## Guidance for Leukapheresis Description and Risks for Cell Therapy Informed Consents

**Overview:** Protocols involving leukapheresis to acquire material for cell therapy manufacturing and clinical product infusion or to obtain immune cells for research purposes are subject to additional institutional and regulatory requirements. This information sheet provides consent form guidance and recommended language for these studies. This langauge has been previously vetted by Cell Therapy Staff at DFCI, BWH, BCH, MGH, BIDMC and has been viewed by DF/HCC IRB Chairs. Study teams are encouraged to adhere to this guidance when drafting consent forms in order to avoid delays during IRB submission and reviews. (For guidance related to other aspects of Cell Therapy ICFs in addition to leukapheresis, please refer to "*Guidance for Reg Staff and IRB Reviewers on Cell Therapy ICFs*" and "*Guidance for Genetically-Modified Cell Therapy Description and Risks for Cell Therapy ICFs*".

**Description of Apheresis –** typically up in earlier section of ICF describing TP/study related events:

**Stem Cell Collection** (**if HPC-A**) or **Mono-nuclear/Lymphocyte Collection (if MNC-A)** (e.g., DLI, IEC, dendritic cells)

> Stem cells/Lymphocytes (or T cells, etc.) are a type of white blood cell that play a role in your immune system. The process for collecting these cells is called leukapheresis. Apheresis requires an intravenous needle be placed in each arm. Or if you do not have good vein access, a temporary central line may be placed prior to the procedure. (If relevant, you will sign a separate consent that outlines this catheter placement procedure and associated risks in more detail.) During apheresis, blood is taken from you, processed in a sterile cell separator to remove the white blood cells, and the remaining blood components are returned to you. This process will take approximately 4-8 hours and will take place in the Brigham and Women's Hospital (BWH) Kraft Family Blood Donor Center (*** insert site apheresis unit as relevant) as an outpatient service. The peripheral IV needles (or central line) will be removed after the apheresis session(s) is complete.

**HPC-A + MNC-A (if only one apheresis possible per sponsor/PI – then sentence deleted):**

> Most of the time, only one collection session is necessary to collect enough cells. Rarely, we may need to perform a second collection which will mirror exactly the process described above.

**HPC-A only:**

> Collection of your blood stem cells will typically begin on the fifth ($5^{th}$) day of taking Filgrastim. You will continue to take Filgrastim, perhaps with an additional mobilization agent plerixafor, until all apheresis sessions are completed.

**Monitoring of counts:**

> **HPC-A + MNC-A:** Your blood counts will be monitored prior to and after the apheresis processes to ensure your safety.

**HPC-A only**: Based on results from these blood samples, we may need to adjust your Filgrastim dose or introduce plerixafor.

**Description of Apheresis Risks** – Located in risks section in temporal order of when will encounter each therapy, e.g., prior to chemo for auto HSCT and IECs. Risks are the same for HPC-A and MNC-A.

**Risks associated with leukapheresis (procedure to collect your stem cells/lymphocytes or immune cells)**

Serious problems from apheresis are rare, but they can occur. The risks associated with apheresis include the following:

***More common:***

- Pain, bruising and discomfort where the needles or central lines enter your veins
- Tingling in your lips or fingers, numbness or a "vibrating" sensation caused by the anticoagulant used during the apheresis process, which may be managed by calcium administration
- Lightheadedness or dizziness while your blood is being circulated through the apheresis machine
- Lower number of red blood cells that can cause tiredness and shortness of breath. This may require a blood transfusion

***Less common:***

- Low number of platelets. This may require a platelet transfusion
- Nausea, vomiting, chest tightness and muscle cramps
- Flushing or reddening of the skin

***Very rare:***

- Clotting in the apheresis machine or in a participant, that may be life-threatening
- Allergic reactions, seizures, air emboli (which are air bubbles in your blood veins or arteries) or abnormal heart rhythms
- Swelling of the hands and feet or fluid retention
- Low blood pressure, high blood pressure or a slow pulse
- Infection at the site where the needles enter your veins

* For guidance on other Cellular Therapy ICF Language please see "Guidance for Reg Staff and IRB Reviewers on Cell Therapy ICFs, also on OHRS website.