Protocol Title:

A Phase 2 Study of letermovir treatment for patients experiencing refractory or resistant cytomegalovirus infection or disease with concurrent organ dysfunction

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If you are a parent or guardian of a child under 18 years old, the word "you" refers to your child. You, the parent, will be asked to read and sign this document to give permission for your child to participate.

A. INTRODUCTION

You are invited to take part in a clinical trial, a type of research study, because you have a cytomegalovirus infection resistant to standard treatments. This research study is studying a drug named letermovir as a possible treatment for this diagnosis.

For purposes of this research, you will be referred to as a "participant".

It is expected that about 32 people will take part in this research study. Merck Dohme & Sharp Co. is the pharmaceutical company that is supporting this study by providing the research funding and study drug and will be referred to as the "sponsor".

This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of participation, alternatives to participation, and your rights as a research participant. The decision to participate is yours. If you decide to participate, please sign and date at the end of this form. We will give you a copy so that you can refer to it while you are involved in this research study. If you choose not to participate in this research study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor.

Because information about you and your health is personal and private, it generally cannot be obtained without your written permission. By signing this form, you are providing that permission and your information may be obtained and used in accordance with this informed consent and as required or allowed by law. This means that researchers may obtain information regarding your past medical history, as well as specimens and samples from previous health care providers such as hospitals and labs.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions now and at any time in the future.

B. WHY IS THIS RESEARCH STUDY BEING DONE?

This is a Phase II clinical trial. Phase II clinical trials test the safety and effectiveness of an investigational drug to learn whether the drug works in treating a specific disease. "Investigational" means that the drug is being studied.

The FDA (the U.S. Food and Drug Administration) has not approved letermovir for treatment of cytomegalovirus infection, but it has approved letermovir for the prevention of cytomegalovirus infection in bone-marrow transplantation patients.

This is the first time that letermovir will be given to children in a clinical trial.

Cytomegalovirus (CMV) is a common virus, which a majority of people acquire at some time in their life. CMV remains in your body, but does not cause symptoms in the majority of people. Patients with a weakened immune system (a system that protects you from infections) may be more at risk for the virus becoming active and causing damage to some of your organs, especially in the gut and lungs. If the virus becomes present above a certain quantity, your doctor usually prescribes a drug to treat the infection at this stage to avoid damage to your organs.

In your case, the virus is no longer responding to the prescribed drug, and other drug options will be harmful to your health. You are being invited to take part in a research study for an investigational drug called letermovir. The purpose of this study is to find out whether letermovir is as effective and as safe in treating CMV infection in patients who cannot tolerate standard treatments such as ganciclovir or foscarnet.

C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this research study is voluntary. Instead of being in this research study, you have other options which may include the following

- Receive standard treatment, including oral valganciclovir; or intravenous ganciclovir, foscarnet, or cidofovir
- Take part in another research study.
- Receive no therapy specific to your CMV infection

Please talk to the research doctor about your options before you decide whether you will take part in this research study.

D. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Sometimes it is hard to keep track of all of the details and procedures that are part of a research study. We will describe them in this consent form and you can refer to this at any time during the research study.

Before the research starts (screening):
After signing this consent form, you will be asked to undergo some screening tests or procedures to find out if you can be in the research study. Many of these tests and procedures are likely to be part of regular cancer care and may be done even if it turns out that you do not take part in the research study. If you have had some of these tests or procedures recently, they may or may not have to be repeated.

At this visit, we will:

- Ask you about your medical history including medications and procedures
- Gather basic information about you
- Measure your vital signs, including height and weight
- Draw about 1 tablespoon of blood (to check your general health and the CMV in your body)
- Test your blood for pregnancy, if you are a woman of child bearing potential. Pregnant women cannot take part in this research study.

If these tests show that you are eligible to participate in the research study, you may begin the study treatment. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

Additional research procedures to be performed at the time of screening but not required to determine eligibility:

- A physical exam
- An electrocardiogram (EKG) to measure your heart function
- If there is no documentation of your HIV status, an HIV test will be done.
- Your transplant status and any other conditions you may have during the study will be assessed

Study Treatment Overview:
Letermovir will be given daily for up to 12 weeks, with a possible additional 12 weeks depending on your transplant status, CMV status, and clinical status.

If you take part in this research study you will be given a drug diary. You will be asked to document information in the drug diary about the study treatment you are being asked to take.

