

## Cell Manipulation Core Facility Policy for Off-Protocol Use of Isolex 300i to Enrich CD34+ Cells

Isolex 300i Magnetic Cell Selection System is a FDA approved device for processing autologous peripheral blood progenitor cell (PBPC) products to obtain a CD34+ cell enriched population intended for hematopoietic reconstitution after myeloablative therapy in patients with CD34-negative tumors. Selection of CD34+ stem cells has also been used extensively for processing allogeneic stem cell products from normal donors. In these cases, positive selection of CD34+ hematopoietic stem cells is used to deplete mature T cells from the stem cell product. Many reports in the literature have documented that the use of CD34 selected allogeneic stem cells reduces the incidence of acute and chronic GVHD following transplant. CMCF is experienced in using Isolex 300i to process PBPC for CD34 selection of allogeneic stem cells under previous INDs. Transplant physicians may request the use of Isolex 300i as part of patient's treatment plan in an off-protocol setting. This policy is developed to standardize the procedure for off-protocol use of Isolex for CD34 selection of PBPC from normal donors for allogeneic transplantation.

The policy is summarized as follows:

- A. All CD34+ cell selection must be scheduled with CMCF 4 weeks prior to date of cell processing.
- B. CMCF will only use the Isolex 300i Magnetic Cell Selection System to enrich CD34+ cells from PBPC products.
- C. CMCF will not routinely cryopreserve the CD34 **negative** fraction of the product after CD34+ cell enrichment.
- D. CMCF will perform CD34+ enrichment for NMDP products under the following conditions:
  1. Written approval from NMDP
  2. No cryopreservation of the unused fraction of the product.
- E. Complete and obtain the following documents and return to CMCF prior to the date of cell processing:
  1. A copy of patient informed consent indicating the use of Isolex for CD34+ cell enrichment of donor cells.
  2. **CMCF Off-protocol Use of Isolex 300i Approval Form** must be completed and signed by CMCF Assistant Medical Director or Director.
  3. Physician's written order for CD34+ cell selection using Isolex.
- F. The order for cell processing must include the following information:
  1. Dates for cell processing
  2. Target dose of CD34+ cells requested
  3. Minimum number of cells to be infused
  4. Maximum number of CD3+ cells to be infused.
  5. Cryopreservation of excess CD34+ cells not infused.
- G. CMCF Assistant Medical Director or Director must review the order prior to cell selection procedure.
- H. Additional requirements for products processed for patients outside of DFCI, BWH, and CHB:
  1. Approval from Medical Director/Director of receiving laboratory facility (included in **CMCF Off-protocol Use of Isolex 300i Approval Form**).
  2. The ordering physician/facility will need to arrange for the transportation of the products.
  3. All processed products need to be infused within the expiration time (**One hour post cell selection**).
  4. Receiving laboratory technologist will need to be trained if a cryopreserved product is to be thawed outside of CMCF.
- I. Billing of CD34+ cell selection:
  1. All CD34 enrichment procedures using Isolex should have medical insurance approval.
  2. For patients outside of DFCI, BWH, and CHB, the cost of processing will be charged to the institution that requested the procedure.
  3. The cost of selection process will include:
    - a. Isolex reagent kits used for each selection procedure
    - b. Processing cost per selection

