UVMMC, contact UVMMC’s Radiation Safety Committee for review. |
|  |
| **f.** Does the research involve the use of any Clinical Research Center (CRC) facilities or resources? |
|  | Yes |  | No |  |  |
| **If yes,** research is subject to a separate review by the CRC. Click here, [Scientific Advisory Committee](http://www.uvm.edu/medicine/clinicalresearch/), for the requirements.  |
| **g.** Does the research involve any work with biohazardous materials including but not limited to,  |
| infectious biological agents, toxins, pathogens, gene therapy or recombinant DNA? |
|  | Yes |  | No |  |  |
| If yes, please list the IBC protocol number this IRB protocol will be linked to \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **If yes,** research is subject to a separate review by the Institutional Biosafety Committee. Click here, [Institutional Biosafety Committee](http://www.uvm.edu/~ibc/?Page=m1_forms.html), for the requirements. |
| **h.** Is this a Student Project?  | Yes |  | No |  |  |
| If yes, faculty sponsor needs to complete section 17. |
| **i.** Will genetic information be collected, stored, and or analyzed? | Yes |  | No |  |  |
| If yes, this research activity invokes the [Genetic Information Nondiscrimination Act (GINA)](http://www.hhs.gov/ohrp/policy/gina.html) 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).  |
| **University of Vermont Medical Center 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”](https://www.uvmhealth.org/medcenter/pages/Clinical-Trials-and-Research/Research-Billing-Compliance.aspx) on the University of Vermont Medical Center website. For additional questions, call Denise Quint in the UVM Medical Center Integrity and Compliance department at 847-9482.  |

|  |  |
| --- | --- |
| k. | UVM Medical Center Electronic Medical Record TitleA Research Subject Registration form must be completed for all active research participants in studies involving the University of Vermont Medical Center. A protocol title must be included in the PRISM electronic record. In some instances, there may be justification for requesting a waiver of this requirement or changing the study title that will be listed in the PRISM research flag.  |
|  | a. Are you requesting a waiver of inclusion of the title in PRISM? |  | Yes |  | No |
| b. Are you requesting an alternate study title? |  | Yes |  | No |
| If you feel that the study title as written may disclose too much confidential information, please provide an alternate study title that will be used in PRISM. |
|  |
| If yes to either, provide justification below. See guidance for waiver. |
|  |

|  |
| --- |
|  l. Will this protocol access, use or disclose protected health information (PHI) from UVMMC? |
| *If the subjects are being recruited within UVMMC or a health care clinic you may be obtaining PHI.* |
| Yes |  | Include authorization language within your consent  |
|  |  | **OR****Complete a Request for a Waiver of Authorization Form** |
| No |  | **Next question.** |  |
| If you are using a health care clinic other than UVMMC then contact the RPO Office. m. Will this protocol utilize human gene therapy as one of the research interventions?*Human gene therapy is a medical intervention based on the administration of genetic material to modify or manipulate the expression of a gene or to alter the biological properties of living cells.* |
| Yes |  | If yes, please consult with the Research Protections Office before proceeding. |
| No |  | **Next question.** |  |

|  |  |
| --- | --- |
| **5.** | **OTHER KEY PERSONNEL**  |
| Please complete the “Personnel Roster eForm” through InfoEd. Once all personnel have been added to the eForm, click "Save & Complete" on the top right of the page. You will be required to complete the eForm when uploading documents to the new submission. |
| All key personnel are required to complete online training prior to being added to the protocol. Please do not include individuals on the roster eForm who have not completed required training.  |

