**Instructions for requestor:**

Return this completed request, IRB protocol/summary/exemption, and letter of intent to biomaterials@versiti.org.

|  |
| --- |
| **Requestor Information** |
| **Requestor Organization** | **Requestor Name** |
|       |       |
| **Phone #** | **Email** |
|       |       |

|  |
| --- |
| **Billing Information** |
| **Company Name** | **Billing Contact Name** |
|       |       |
| **Billing Address** (include City, State, Zip) | **Telephone** | **E-mail** |
|       |       |       |

|  |
| --- |
| **Shipping Information**(Completed byRequestor) |
| **Contact at Receiving Location**(for shipping communications) | **Shipping Temperature** |
| Name:  |       | [ ]  Ambient [ ]  Ice Pack [ ]  Dry Ice [ ]  Other:       |
| E-mail:  |       |
| Telephone #: |       |
| **Ship to** **Address** |
| Street address: |       |
| City, State, Zip |       |
|  |
| **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  |  |
|  |  |  |  |

|  |
| --- |
| **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 project is intended to support the **creation of data for an FDA submission** under FDA regulations? |
| [ ]  | The requestor holds **IRB approval, exemption, or waiver of consent** in order to use this blood or blood product. (Please submit documentation from IRB) |
| [ ]  | The project requires material is collected under an **IRB-approved informed consent** disclosing the material may be used for commercial purposes |
| [ ]  | The materials are requested solely for **educational or training** purposes |
| [ ]  | The materials are requested solely for **further manufacturing** |
| **Describe the intended use:** |
|       |

|  |
| --- |
| **Perspective 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 |
| [ ]  | Whole Blood Unit (processed into components) | [ ]  | Collection date |
| [ ]  | Whole Blood derivatives | [ ]  | Cell count: | [ ]  | TNC | [ ]  | CD34+ | [ ]  | CD45+ |
|  | [ ]  | Red blood cells (leukoreduced/non-leukoreduced) |  | [ ]  | Other:       |
|  | [ ]  | Plasma  | [ ]  | Other: |       |
|  | [ ]  | Platelet Rich Plasma (PRP)  |  |  |
|  | [ ]  | Buffy coats  |  |  |
| [ ]  | Tubes |  |  |
|  | [ ]  | EDTA | [ ]  | Serum | [ ]  | Other:       |  |  |
| [ ]  | Buccal swabs |  |  |
| [ ]  | Other:       |  |  |

|  |
| --- |
| **Other Products**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 | [ ]  | Cell count: | [ ]  | TNC | [ ]  | CD34+ | [ ]  | CD45+ |
|  | [ ]  | Leukoreduction Filters |  | [ ]  | Other:       |
| [ ]  | Remnant Sample Tubes | [ ]  | Other:       |
| [ ]  | 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.* |

|  |
| --- |
| **Other Comments or Requirements** |
|       |

|  |
| --- |
| **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** |
|       |
|  **Approval Status** | **Project #** |
| [ ]  Approved | [ ]  Not Approved |       |