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

**Blood Collection Protocol for Non-Clinical Laboratory Research**

**This form is to be used when the only procedure involving human subjects is blood collection. If any other procedures are being included STOP and complete the Common Protocol Cover form and submit a written protocol. See forms page for forms and instructions.**

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| **1. Title of this Blood Collection Protocol** |
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| **Protocol(s) in which this blood will be used**  *(this could be a human subjects (IRB), animal (IACUC) or biosafety (IBC) protocol)* | | | | | |
| Committee |  | Number |  | Protocol Title |  |
| Committee |  | Number |  | Protocol Title |  |
| Committee |  | Number |  | Protocol Title |  |

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| **2.** | **Investigator Information** | | | | |
|  | Principal Investigator (PI): | |  | | | | | Degree |  |
|  | Dept. |  | | Phone | | |  | Email |  |
|  | Campus/Office Address: | | | |  | | | | |
|  | PI’s Dept. Chair(s) | | | |  | | | | |

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|  | **Do you want to appoint a primary contact other than the 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 |  | Phone |  | | | | | |

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| **3. Purpose of Blood Collection** |
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| **4. Committee Review Type**  *The type of review depends upon the amount of blood you are collecting over what time period. Check below the intended collection requirements.* | | |
|  | **Expedited Review Required** |
|  | Collection of blood samplesby finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds as long as the amounts drawn **will not exceed** 550 ml in an 8 week period and collection **will not** occur more frequently than 2 times per week. |
|  | **Full Board Review Required** |
|  | Collection of blood samplesby finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, non-pregnant adults who weigh at least 110 pounds as long as the amounts drawn **will exceed** 550 ml in an 8 week period and collection **will** occur more frequently than 2 times per week. |

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| **5.** | | **Source of Support** | | | | | |
|  | | Is there any external funding for this project? | Yes |  | No |  |
|  | If “Yes” and there is a SPA Proposal provide the InfoEd # | | | | | |  |

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| **6.** | | **Donor Information** | | | | | | | | | | |
| **a. Donor Demographics** | | | | | | | | | | | |
| **Estimate the Total Number of Donors Required** | | | | | | | |  | |
| **Type of Donors** (check all that apply):  *This form cannot be used for research with minors, vulnerable subjects, immunocompromised subjects, or persons with specific disorders.* | | | | | | | | | |
|  | Male |  | Female | Age Range |  | | *(must be >18 yo)* |
|  | \*Students or Employees or Colleagues | | | | | | |
| **\*If donors are employees, colleagues, or students explain how undue influence will be avoided.** *Blood donation must always be voluntary.**These donors should not be placed under pressure to give samples. All potential donors should be able to refuse to give blood, without having to give an explanation for a refusal. Any personal information obtained in connection with collection or use of a sample must be held in confidence.* | | | | | | | | |
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| **b. Donor Selection:**  Provide rationale, if any, for specific donor selection in terms of the scientific objectives of the protocol(s) in which the blood will be used. (e.g. gender, weight, etc) | | | | | |
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| **c. Donor Compensation** | | | | | |
| Will donor be compensated? |  | Yes |  | No |

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| If yes, amount per donation | $ | Total Amount | $ | |
| For all UVM studies, the Payment Acknowledgement form is required to reimburse subjects. If not using this form, explain how you will be obtaining the subjects’ social security number for payment purposes (e.g., on paper, verbally). 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.)*  Explain how you will collect name and contact information, and if applicable, the social security number. How will you protect this information? | | | | |
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| **7. Recruitment**  *Describe plans for identifying and recruiting donors. All recruitment materials (flyers, ads, letters, etc) need to be IRB approved prior to use.* | | | | | |
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| **8. Consent Procedures**  *Describe the consent procedures to be followed, including the circumstances under which consent will be obtained, who will seek it, and the methods of documenting consent.*  *Note: We would recommend that our consent template developed specifically for this situation be used. It can be found on the forms page of our website under consent.* |
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| **9. Procedures** **for Obtaining Blood**  *Provide a narrative of the collection procedures.* | |
| Example below, please review and revise as necessary for this protocol.  Procedure:   1. Healthy adults individuals will be asked to participate in this minimal risk procedure. Education and review of the consent will be performed. To avoid the risk of fainting, the person should have eaten something prior to the draw. 2. After the consent is signed, the volunteer will be brought to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 3. Phlebotomy of a peripheral arm vein will be performed by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_using sterile procedures and seated position. A sterile bandage will cover the phlebotomy site after the procedure and the arm will be elevated to ensure that bleeding has stopped. 4. The volunteer will be observed for any lightheadedness, bruising or bleeding during and after the procedure. 5. If the volunteer is lightheaded, he/she will be reclined and monitored until symptoms resolve. 6. If the volunteer is asymptomatic after the phlebotomy procedure, he/she will be released. 7. Any volunteer with any side effects during or after phlebotomy will not be used again to obtain the blood products. In addition, any volunteer that requires more than three attempts to access a vein will also not be used as a volunteer. |