|  |  |
| --- | --- |
| **6.** | **SOURCE OF SUPPORT: INTERNAL/GRANTS/CONTRACTS/AGREEMENTS/FEES** |
|  |  |
|  | **a. Do you have any source of support for this project? (e.g. per subject enrollment, provision of drugs, devices or equipment, departmental resources)** *This information is important as the source of support must be included in the subject consent form.* |
|  |  | No, this is a research requirement with no monetary or other support. Skip to #7. |
|  |  | Yes, check below all that apply. |
|  |  | **Internal (Department, Pilot funds)**  | Specify Dept(s) or Pilot fund: |  |
|  |
|  |  | **Sponsored project processed through Sponsored Project Administration (SPA) at UVM –** 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 |
|  |  | 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.*  |
|  |  | **The institution is required to conduct a congruency check between the grant and the protocol. To conduct this review, you must submit the grant document.**  |
|  |  | Check here to indicate that you have attached the corresponding grant.  |
|  |  | **Industry supported research processed through SPA at UVM** |
|  |  | InfoEd Proposal #  |  |
|  |  | Name of Company |  |
|  |  | **Industry supported research processed through UVM Medical Center Office of Clinical Trials Research** |
|  |
|  |  | 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. Industry Contracts/Agreements** – ***Contracts/agreements are required.*** |
|  |  | 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  |
|  | **c.** | **Protocols Subject to IRB Fees**  |
|  |  | *“The University’s Institutional Review Boards (IRBs) charge fees for initial and annual continuing review for all University and UVM Medical Center studies sponsored by pharmaceutical firms, other for-profit entities, non-profit foundations unless prohibited, and to review protocols for outside organizations. Fees are not charged for University or UVM Medical Center federal, non-profit foundations where such fees are prohibite, or departmentally-funded studies. The fee schedule is reviewed each year by the IRB and is subject to change.”* |
|   |  |
|  | **Does the protocol meet the criteria for IRB fees?**  |  | 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 |  |

|  |  |
| --- | --- |
| **7.** | SUBJECT INFORMATION |
|  |  |
| a. Estimate the number of subjects you need for this protocol. |
| Include all subjects who are expected to screen fail or drop.  |  |
| **b. What are the Categories of Subjects (check all that apply)** |
| Are the subjects |
|  | Male or |  | Female |
|  | Adults, provide age range |  |  or |  | Minors, provide age range |  |
|  | Healthy or |  | Persons with a specific disorder list disorder |  |
|  |
| Regulations require that IRBs give special consideration for the following particularly vulnerable subjects. Please check below if any of these classes of subjects are included in this research as your primary focus. |
|  |
|  | Cognitively Impaired |  | Mentally Ill |  | Pregnant Women |  | Fetuses |  | Prisoners |
|  | Wards of the State |  | Non-English Speaking |  | Students |  | Employees |
| ***\*If the research population involves prisoners, all personnel on protocol must take additional training when research involves prisoners. See CITI resource page.*** |
| If you believe there are other potentially vulnerable populations not listed above, please list below. |
|  |
| **c. Will subjects be compensated?** | Yes |  | No |  |
| c.i. If yes, explain which subjects in your pool will be compensated and how. *(e.g. with or without disease/condition, monetary or other)* |
|  |
| c.ii. For all UVM studies, the Payment Acknowledgement form is required to reimburse subjects. UVMMC does not require this form to be used, however it does require social security numbers regardless of amount. *(The UVM payment threshold for collecting a person’s social security number is equal to or less than $100.00 while UVMMC requires subject social security numbers regardless of amount. Seek additional guidance from UVM’s Procurement Services Office or UVM Medical Center’s Accounts Payable Department.)* |
|  |

|  |  |
| --- | --- |
| **8.** | **Research Data Management Plan** |
| **a.** | **Is the research team collecting the research data?** |  | Yes |  | . |

If yes, the Research Data Management and Security Plan form must be filled out. The form, along with guidance, can be found in our [forms library](https://www.uvm.edu/rpo/human-subjects-research#IRB_Initial) and must be submitted with your initial application.