Treatment Phase:
Visits 1-10 (Weekly for first 6 weeks, Weeks 8, 10, 12)
This visit will involve the following:

- Letermovir dosing
- The investigator will ask you questions about side effects or health problems since your last visit
- The investigator will ask you about what medications you are taking
- There may be an evaluation of how you are able to carry on with your usual activities.
- Your vital signs will be taken
- Your weight may be checked
- About 1 tablespoon of blood will be drawn to check your general health, to check the CMV in your body, and to monitor your immune system
- About a quarter of a tablespoon of blood may be drawn to check the amount of letermovir in your body (not done at Visit 1)

(Optional) Visits 10-12 (Weeks 16, 20, 24)
This visit will involve the following:

- Letermovir dosing
- The investigator will ask you questions about side effects or health problems since your last visit
- The investigator will ask you about what medications you are taking

- There may be an evaluation of how you are able to carry on with your usual activities.
- Your vital signs will be taken
- Your weight may be checked
- About 1 tablespoon of blood will be drawn to check your general health and CMV in your body
- About a quarter of tablespoon of blood may be drawn to check the amount of letermovir in your body

Follow-up Phase: Post Treatment Visits 1-5 (Upon stopping study drug and at Weeks 1, 4, 8, and 12 afterwards)
We would like to keep track of your medical condition. There will be 4 visits after the end of treatment, up to 12 weeks after you stop taking study drug.

This visit will involve the following:

- A physical exam
- Your vital signs will be taken
- The investigator will ask you questions about side effects or health problems since your last visit
- The investigator will ask you about what medications you are taking
- About 1 tablespoon of blood will be drawn to check your general health and CMV in your body

Research Study Plan:

Treatment phase:

	Pre-Study	Wk 0	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 8	Wk 10	Wk 12	Wk 16	Wk 20	Wk 24
Letermovir		X	X	X	*	*	*	*	*	*	*	*	*	*
Informed consent	X													
Demographics	X													
Medical history	X													
Concurrent meds	X	X----------X												
Physical exam (as indicated)	X													
Eye exam	X													
Vital signs	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Height	X													

Weight	X					X			X		X	X	X	X
Performance status	X					X			X		X	X	X	X
CBC w/diff [a]	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Serum chemistry[a]	X	X	X	X	X	X	X	X	X	X	X	X	X	X
CMV viral load[a]	X	X	X	X	X	X	X	X	X	X	X	X	X	X
CMV immunity panel		X				X			X		X	X	X	X
PK sample (predose, if on drug)				X		X		X	X	X	X			
EKG (as indicated)	X		X											
Adverse event evaluation		X----------X												
B-HCG	X[b]													

*: *Letermovir*: Dose as assigned if clinically indicated; once daily for 8 weeks. Refer to section 5.1 for detailed
a: These tests are done as part of routine clinical care and no extra tubes will be drawn for the study

Follow up phase:

	End of Treatment	Post-Treatment Wk 1	Post-Treatment Wk 4	Post-Treatment Wk 8	Post-Treatment Wk 12
Medical history					
Physical exam	X	X	X	X	X
Eye exam	X				
Vital signs	X	X	X	X	X
Weight	X	X	X	X	X
Concurrent meds	X	X----------X			
Performance status	X	X	X	X	X
CBC w/diff[a]	X	X	X	X	X
Serum chemistry[a]	X	X	X	X	X
CMV viral load[a]	X	X	X	X	X
CMV immunity panel	X		X		
EKG (as indicated)		X			
Adverse event monitoring		X----------X			

a: These tests are done as part of routine clinical care and no extra tubes will be drawn for the study

Blood samples will be sent to a third-party laboratory, Viracor, who will analyze the amount of CMV in your blood. They will also run tests to analyze your immune system in response to CMV. Additionally, we will send blood samples to measure the amount of letermovir in your system to a third-party laboratory, PMRI.

E. HOW LONG WILL I BE IN THIS RESEARCH STUDY?

You will be in this research study for up to 36 weeks.

You may be taken off the research study drug for many reasons including if:

- It is considered to be in your best interest
- The study treatment or procedures are found to be unsafe or ineffective
- There is any problem with following study treatments and procedures
- You are a female and become pregnant or plan to become pregnant
- Your condition worsens
- A decision is made to close the study
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

If you are removed from the research study, the research doctor will explain to you why you were removed. The research doctor and research team will help arrange for your continued care.

In addition, you can stop participating in the research study at any time, however, the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study. If you decide to stop participating in this research study, we encourage you to talk to the research doctor and your primary doctor first.

F. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

There are risks to taking part in any research study. One risk is that you may get a study drug that does not help treat your disease or that makes your condition or disease worse. Another risk is that there may be side effects.

All antiviral treatments can have side effects, which can range from mild and reversible to severe, long lasting and possibly life-threatening. There is a great

deal of variability among side effects of different antiviral treatments and between individuals. In a research study, all of the risks or side effects may not be known before you start the study. You need to tell your doctor or a member of the study team immediately if you experience any side effects.

Everyone in the research study will be watched carefully for side effects. You will be monitored during the administration of study drugs to keep track of your blood counts and organ function, particularly your kidney and liver function. If you experience side effects, they may go away after you stop taking the study drug. Some side effects can be mild; but others can be long lasting and may never go away. Some may be life-threatening or fatal.

