NAME OF INSTITUTION/MEDICAL CENTER

Consent to Participate in a Research Study Called:

A MULTI-SITE, RANDOMIZED TRIAL OF SUBJECT-COLLECTED DRIED BLOOD SPOT CMV TESTING WITH MOBILE TECHNOLOGY SUPPORT TO OPTIMIZE PREEMPTIVE THERAPY LATE AFTER ALLOGENEIC HCT

Who is in charge of this research study?

Principal Investigator:

Name Title Phone number

Co-Investigators:

Research Staff:

Emergency (24-hour) phone: Number; Fax: Number

Doctors at [insert site] are conducting this study. This study is funded by the National Institutes of Health (NIH).

What is the purpose of this consent form?

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to enroll in the study or not. This process is called "informed consent". We will give you a copy of this form for your records.

Why is this research study being done?

You are being asked to participate in this research study because you have had a hematopoietic cell transplant (HCT) and your transplant team recommends that you continue to monitor for cytomegalovirus (CMV) infection after your discharge from the Cancer Center.

CMV infection is very common and over half of the adults in the US have been infected. Once you have had a CMV infection, CMV remains in your body and can become active again when your immune system is weakened. In HCT patients, CMV can cause serious infections that can be life-threatening, even fatal, if not treated.

The current standard for HCT patients is to test their blood after transplant weekly or twice-weekly to watch for evidence of CMV. Standard CMV testing requires a blood draw in the clinic or at a laboratory. There is an alternative test that uses dried blood spots (DBS) obtained

from a simple finger-stick process that does not require a standard blood draw. The DBS sample collection can be done at home and the sample can be mailed to the laboratory for testing.

How well patients follow their doctor's recommendations for CMV testing after discharge from the Cancer Center can change over time. The purpose of this research study is to see whether patients who use DBS testing may follow their doctor's recommendations for CMV testing better than those who are asked to go to a clinic or lab for blood draws (standard practice). In the study, patients who use DBS testing will also receive reminders to collect their DBS sample via their mobile device. The research will also evaluate the safety of the DBS finger-stick process.

Collection and testing of dried blood spots for monitoring CMV infection is considered investigational. Investigational means that the U.S. Food and Drug Administration (FDA) has not approved the sample collection method and test method

A total of 150 participants will be enrolled in this study at sites throughout the US. About XX will be from [insert the name of your institution]. You will be in the study for about six to ten months.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

You will be assigned to a study group

If you join this study you would be put into either the DBS group collecting samples at home or the standard practice (blood draw at a clinic) group. The results of the two groups will be compared at the end of the study. Which group you will be in will be determined randomly (like pulling a number from a hat). Neither you nor your doctor would be allowed to choose which group you are in.

The chance that you will be in the self-collection DBS group or standard practice group is 2 to 1. That means that for every one patient in the standard practice group, there will be two in the DBS group. No matter which group you are assigned to, you will still receive the standard treatment that your medical center provides for patients with your condition.

What will happen during the study?

Self-collection DBS with reminders via mobile device

If you are in the DBS group, study staff will train you how to prick your finger and collect a dried blood spot sample, how to mail the sample to the laboratory, and how to use the web/mobile tool. This web tool will send you reminders to collect and send your DBS samples and to complete study questionnaires. We will give you enough sample collection kits to start the study and send you more when you need them. You should collect DBS on the same day and at about the same time each week (Sunday through Wednesday) until one year after your transplant.

You will be asked to complete a questionnaire three times during the study, (1) After a third training session, (2) one month after discharge from the clinic, and (3) before you complete the

study. The questionnaires will take about five minutes to complete. We will review your medical records after you enroll in the study and at three, six, nine, and 12 months from the date of your transplant to record your general health and CMV status. Your caregiver may help you with the finger-stick DBS collection and mailing the kit to the laboratory if they receive training by the study staff. Your caregiver cannot complete the questionnaires for you.