|  |  |
| --- | --- |
| **9.** | **RECRUITMENT** |
| **a.**  | How will subjects be recruited? |  | Check here if recruiting is not applicable to the research. |
|  | PI/Collaborators will recruit own patients |
|  | PI will send an IRB approved letter to colleagues asking for referrals of eligible patients who  |
|  | are interested in the research study. *(In these cases, the interested subject must contact the investigator. The investigator cannot contact the subject directly.)* |
|  | PI will send a letter to colleagues requesting them to send out an IRB approved “Dear Patient” letter which describes the research study. *(The PI may draft the letter* |
|  |
|  | *with the treating physician’s signature, but may not have access to the patient names or addresses for mailing.)*  |
|  | Advertisements/media (*All materials must have IRB approval.)* |
|  |  PI is recruiting subjects for behavioral or non-clinical research. *(If checked, explain process below.)* |
|  |  E-Mail using list-serves. If checked, attach documentation that you have been given |
|  | permission from the list-serve owner to use the list-serve for recruitment purposes.  |
|  | Will utilize the Emergency Medicine Research Associate Program (Surgery Class 201 |
| *To utilize the students you must contact eike.blohm@uvmhealth.org to establish an agreement prior to protocol submission. Attach the required signed agreement for utilization of this program. You must also check the Surg 201 checkbox in Section 18. Personnel Roster as this indicates that the student associates are key personnel.* |
|  | Will utilize the SONA Psychology Pool |
|  |  Other explain below: |
|  |  |
|  |  |
| **b.** | The PI requests a Partial Waiver of Authorization for Recruitment Purposes *(this would be necessary if you are intending to review protected health information of potential subjects with whom you do not have a treating relationship as defined in the UVM Medical Center HIPAA policy) (Research staff working with the investigators that are within the practice group are allowed to review records without a partial waiver as they are “agents” of the practice group.)* |
|  |  |
|  | Yes |  | No | If yes, *Complete form Request for Partial Waiver of Authorization for Recruitment Purposes* |

|  |  |
| --- | --- |
| **10.** | CONSENT  |
| a. Type of Consent  |
| i. Are you obtaining Written Consent? |  | Yes |  | No |
|  If yes, will there be more than one consent document? |  | Yes |  | No |
|  If yes, how many consent documents and for what populations. |
|  |
| ii. Are you requesting a Waiver of Informed Consent? |  | 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.* |
| **iii.** Are you requesting an Alteration of Informed Consent Procedures? |  | Yes |  | No |
| *This is a request to alter an individual’s informed consent or elements of informed consent. Deception in research would be one example when consent would be altered. See research manual section 8.b.4.for more information about when a subject’s consent may be altered.* **If yes**, complete the form *Request for a Waiver of Informed Consent/ Authorization/ Documentation Section I.* |
| iv. Are you requesting a Waiver of Documentation of Informed Consent? |  | Yes |  | No |
| *This request means you are obtaining verbal or implied consent without obtaining the subject’s signature on a consent form. See manual for the criteria required to obtain this type of waiver.*If yes, complete the form *Request for a Waiver of Informed Consent/Authorization/Documentation Section III.* |
| **v.** Do you intend to obtain consent from a legally authorized representative? |  |  Yes |  |  No |
| If yes, who did you intend on obtaining written consent from? Check below. |
|  | a. Individual with Durable Power of Attorney |
|  | b. Individual with Court-Appointed Legal Guardian |
|  | c. Parent signing for minor children |
|  | d. Next of Kin \* *(for treatment studies only)* |
|  | *Please see Section 11.F. Cognitively Impaired Individuals located in the Research Manual. This section describes guidelines for obtaining consent from individuals with questionable capacity to consent. The protocol should address questions 1-6, and requirements 1-3, from this section of the manual.*  |
|  |
| **b.** | **Consent Process** |
| **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?  |
|  |
| **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*](https://www.uvm.edu/rpo/human-subjects-research#Consent) *of the informed consent* ***process*** *under consent templates on our forms page.* |
|  |