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| **10. Donor Risks** | | | | | | | |
| **a. Explain experience/training of the collector.** | | | | |  | |
| *See policy on acceptable experience.* | | | | | | |
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| **b. Will any private information be collected from the individual? Describe what information you need below and whether you need to keep any of the individual’s answers.** *(Justification for maintaining private information will be required. A plan for protecting the information will also be required.)* | | | | | | |
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| **c. Will the blood samples be linked with identifiers or codes?** | | | | | | |
|  | Yes |  | No | |  |
| If yes, explain why identification is necessary and how the data will be protected. | | | | | | |
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| **e. How, where and for how long will the samples be maintained? (will samples be secure?)** | | | | | | |
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| **f. Amount and Number of Donations:** How many times will donors potentially donate? Over what time period? |
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| *Where blood is to be collected regularly from a donor, a record of donations and the total collected should be maintained. The total (including donations elsewhere) should not exceed 550ml in an 8 week period. Note: Hemoglobin measurements may be indicated if the same person is donating very frequently.* |

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| **f.1. The researcher is required to maintain a blood drawing log. This log should include**  **1. Date of donation 2. Person’s name 3. Amount drawn** | | | | |
|  |  | **Confirm that a log will be maintained by checking here.** | | |
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| **f.2. What is the largest sample size to be collected in one sitting?** | | |  |  |
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| **g. Where will the collection take place?** List all potential sites. *See policy regarding Blood Draws Outside of Clinical Care Areas.* | | | | |
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| **h. Unanticipated Problems** with a donor needs to be reported to the Institutional Review Board.  *Explain the process for this notification.* |
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| **11. Collector Risk** | | | | | | | | | | |
| **a. Has collector had appropriate blood-borne pathogen training?** *Required per policy.* | | | | | | | | | |
|  | Yes |  | No | | | | |
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| **b. Confirm by checking here, that collector(s) have been trained in phlebotomy.** | | | | | | | |  | I Confirm | |
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| **c. If the intent is to transform lymphocytes, confirm here that the collector will not be working with their own blood samples.** | | | | | | | | | |
|  | I Confirm | | |  | Not Applicable | | |
| *No one should work with their own blood samples if the intention is to transform lymphocytes. In the event of an accidental exposure, their immune system will not challenge the transformed cells.* | | | | | | | | |
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| **d. Confirm that the collector will use the following safe Sharps practices.** | | | | | | | |  | I Confirm | | |
| * Use a Vacutainer collection equipment whenever feasible * Wear gloves when taking blood * Needles should never be recapped * Never carry used sharps in your hand * Sharps disposal containers should be available at the point of use * Used equipment should be discarded into a sharps disposal container immediately after use * Equipment should never be reused * Sharps containers should never be over-filled: discard when ¾ full * Needles and syringes should be discarded as a single unit * Any inoculation accident from contaminated equipment should be reported as an accident to both the IRB and IBC and advice sought from UVM’s or UVM Medical Center’s Occupational Health Program as soon as possible. | | | | | | | | | |
| **e. Confirm that the collector will use BSL-2 Laboratory Safety Practices** | | | | | | | |  | I Confirm | |
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| **f. Donors should be asked not to donate if they may be infected with a blood-borne virus** | | | | | | | | | |
| **or become a regular donor if they think that they may be at risk of infection from, for example, sexual partners. The template consent language only lists exclusion criteria relating to infection control and donor protection.** *Note: The researcher may need to specify additional exclusion criteria to avoid use of samples that may confound test results, e.g., the donor taking drug treatment or the donor suffering from hematological disease.* | | | | | | | | | |
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| **g. Unanticipated Problems** with the collector needs to be reported to the Institutional Review Board and the Institutional Biosafety Committee. *Explain the process for this notification.* | | | | | | | | | |
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| **12.** | **PERSONNEL ROSTER** |  | |  |
|  | **All key personnel are required to complete required training. For more information about required training can be found at** [**http://www.uvm.edu/irb/?Page=training\_faqs.html**](http://www.uvm.edu/irb/?Page=training_faqs.html) | | | |
|  | **PLEASE DO NOT INCLUDE INDIVIDUALS WHO HAVE NOT COMPLETED THE**  **REQUIRED TRAINING**  **Check tutorial completions at** [**http://www.uvm.edu/~irb/education/TutorialCOMPLETION.htm**](http://www.uvm.edu/~irb/education/TutorialCOMPLETION.htm) | | | |
|  | **Personnel Name** | | **Email Address** | | |
| 1. | PI: | |  | | |
| 2. | Contact Person: | |  | | |
| 3. |  | |  | | |
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| **12. AGREEMENT** | | | |
| **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 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 will maintain records of this research according to applicable guidelines. | | | |
| x |  |  |  |
| Original Signature of PI |  | Date | |
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All materials must be submitted electronically to the IRB via InfoEd. Proper security access is needed to make electronic submissions. Visit the [InfoEd Resource Materials](http://www.uvm.edu/~irb/?Page=infoed.html) page for more information.