**Instructions for requestor:**

Return this completed request, requested paperwork for specific intended use, and signed letter of intent to [biomaterials@versiti.org](mailto:biomaterials@versiti.org).

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| **Requestor Information** | | | |
| **Requestor Organization** | | **Lab Name (if applicable)** | |
|  | |  | |
| **Requestor Name** | Phone Number | | Email |
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| **Billing Information** | | |
| **Company Name** | | **Billing Contact Name** |
|  | |  |
| **Billing Address** (include City, State, Zip) | **Telephone** | **E-mail** |
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| **Shipping Information**  (Completed byRequestor) | | | | | | |
| **Primary Contact at Receiving Location**  (for shipping communications) | | | | | **Shipping Temperature Options** | |
| Name: |  | | | | Ambient  Ice Pack (2-8°C)  Dry Ice  Other: | |
| E-mail: |  | | | |
| Telephone #: |  | | | |
| **Ship to** **Address** | | | | | | |
| Street address: | |  | | | | |
| City, State, Zip | |  | | | | |
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| **On-Site Pickup** for some products may be available at the Versiti Location listed below: | | | | | | |
|  | | |  |  | |  |
|  | | | **Location** | **Physical Address** | |  |
|  | | | Austin, Texas | 2111 W Braker Ln #200, Austin, TX 78758 | |  |
|  | | | Columbus, Ohio | 3132 Olentangy River Road, Columbus, OH 43202 | |  |
|  | | | Grand Rapids, Michigan | 1036 Fuller Ave NE, Grand Rapids, MI 49503 | |  |
|  | | | Indianapolis, Indiana | 3450 N. Meridian St., Indianapolis, IN 46208 | |  |
|  | | | Milwaukee, Wisconsin | 638 N. 18th St, Milwaukee, WI 53233 | |  |
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| **Intended Use Information**  (Check all that apply) | | |
|  | The project and use of material are solely limited to **quality assessments** or **quality improvements**. For example, activities conducted to assess, analyze, critique and/or improve current procedures | |
|  | The requestor holds **IRB approval, exemption, or waiver of consent** in order to use this blood or blood product. | |
|  | Research that does not fall under the definition of Human Subject Research found in 45 CFR 46 | |
|  | The materials are requested solely for **educational or training** purposes | |
|  | The materials are requested solely for **further manufacturing (Defined as Manufacturing for an Approved Biologic, Device, or Drug, or a Clinical Investigation subject to 21 CFR 312)** | |
| **Paperwork Requested for Project Setup**  (As part of our ethical duty, Versiti requests information on the intended use of the Biomaterials) | | |
| For Research that will be published or governmentally funded, please provide **an IRB Protocol Approval Letter** or **IRB Letter of Protocol Exemption**attached to this form. If you are seeking IRB approval concurrently, please fill out the Letter of Intent Section.    For Further Manufacturing (Defined as Manufacturing for an Approved Biologic, Device, or Drug, or a Clinical Investigation subject to 21 CFR 312), please provide an **Investigation New Drug Application Number,** **Biologics License Application Number** or **FDA Approval Letter** for either and attach letters to the form or provide the numbers in the Letter of Intent Section.    If your research does not fall under the definition of Human Subject Research found in 45 CFR 46, or the use of the materials would be considered for Internal Training, Validation, Calibration, Quality, Education, or Feasibility studies that will not be published or used for submission, please fill out the Letter of Intent section. | | |
| **Letter of Intent**  (Please state what type of materials you are looking for, in general, what they will be used for, and state that “it is not the intent to transfuse, inject, treat, or diagnose patients with these materials”) | | |
|  | | |
| Company/University Department Name: | | Company/University Department Name: |
| Signature: | | |

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| **Prospective Collections (recruited research donors for fresh blood collections)**  Indicate all product types and accompanying data that may be requested for the intended use(s) described. | | | | | | | | | | | | | | | | | | |
| **Product Type** | | | | | | | **Additional Information Requested** | | | | | | | | | | | |
|  | Clinical Grade (GTP) Apheresis Leukocytes (MNC/Leukopak) | | | | | |  | Donor Age (years) | | | | | | | | | | |
|  | Research Use (RUO) Apheresis Leukocytes (MNC/Leukopak) | | | | | |  | Donor Gender | | | | | | | | | | |
|  | Apheresis Platelets | | | | | |  | Donor Ethnicity | | | | | | | | | | |
|  | Apheresis Plasma | | | | | |  | Infectious disease screening results | | | | | | | | | | |
|  | Apheresis Red Cells | | | | | |  | Lookback notification requested | | | | | | | | | | |
|  | Whole Blood Unit (unprocessed) | | | | | |  | ABO/Rh | | | | | | | | | | |
|  |  | | | | | |  | Collection date | | | | | | | | | | |
|  | Whole Blood derivatives | | | | | |  | Immunophenotyping: | | | | |  | TNC | | |  | CD45+ |
|  |  | Red blood cells (leukoreduced/non-leukoreduced) | | | | |  |  | CD3+ (T cells) | |  | CD4+ (T helper cells) | | |  | CD8+ (Cytotoxic T cells) | | |
|  |  | Plasma | | | | |  | Other: | |  | | | | | | | | |
|  | Tubes | | | | | |  |  | | | | | | | | | | |
|  |  | EDTA |  | Serum |  | Other: |  |  | | | | | | | | | | |
|  | Buccal swabs | | | | | |  |  | | | | | | | | | | |
|  | Other: | | | | | |  |  | | | | | | | | | | |

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| **Other Products (waste/non-conforming)**  Indicate all product types and accompanying data that may be requested for the intended use(s) described.  Note: These product types and accompanying data are subject to availability. | | | | | | | | |
| **Product Type** | | | | | | | **Additional Information** | |
| **Expired or Nonconforming Products** | | | | | | |  | Donor Age (years) |
|  |  | Apheresis Platelets | | | | |  | Donor Gender |
|  |  | Red Blood Cells | | | | |  | Donor Ethnicity |
|  |  | Whole Blood (unprocessed) | | | | |  | Infectious disease screening results |
|  |  | Plasma | | | | |  | Lookback notification requested |
| **Leukoreduction Byproducts** | | | | | | |  | ABO/Rh |
|  |  | Apheresis Leukoreduction Chambers (cones) | | | | |  | Collection date |
|  |  | Buffy Coats | | | | |  | Other: |
|  |  | Leukoreduction Filters | | | | |
|  | Remnant Sample Tubes | | | | | |  |  |
|  | Platelet Rich Plasma (PRP) | | | | | |  |  |
|  | Cord blood: | |  | Fresh |  | Cryopreserved |  |  |
|  | Other: | | | | | |  |  |
| **Note:** *We cannot guarantee that any units picked up or shipped prior to completion of infectious disease testing are negative/nonreactive.* | | | | | | | | |

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| **Other Comments or Requirements** |
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| **For Versiti Use Only** | | | | |
| Yes | No | **Written executed agreement confirmed?**  (e.g. Material Transfer Agreement, Data Use Agreement or Research Material Supply Agreement) | | |
| Yes | No | **Appropriate Documentation Received?**  (IRB Approval, IRB Protocol/Summary, IRB Non-Human Subject Determination, Letter of Intent, Biologics License Application) | | |
| Yes | No | **Proposed use of the biomaterial has legitimate scientific merit?** | | |
|  |  | Name of individual(s) making determination: | | |
| **Versiti Reviewer Notes** | | | | |
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| **Approval Status** | | | | **Project #** |
| Approved | | | Not Approved |  |