|  |  |
| --- | --- |
| **11.** | PROTOCOL INFORMATION |
|  **a.** | Study will begin (month/year) |  | Study will end |  |
|  **b.** | Is this a multi-institutional study where UVM/UVM Medical Center is the Operations Center? |  | Yes |  | No |
| If yes, you must also complete and attach the “Operations Center (OC) Activities Supplement” form found on our forms page. *See Section 13.C. of the Research Manual for requirements when acting as the Operations Center.* |
|  |
| c.  | Does this protocol meet the NIH definition of a Clinical Trial? |  | Yes |  | No |
|  | *A clinical trial is defined by NIH as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. If you answer “Yes” to all four of the questions below, this study meets the definition of a Clinical Trial.* |
|  | Does the study involve human participants? |  | Yes |  | No |
|  | Are the participants prospectively assigned to an intervention? |  | Yes |  | No |
|  | Is the study designated to evaluate the effect of the intervention on the participants?  |  | Yes |  | No |
|  | Is the effect that will be evaluated a health-related, biomedical, or behavioral outcome? |  | Yes |  | No |
|  | If yes, the PI and all key personnel are required to complete Good Clinical Practice training.  |
|  |  |
|  d. | Identify the phase of study if applicable. |
|  |  | Phase I |  | Phase II |  | Phase III |  | Phase IV |  | Not applicable |
|  |  |
|  **e.** | Is this protocol either a |
|  | Trial of Drugs and Biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation |
|  | Trial of Devices: Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance |
|  |  | Yes |  | No |
|  | If yes, prior clinical trial registration is required by FDA and inclusion of the following language in your consent form is also required: *(please copy verbatim, even the caps on the word ‘Web’)* |
| “A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.” |
|  **→** | **Please note that prior clinical trial registration may also be required for publication in many journals but would not require the above FDA statement in the consent form. For guidance, see** [**Clinical Trials Registration Information**](http://www.uvm.edu/~irb/ClinicalTrialRegistryInstruction.pdf) **located in the “news” section of our website.** |
|  |  |
|  **f.** | **Data Safety & Monitoring Plan** |
|  | Each research application, excluding “Exempt” research, must include a plan to assure the safety and welfare of subjects, data integrity and confidentiality. The extent of monitoring research data will vary depending upon the risk/benefit ratio, sample size, and complexity of the research. |
| **Recognizing and Responding to Risks**  Provide a *description* of how you will identify, evaluate and report:  |
| 1. Adverse Events
 |
|  |
| 1. New Safety Information
 |
|  |
| 1. Unanticipated Problems to Subjects or Others
 |
|  |
|  | **ii. Identify who will be responsible for the data and safety monitoring.** |
|  |  | Independent Data and Safety Monitoring Board or Committee *(if checked skip to section iv.)* |
|  |  | Principal Investigator |  |  |
|  |  | Other, specify |  |  |
|  |  | Name/Title |  | E-mail |  |
|  |  | Affiliation/Department |  | Phone |  |
|  | **iii. What data or other information will be reviewed?** (If DSMB is checked above, do not complete section.) |
|  |  |  | Adverse Events Protocol Deviations |  | Data Collection Tools (questionnaires, surveys) |  | Protocol Compliance Literature Reviews |
|  |  |  |
|  |  |  | Unanticipated Problems to Subjects or Others |  | Laboratory Tests Procedure Reports |  | Outcomes (primary, secondary) |
|  |  |  |
|  |  |  | Enrollment #s Dropout/Withdrawal #s  |  | Medication Compliance Raw Data |  | Preliminary Analyses Other; specify: |
|  |  |  |
|  |  |  | Patient Charts/Clinical Summaries |  | Data QualityData Collection Timeliness |  |  |
|  |  |
|  |  |
|  | **iv. Are there criteria defined in the protocol to be used for decision making regarding continuation, modification, or termination of the entire study (not individual participation) (i.e. “stopping rules)?** If yes, please specify where in the protocol this information can be found. If the protocol does not include stopping rules please describe what criteria will be used for decision-making in order to minimize risks? |
|  |  |
|  | **v. What will be the frequency of the review?** Please note that the frequency of reviews should be commensurate with the risk of the study. At a minimum, a review of the data should be conducted annually at time of continuing review. **Forward copies of the data and safety monitoring reports to the 1) IRB, 2) CRC (if applicable), and/or 3) UVMCC (if applicable).** |
|  | Monthly  |  | Bi-annually |  | Other (e.g. by dosing level, no. of subjects enrolled): |
|  | Quarterly |  | Annually  |  |
|  |
|  | **vi. Will the sponsor be conducting data monitoring visits for this study?** |
|  |  | Yes |  | No |  | NA |
|  | If yes, how often? |
|  |  |
|  |