We will notify you when your CMV test results are positive. If your results are positive, we ask you to have 6ml (1/2 tablespoon) of blood drawn and to collect an additional DBS sample. You will ship these samples to our study lab at the University of Washington using provided prepaid mailers.

Standard practice group

If you are in the standard practice group, we will collect CMV and health status from your medical records after you enroll in the study and at three, six, nine, and 12 months from your date of transplant. We will ask you to follow your doctor's standard patient instructions for CMV monitoring after HCT transplant.

Information letter

Participants in both groups will receive a letter that describes the study. If you are hospitalized for any reason, you are asked to give this letter to your admitting physician.

What are the side effects (risks)?

Use of the dried blood spot test to monitor CMV levels after HCT is investigational. The DBS test is less sensitive in detecting CMV than the test that uses standard blood draws. Researchers conducted a study to compare results from the two tests (dried blood spot and the standard test done after a blood draw). They evaluated whether results from the DBS and standard tests would result in detecting the same level of CMV. When the amount of CMV in the blood was at the level where transplant patients commonly begin drug treatment (1000 IU/ml), the DBS test and the standard blood test would agree 96% of the time. However, when less CMV was present in the blood (500 IU/mL), the sensitivity of the DBS test did not pick up as many CMV positive samples. The sensitivity decreased to 85%. Therefore, DBS testing may not detect levels of CMV that would otherwise be treated, if found with a standard blood draw. This could lead to a greater frequency of missed cases of CMV disease than with standard blood draws, and your risk of CMV disease could be increased <u>if you miss your prescribed blood draw appointments.</u>

It is likely you may feel minor pain from pricking your finger.
It is less likely that you could bruise where you prick your finger.
It is rare that you would get an infection at where you prick you finger.

What are the benefits?

There may be no direct benefit to you for participating. Some participants may benefit if more regular CMV testing helps to detect CMV infection earlier, prompting more timely start of care.

Will you pay me to be in this research study?

[There is no payment for participation in this study. OR To compensate for your time, you will

be paid $XXX.]

Will it cost me to be in this research study?

You will not be financially responsible for the cost of procedures or materials required specifically for this research study. If you are in the DBS group, this includes your CMV testing, materials for collection and shipping of samples, and shipping costs.

You or your insurance company will be responsible for the costs of your regular treatment and care. If you are in the standard practice group, you will follow standard instructions for CMV monitoring, so you or your insurance will be responsible for CMV blood draws and tests.

What will happen if I get sick or hurt while in this study?

For a life threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can. For other emergencies call the Emergency phone number on page 1 of this consent form.

If you think you have an injury or illness related to this study, tell the study doctor in person or call [phone number]. Emergency medical treatment is available at the usual charge. No long-term medical care or financial compensation for research-related injuries will be provided by the sponsor of the study (NIH). You or your insurance company will have to pay for medical care or hospitalization. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. [Enter site-specific compensation information for research-related injuries. The study grant does not pay for injuries.] However, you do not waive any rights by signing this consent form.

What are my options if I am not in the study?

Being in this study is voluntary. You are free to say "yes" or "no", or to drop out after joining. If you say "no", you would have no penalty or loss of benefits. Whatever you decide, your regular medical care will not change. If you choose not to join, your doctor will still ask you follow standard recommendations for monitoring CMV after HCT transplant.

Termination of the Study

Your study doctor may decide to take you off this study if a decision is made to end the study early, if your own doctor thinks it is best for you, or for any other reason.

If you decide to drop out, please let one of the people listed on page 1 of this consent form know. There would be no penalty or loss of benefits if you decide to drop out. Before you leave the study, the study staff might ask your permission to let us continue to look at your medical records until one year after your transplant.

If you withdraw from the study for any reason, information already collected from you or your medical record would remain in the study records and would be included in the analysis of results. This information could not be removed from the study records.

During the study, we may learn new information you need to know. For example, some information may affect your health or well-being. Other information may make you change your mind about being in this study. If we learn this kind of information, we will tell you.

