**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.

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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 |  |
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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 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** |
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| **4.** | | **Donor Information** | | | | | | | | | |
| **a. Donor Demographics** | | | | | | | | | | |
| **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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| **5. 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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| **6. 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*](https://www.uvm.edu/rpo/uvmclick-irb-forms-library) *under consent.* |
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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 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 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 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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| **8. Donor Risks** | | | | | | | |
| **a. Explain experience/training of the collector.** | | | | |  | |
| *See policies and Procedures Manual for information regarding 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 Policies and Procedures Manual for information regarding Blood Collection Protocols.* | | | | |
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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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| **9. Collector Risk** | | | | | | | | | | |
| * **Has collector had appropriate blood-borne pathogen training?** *Required per policy.* | | | | | | | | | |
|  | Yes |  | No | | | | |
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| * **Confirm by checking here, that collector(s) have been trained in phlebotomy.** | | | | | | | |  | I Confirm | |
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| * **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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| * **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. | | | | | | | | | |
| * **Confirm that the collector will use BSL-2 Laboratory Safety Practices** | | | | | | | |  | I Confirm | |
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| * **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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