

## **HS: GVHD Research**

### **Background**

Bone marrow transplants are commonly used to treat leukemia to rebuild the blood supply and create a new immune system capable of attacking the cancer. There are approximately 900 bone marrow transplant patients a year in Canada and nearly half of them develop GVHD. Graft-versus-host disease (GVHD) occurs when this new immune system turns against its host's body with sometimes fatal results. A rash in a transplant patient may indicate the onset of acute GVHD or it could be a side effect of the antibiotics commonly used in after-transplant care. A skin biopsy has been the only reliable way of differentiating the two causes. Physicians would like a simple blood test that will reliably indicate whether the patient has GVHD more quickly than a biopsy.

### **Research Question**

Dr. Smith is leading a five-year study, funded by the Canadian Institutes of Health Research, to identify blood based biomarkers that will allow doctors to diagnose acute GVHD more quickly than they can now. A biomarker is any protein present in blood whose level can be measured to determine if a disease is present; any protein has the potential to be a biomarker.

### **Participants (Inclusion/Exclusion Criteria)**

One hundred bone marrow transplant patients, including those with and without GVHD, who have been treated at the Bayley Cancer Centre in the last three years.

### **Proposed Method**

Dr. Smith's team will be screening a large number of proteins in the blood of 100 bone marrow transplant patients, including those with and without GVHD, to search for biomarkers. The patient blood samples being used in the study were originally collected for diagnostic purposes. Dr Smith has noted that there may be a need to collect new blood samples from the original patients if his analysis reveals new information relevant to the original participants' immediate or future welfare.

### **Risks**

Previously collected blood samples are being used, therefore there is no risk to the participant associated with taking fresh blood samples. There are risks associated with the researcher having access to participant identifiable information. If there is a need to take new blood samples, then there may be a slight risk of bruising.

### **Potential Benefits**

If the study successfully identifies reliable blood-based biomarkers for acute GVHD, the bone marrow transplant community will benefit from earlier diagnosis and treatment of GVHD. There are no additional potential direct benefits to the participants.

### **Recruitment**

The first phase of the research uses existing blood samples; no participants will be contacted. Eligible blood samples will be identified through the staff at the Bone Marrow Transplant program of the Bayley Cancer Centre. If new blood samples are needed, Dr Smith will seek access to patient contact information and have his research coordinator approach them.

### **Consent Process**

Participant consent is not being sought for analysis of the existing blood samples. If new blood samples are needed, each participant will be asked for their consent.

### **Data Security**

Dr. Smith has asked that the staff at the Cancer Centre remove all personal information (e.g., name, address, health number) from the samples being screened. His team will receive numbered blood samples with only the information of whether the patient has been diagnosed with acute GVHD or not.

### **Dissemination**

The results of the research will be published in the journal *Science Translational Medicine*.

**Group Task:** The author of this brief draft proposal is seeking advice with regard to research ethics. Discuss the elements of this project as presented here. Are there any elements that raise ethical concerns? What articles of TCPS 2 may apply? Create a list of the issues your group identifies and indicate how they could be addressed. Choose a spokesperson to report one of the issues that met with the most consensus in your group.