|  |  |
| --- | --- |
| **12.** | LOCATION OF RESEARCH ACTIVITIES (complete all that apply) |
|  |  |  |
|  | UVM Medical Center | University Campus (specify locations below) |
|  |  | Main Hospital/ACC |  |
|  |  | Clinical Research Center |  | School/School System |
|  |  | 1 South Prospect (UHC) |  | Correctional Facility |
|  |  | Other UVM Medical Center Location(s)  |  |
|  | Specify location(s): |
|  | **Other Location** |
|  | Specify location(s): |

|  |  |
| --- | --- |
| **13.** | **TYPES OF PROCEDURES** *(Please do not use the “other” option unless the procedure is not listed.)* |
|  | **a. Check all that apply.** |
|  | Survey (mail, telephone, in-person, on-line) |  | Blood drawing: | Vol. |  | Over days, weeks? |  |
|  | Medical exams/history |  |  | Type & Amt. |  |
|  | Deception **\*see below** |  | Surgery |  | Collection of Urine and/or Feces |
|  | Observation |  | Drug Administration \*\*see 14. |  | HIV Testing |
|  | Photographs |  | Device Use \*\*see 14. |  | Ultrasound (e.g. echocardiogram) |
|  | Audio Recording  |  | Exercise |  | Imaging (e.g. CT scan, DEXA, mammogram, PET scans, SPECT) |
|  | Video Recording |  | Diet |  | Use of Radiation treatment |
|  | Interviews in person or by phone |  | Pathology Specimens (retrospective) |  | Use of Radioactive substances (e.g. radiolabeled antibodies, drugs or contrasts) |
|  | Focus Groups |  | Genetic Materials (DNA) |  | MRI (for treatment studies) |
|  | Review of prospective data |  | Questionnaires |  | MRI (not for treatment studies) |
|  | Review of retrospective data |  | Diaries |  | Tissue (obtained for clinical purposes) |
|  | Recording of Identifiable DataElectrocardiograms |  | Pregnancy Tests |  | Tissue (obtained solely for research) |
|  |  |  |  |  |
|  | Sensitive Data (criminal or sexual conduct, drug or alcohol conduct or use) | (specify): |  |
|  | Other (specify) |  |
|  |  |
|  | **\***Deception typically involves withholding information from the potential subject and would require an alteration to the consent process. Complete Section 10.a.ii. above and the *Waiver of Informed Consent/Authorization/Documentation Section I* |
|  | b. COMPLETE THIS SECTION ONLY if blood is being drawn outside of a clinical area in coordination of other study procedures. If not applicable, skip to Section 14. If the only procedure is blood drawing outside of clinical areas, STOP and complete the “Blood Drawing for Non-Clinical Laboratory Research” instead of this form. |
| *The IRB has developed guidance “*[*Blood Draws in Non-Clinical Settings*](http://www.uvm.edu/irb/inst-guide-template/guidance_blood_handling.pdf)*” for researchers who are collecting blood outside of the clinical area.*  |
|  |
| Why is blood being collected from subjects in a non-clinical setting? |
|  |
|  |
|  |
| b.1. Name of person(s) collecting the blood. |  |
|  |  |
| b.2. Explain experience/training of the collector. |  |
|  |
| b.3. Where will the collection take place? List all potential sites.  |
|  |
|  |
| b.4. Confirm by checking below that you will follow the “Approved Standard Practices for Obtaining Blood” which is located within the guidance noted above. |
|  | I confirm that I will use the approved standard practices |
|  |
| b.5. Will the samples be linked with identifiers or codes? |
|  | Yes |  | No |  |
| If yes, explain why identification is necessary and how the data will be protected. |
|  |
|
|  |
| b.6. How, where and for how long will the samples be maintained? (will samples be secure?) |
|  |

