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

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

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

Researchers conducting bench science often times require human cells for their laboratory research. Healthy research subjects will donate blood for these scientific purposes. While the activity of drawing blood is not a “research protocol”, the collection of the cells is for research, and therefore requires IRB review. No Protected Health Information (PHI) may be collected on this protocol. If your research will involve the collection of PHI or any additional interventions, please use our Human Subjects Research Protocol form.

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| **1. Title of this Blood Collection Protocol**   |  | | --- | |  | |

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| **Protocol(s) in which this blood will be used.**  *(human subjects (IRB), animal (IACUC) or biosafety (IBC) protocol)* | | | | | |
| Committee |  | Number |  | Protocol Title |  |
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| Principal Investigator (PI): |  |

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| **2. Purpose of Blood Collection** |
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| **3. Committee Review Type**  *The type of review depends upon the amount of blood you are collecting over what time period. Check below for the intended collection requirements (also found in section 8.5.1 of our Policies and Procedures) .* | |
|  | | **Expedited Review** |
|  | | Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:   * 1. from healthy, nonpregnant 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   2. 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. * **If collecting more than this amount, Full Committee review is required. Complete the Human Subjects Research Protocol form.** |

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| **4.** | **Donor Demographics** | | | | | | |
| 1. **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 |  |  |
|  | | | \*Students or Employees or Colleagues | | | | | |
| **\*If donors are employees, colleagues, PI, study personnel, 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 explain a refusal. If the PI or personnel participate, another qualified member of the study team must obtain consent. 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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| **7. 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 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 participant should have eaten something prior to the draw. 2. After the consent is signed, the participant will be brought to this location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 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 participant will be observed for any lightheadedness, bruising or bleeding during and after the procedure. 5. If the participant is lightheaded, they will be reclined and monitored until symptoms resolve. 6. If the participant is asymptomatic after the phlebotomy procedure, they will be released. 7. Any participant with any side effects during or after phlebotomy will not be used again to obtain blood products. In addition, any participant that requires more than three attempts to access a vein will also not be used as a participant. | |

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| **8. Donor Risks/Mitigation of Risks** |
| **a. Blood Collection Risks**: Please describe, potential pain, small risk of bruising, a rare risk of infection, fainting, and lightheadedness. | |
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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 Data Management Security Plan is required .)* | |
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| **c. 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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| **d.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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| **d.2. What is the largest sample size to be collected in one sitting?** | | |  |  |
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| **e. Where will the collection take place?** List all potential sites. | | | | |
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| **f.** Describe how adverse events and UAPs will be evaluated and reported to the IRB. Follow the guidelines established in “[Section 18: Reportable New Information](https://legacy.drup2.uvm.edu/rpo/irb-policies-and-procedures#uap_II)”.  *Explain the process for this notification.* |
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| **g.**  **Withdrawal Procedures:** Define the precise criteria for PI withdrawal of subjects from the study. Include a description of study procedures for when a subject withdraws themself from the study. |
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