

Fred Hutchinson Cancer Research Center

**Addendum: Consent for additional risks associated with COVID-19
pandemic to take part in a research study:**

985.03C – Mobilized Donor

**Consent to Participate as a Donor of Mobilized
Peripheral Blood Mononuclear Cells for Laboratory
Research and Process Development Studies.**

Principal Investigator: Derek Stirewalt, MD, Member, FHCRC, (206 667-5386)

Investigators: Michael Linenberger, M.D., FACP Professor, Division of Hematology, UW, Robert & Phyllis Henigson Endowed Chair, Program Director, Hematology/Oncology Fellowship Medical Director, Apheresis and Cellular Therapy, SCCA, Member, FHCRC, Associate Professor of Medicine, UW, (206 667-5021); Laura Connelly Smith, Assistant Member, FHCRC, Assistant Professor, UW (206 606 -6938)

Research Coordinator: Aubrey McMillan, (206) 667-3539

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Donor recruitment and participation: 206-667-5318

Use of this addendum

This addendum is an addition to the regular consent you are signing.

Before you decide if you want to proceed with G-CSF mobilized leukapheresis, it is important for you to understand the additional information set out in this addendum and the additional risks that could apply if you take part. Please take the time to read this form carefully and discuss the information with friends and family if you wish. Your study doctor or a member of the study team will explain the contents of this addendum to you. Please ask your study doctor or a member of the study team if there is anything that is not clear, or if you would like any more information.

COVID-19 pandemic – Additional information

Increased risk of infection caused by exposure to Coronavirus Disease 2019 (COVID-19)

As is already stated in the main consent, there is a chance you may experience side effects and/or risks because of your involvement in this study. These may include but are not limited to

- Higher risks of exposure to COVID-19 during study site visits
- Higher risks of severe infection with COVID-19 if you have COVID-19 when receiving G-CSF
- In the case of an active COVID-19 infection, there is a theoretical concern that G-CSF can result in acute respiratory failure due to G-CSF-induced leukocyte recovery in donors with pulmonary infections. Although donors must be confirmed COVID-19 negative before participating in a mobilized donation, it is imperative that any and all development of potential COVID-19 symptoms during your participation in this study be communicated to your study doctor or a member of study staff immediately.

Additional testing requirements

Testing for COVID-19 will be required before you can undergo administration of G-CSF. Additional COVID-19 testing may be necessary after receiving the G-CSF, as typical side effects of G-CSF can be flu-like in nature and may be difficult to discern from new COVID-19 related symptoms.

Once your COVID-19 test result(s) has been reviewed, your study doctor will discuss with you whether it is appropriate to perform study procedures at this time.

Additional precaution requirements

During the COVID-19 pandemic period, you will need to adhere to the hygiene guidance detailed in Appendix 1. In addition, symptom screening will be required upon each visit to the study site, and a mask must be worn at all times during your visits, including during the donation procedure.

Potential Impact on the research study

COVID-19 may have an impact on the ongoing ability to run the research study. As a result, there could be a delay in the ability to perform study procedures, including an interruption in your participation before completion.

CONSENT FROM ADDITIONAL ADDENDUM

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have and all questions were answered to your satisfaction;
- understand what is involved in being a donor;
- have been told of the risks and benefits of being in this study, including additional risks and responsibilities during the COVID-19 pandemic;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

I hereby consent to the information in this addendum:

Participant or Participant's Legally Authorized Representative:

Printed Name

Signature

Date

Legally authorized representative's relationship to patient: _____

Witness or interpreter:

If you served as an interpreter or witness during the consent process, sign below to indicate you attest to the accuracy of the presentation to the participant and the apparent understanding of the research by the participant.

Printed Name

Signature

Date

Researcher's statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name

Signature

Date

APPENDIX 1

During the COVID-19 pandemic period, you should adhere to the following hygiene and travel guidance based on Centers for Disease Control and Prevention (CDC), World Health Organization (WHO), Canada, France, Spain, and United Kingdom guidelines on COVID-19:

- When outside or in public, follow your national and local recommendations regarding use of face coverings (such as scarves, homemade cloth masks) that are worn over your nose and mouth.
- Wash your hands frequently
 - Regularly and thoroughly clean your hands with an alcohol-based hand sanitizer (at least 60% alcohol) or wash them with soap and clean water for at least 20 seconds.
 - Regular handwashing should occur upon returning home, before preparing food, before and after eating, after using the toilet or changing a child's diaper, and after touching animals.
 - Ensure your hands are dried after cleaning.
- Maintain social distancing
 - Maintain a distance of at least 2 meters (6 feet) from others
 - Stay out of crowded places
- Avoid touching eyes, nose and mouth
- Practice respiratory hygiene
 - Cover your mouth and nose with your bent elbow or tissue when you cough or sneeze. Then dispose of the used tissue immediately and wash hands immediately afterwards.
- Maintain household cleanliness
 - Clean and disinfect frequently touched surfaces daily
 - This includes tables, doorknobs, light switches, countertops, handles, desks, phones, keyboards, toilets, faucets and sinks
 - If surfaces are dirty, clean them by using detergent or soap and water prior to disinfection
- If you have fever, cough and/or difficulty breathing, seek medical attention as directed by your study doctor.
- You should avoid non-essential travel. Your study doctor will discuss with you any precautions related to travel to study visits or procedures.