|  |  |
| --- | --- |
| **14.** | FDA REGULATED ITEMS |
|  | When the principal intent of the investigational use of a test article is to develop information about the product’s safety or efficacy, submission of an Investigational New Drug (IND) or Investigational Device Exemption (IDE) is required. If certain criteria are met, however, a study may be exempt from obtaining an IND or IDE. If the study is sponsored, the sponsor will have this information. If it is not sponsored, these questions should assist the researcher in making the determination prior to submission. |
|  |  |
| **a.** | Does this investigation use an Investigational New Drug?  | Yes |  | No |  | NA |  |
|  | Name of Drug |  | Drug Company (Sponsor) |  |
|  | FDA IND # |  |  |
| **b.** | Does this investigation use an Investigational Biologic?  | Yes |  | No |  | NA |  |
|  | *A biologic is a preparation, such as a drug, a vaccine, or an antitoxin, that is synthesized from living organisms or their products and used as a diagnostic, preventive, or therapeutic agent.* |
|  | Name of Biologic |  | Drug Company (Sponsor) |  |
|  | FDA IND Number |  |  |
| **c.** | Does this investigation use an FDA-approved drug in an investigational manner? (i.e., different indication) |
| Yes\* |  | No |  | NA |  | Name of Drug |  |
|  |  |  | Drug Company (Sponsor) |  |
|  | **\*If yes**, does its use meet all of the following conditions below for exemption from an IND? |
|  | Yes |  | It is exempt from filing an IND application and can be IRB reviewed. |
|  | No |  | PI must submit an IND application to the FDA prior to final IRB approval. |
| If available | FDA IND # |  | Investigator Holding IND |  |
|  | All of the following conditions must be met for exemption from an IND. |
|  | 1. It is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug; |
|  | 2. it is not intended to support a significant change in the advertising of the product; |
|  | 3. it does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreased the acceptability of the risks) associated with the use of the drug product; |
|  | 4. it is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50, respectively; |
|  | 5. it is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7]; and  |
|  | 6. it does not intend to invoke 21 CFR 50.24. |
|  |  |  |
| **d.** | Will an Investigational Device be used? | Yes |  | No |  | NA |  |
|  | Name Of Device |  | Manufacturer (Sponsor) |  |
|  | FDA IDE Number |  |  |
|  | Exempt from IDE? | Yes |  | No |  | If yes, which exemption # from below. |  |
|  | To be exempt from a IDE the device needs to fall into one of the following categories:1. A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time.2. A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.3. A diagnostic device, if the sponsor complies with applicable requirements in Sec. 809.10(c) and if the testing: (i) is noninvasive; (ii) does not require an invasive sampling procedure that presents significant risk; (iii) does not by design or intention introduce energy into a subject, and (iv) is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.4. A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.5. A device intended solely for veterinary use.6. A device shipped solely for research on or with laboratory animals and labeled in accordance with Sec. 812.5 (c).7. A custom device as defined in Sec. 812.3 (b), unless the device is being used to determine safety or effectiveness for commercial distribution. |
|  | **e.** | Is Device Significant Risk (Per FDA definition)? |  | **Or**  | Is Device Non-Significant Risk? |  |
|  | **f.** | Is this a Humanitarian Use Device (HUD)? | Yes |  | No |  |
|  | See guidance on HUDs in the research manual. |
|  | g. \*\*List all (investigational and non-investigational) drugs and or devices here. |
|  | Investigational Drugs: |  | Investigational Devices: |
|  |  |  |  |
|  | Non-Investigational Drugs: |  | Non-Investigational Devices: |
|  |  |  |  |

|  |  |
| --- | --- |
| **15.** | **Disclosure of Financial Interest** |
|  | **If yes, to any of the questions below, disclosure in the consent may be required by the Institutional Review Board (IRB) and you must also complete number 16 below. Refer to the Research Manual for the IRB policy and the consent form language.** |
|  | **a.** Do any members of the investigative team or members of their immediate families receive from the sponsoring entity salaries, consulting fees, or other compensation for services that exceed $5,000 in any twelve month period? |
|  |  | Yes |  | No |
|  |  |
|  | **b.** Do any members of the investigative team or members of their immediate families have an equity interest that exceeds $5,000 in value or represents more than 2% ownership interest in the sponsoring entity? |
|  |  | Yes |  | No |
|  |  |
|  | **c**. Do any members of the investigative team or members of their immediate families have any intellectual property rights (inventorship, patents, copyrights, royalties) in any article(s), product(s), drug(s), device(s), or other material(s) that will be involved in this research? |
|  |  | Yes |  | No |  |
|  |  |
|  | **d.** Do any members of the investigative team or members of their immediate families have any financial interests similar to those described in a.,b.,c., above in an entity other than the sponsor that would, to a reasonable objective observer familiar with such issues, appear to affect or be affected by the research being undertaken? |
|  |  | Yes |  | No |  |
|  |  |