Protecting your privacy

In order to analyze study results, the researchers and study staff at the Fred Hutchinson Cancer Research Center will need to review your research records. Only authorized people will see your research records. People who look at your records will be very careful to protect your name and identity. Research records are kept in locked files and kept indefinitely. We may write reports and give talks about this study. If we do, we will not use your name or share anything that would let others know who you are.

Certain other people may look at the records to be sure that we are doing the study in the right way. They also make sure that we protect your rights and safety. These may include the following institutions and their representatives or agents:

- [site name]
- Fred Hutchinson Cancer Research Center (FHCRC)
- Institutional Review Boards (IRB) of the above institutions
- U.S. Food and Drug Administration (FDA)
- The Emmes Corporation, responsible for study data management and quality assurance.
- National Institutes of Health (NIH) and U.S. Office for Human Research Protections (OHRP), and other regulatory agencies as required.

Some tests for this study are done at laboratories outside of [medical center]. Samples sent to these labs will not include your name. They will be labeled with study numbers instead.

A copy of this consent will be placed in your medical record, and results from the CMV DBS testing will be provided to your medical doctor.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use your information, documents, or specimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action such as a suit or other proceeding without your consent. If there is a court subpoena, information, documents or specimens collected about you as part of this study cannot be disclosed to anyone else who is not connected with the research, except if there is a law that requires disclosure (such as to report child abuse or a communicable disease). This certificate does not prohibit requests for information from the groups listed above, who are responsible for overseeing the study.

The Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

How is my genetic information protected?

A federal law called the Genetic Information Nondiscrimination Act (GINA) helps protect genetic information about people who join research studies.

GINA restricts access to genetic information so that it cannot be used for health insurance coverage decisions. GINA prevents health insurance companies or group health plans from

- Asking for genetic information obtained in research studies, or
- Using genetic information when making decisions regarding your eligibility or premiums

GINA *does not* help or protect against genetic discrimination by companies that sell life, disability or long-term care insurance.

Donation of your leftover specimens (for participants in the DBS group only)

If you are in the DBS group, there may be leftover material after we test your specimens (blood spots and blood samples). We would like you to donate these leftover specimens for future research. This may include genetic research to look at things such as which genes affect infection or how genes work. You do not have to donate your specimens for research. You are free to say yes or no. There is a checkbox at the end of this consent form to indicate your decision. Your regular medical care will not change, if you say no. If we want to use your specimens for other research or share them with other scientists for research, we will ask an IRB. The IRB will decide if we need to ask for your consent to do the research. If we shared any specimens with other scientists, we would first remove your name or any information that would identify you.

Your donated specimens will be stored at the laboratories at Fred Hutch in Seattle, Washington. They will be used for research only. Researchers will not report their results to you or your doctor. The research results will not appear in your health record. They will not affect your care.

Who should I call if I have questions or research study problems?

For Questions About	Please Contact
This study and what it involves	The doctor or one of the investigators listed at the beginning of the consent
Your rights as a participant in a research study	IRB contact
Your bills and health insurance coverage	Medical center contact
Research use of your blood or tissue sample, or research files	Site contact or coordinating center contact
Research related injury	Your physician or one of the investigators listed at the beginning of this consent
What if I need emergency care?	**Emergency (24 hour) phone**: Number

CONSENT TO PARTICIPATE IN THE RESEARCH STUDY

If you have read this form (or had it read to you), asked any questions, and agree to participate, please sign:

Signature of Research Participant (Age 15+)	Printed Name	Date
Signature of Parent or legal guardian	Printed Name	Date

Please read the question and initial by YES **or** NO**.**

Do you agree to donate leftover specimens for future studies? Future studies may involve testing which genes affect infection or how genes work.

(This applies only if you are randomized to the DBS group. If you are randomized in the standard of care group, we will not be collecting any specimens from you.)

Please initial one: (**YES** _____) (**NO** _____) _____ 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.

Signature and Title of Medical Staff Person	Printed Name	Date

Signature of Additional Staff Person Present During Consent Process (if present)