|  |  |
| --- | --- |
| **16.** | **If you answered “yes” to any question in number 15, answer question 16. Otherwise skip to question 17.** |
|  |  |
|  | **a.** Is an FDA Financial Disclosure Form (3455) required for the principal investigator or key personnel? |
|  |  | Yes |  | No |
|  | If yes, attach a copy. If disclosure is required and not attached, your approval will be withheld until this is provided. |
|  |  |
|  | **b.** For UVM sponsored projects processed through SPA, is disclosure to UVM of a financial interest for this project required for the principal investigator or key personnel? |
|  |  | Yes |  | No |
|  | If yes, attach a copy. If disclosure is required and not attached, your approval will be withheld until this is provided. |
|  |  |
|  | **c.** For clinical trial agreements processed through UVM Medical Center, is disclosure to UVM Medical Center of a financial interest for this project required for the principal investigator or key personnel? |
|  |  | Yes |  | No |
|  |  |
|  | **d.** Provide the names of all individuals with potential conflicts with a description of their roles and activities in this project, e.g., determine eligibility, recruitment, obtain consent, data analyses, conduct study procedures (describe), etc. |
|  |  |
|  |  |
|  | **e.** What is the amount (dollar value) and nature of the conflict (consulting fees, serving as director or on advisory board, intellectual property royalties, etc.)?, conduct study procedures (describe), etc. |
|  |  |
|  |  |
|  | **f.** Describe how the project outcome may or may not affect this financial interest, e.g., a good result would lead to more consulting or a product that I have invested in may appear more effective and have higher sales. |
|  |  |
|  |  |
|  | **g.** What actions do you think are appropriate to reduce or manage any potential harmful effects on human subjects arising from the potential conflict? Consider actions to preserve scientific objectivity, guard against coercive recruiting, objectively determine subject eligibility, etc.  |
|  |  |
|  |  |
|  | **h.** Please provide any additional information that may be helpful to the IRB in reviewing the potential conflict. |
|  |  |
| **17. 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 |
|  |  |  |
|  |  |  |
| **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.”* |
|  |
| 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. |
|  |  |  |
|  |  |  |
| x |  |  |
| Original Signature of Faculty Sponsor |  | Date |
|  |  |  |
| Printed Name |  |  |

|  |
| --- |
| **18. Attachments to this Common Protocol Cover Form**  This checklist is optional. |
|  |  | If applicable |
|  | Item | Version # | Dated |
|  | Protocol |  |  |
|  | Complete copy of grant proposal with budget (if applicable) |  |  |
|  |  |  |  |
|  | Consent Form (primary study) |  |  |
|  | Consent Form (substudy)(e.g. pharmacokinetic studies, quality of life studies, etc.) |  |  |
|  | Consent Form (controls/normals) |  |  |
|  | Request for Waiver of Consent |  |  |
|  | Child Assent Form (if applicable) |  |  |
|  | HIPAA Authorization |  |  |
|  |  |  |  |
|  | Surgery 201 Class Agreement (if applicable) |  |  |
|  | Drug/Device – Industry Sponsored Contract |  |  |
|  | Investigational Drug Brochure |  |  |
|  | Investigational Device Brochure |  |  |
|  | Drug/Device Exemption Documentation |  |  |
|  |  |  |  |
|  | Recruitment Materials |  |  |
|  | Advertisements |  |  |
|  | Surveys/Questionnaires |  |  |
|  | Other: |  |  |