Since the effect of the study drug(s) taken with other medications may not be known, it is important that you tell the research doctor about all prescription and non-prescription drugs, herbal preparations and nutritional supplements that you are taking or planning to take. There may also be some foods that you should avoid while on this research study and your research doctor will review this information with you.

During the research study, you will be notified of newly discovered side effects or significant findings, which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

Risks Associated with letermovir

Frequent side effects (greater than 10%):

- Nausea
- Diarrhea
- Vomiting
- Swelling (usually in legs)
- Cough
- Headache
- Fatigue

If left untreated, vomiting and diarrhea may lead to excessive loss of body fluids and nutritional problems, so it is important to let your study doctor know if you develop any new health problems or if the problems you had before the study get worse.

Rare side effects (less than 10%)

- Irregular heartbeat

- Kidney damage (may occur with the intravenous formulation only)

Reproductive Risks:
The drugs used in this research study may affect a fetus. While participating in this research study, you should not become pregnant or father a baby, and should not nurse a baby. We can provide counseling about preventing pregnancy for either male or female study participants. Let your doctor know immediately if you become pregnant or find out that you are going to be the father of a child.

In the event that your partner becomes pregnant, it may be critical to share information regarding your participation in this research study with that person. Your research doctor should also be told if this happens. The study sponsor may want to collect data on your partner's pregnancy.

Non-Physical Risks:
Because of side effects or the time required for tests and clinic visits while you are on this research study, you may be unable to keep up with your normal daily activities.

Unforeseen Risks
In addition to the risks described above, there may be unknown risks, or risks that were not anticipated, associated with being in this study. If new information becomes available about the study drug that might affect your willingness to continue participation your study doctor or staff will inform and discuss with you whether you want to continue to participate in the clinical study.

You may even be asked to sign a revised consent form if this occurs. You have the right to decide either to continue with the clinical study or to withdraw.

G. WHAT ARE THE BENEFITS OF THE RESEARCH STUDY?

We do not know if taking part in this study will help you. This study may help researchers learn information that could help people in the future.

H. CAN I STOP BEING IN THE RESEARCH STUDY AND WHAT ARE MY RIGHTS?

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study.

You can stop being in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

It is important to tell the research doctor if you are thinking about stopping so your research doctor can evaluate the risks from stopping the drug. In some cases, the abrupt stopping of a drug can have risks in itself. Another reason to tell your research doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

I. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?

You will not be paid for participating in this study.

We may use your samples and information to develop a new product or medical test to be sold. The sponsor and hospital may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.

J. WHAT ARE THE COSTS?

Routine costs for standard clinical care will be charged to your insurance. You will not be charged for letermovir or for participation in this study.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services are:

- Brigham and Women's Hospital: (617) 732-5524 or (617) 732-7485
- Dana-Farber Cancer Institute: (617) 632-3455

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team:

www.cancer.gov or 1-800-4-CANCER (1-800-422-6237)

K. WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. These treatments will be billed to your insurance company. You will be responsible for deductibles, co-insurance and co-payments. There are no plans to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

We will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

L. WHAT ABOUT CONFIDENTIALITY?

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Medical information created by this research study may become part of your hospital medical record and may be forwarded to your primary doctor. Information that does not become part of your medical record will be stored in your study file. It may also become part of a DF/HCC research database.

The study team plans to publish the results of this research study and when we do, we may be asked to make the data we collect available to other researchers. We will not include information that identifies you in any publications or to the researchers who request the data to do additional research.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can

identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

M. CERTIFICATE OF CONFIDENTIALITY

To help protect your privacy a Certificate of Confidentiality (CoC) from the Department of Health and Human Services (DHHS) has been issued on this research study.

With this Certificate, the sponsor of the study cannot be forced (for example, by court subpoena) to disclose information that may identify you in federal, state, or local civil, criminal, administrative, legislative or other proceedings. Disclosure will be necessary, however, upon request of the Department of Health and Human Services for audit or program evaluation purposes.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family or even the research doctor from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer, learns about your participation, and obtains your consent to receive research information, then the sponsor may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

N. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the research doctor or study staff as listed below:

Amy Sherman, M.D. is the person in charge of this research study. You can call her at 617-732-6660, pager 31811 (24 hours a day, 7 days a week), with questions about this research study or with Dana Farber site related questions.

Sandra Burchett, M.D. is the site responsible investigator for Boston Children's Hospital. For questions at this site, please contact 617-875-4686.

Sarah Hammond, M.D. is the site responsible investigator for Massachusetts General Hospital. For questions at this site, please contact 857-753-1235.

If you need emergency medical treatment, contact the nearest available emergency medical center.

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at Dana-Farber Cancer Institute (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

O. FUTURE USE OF DATA AND SPECIMENS

Your personal information and/or biospecimens collected during this study may be stored and used for future research. If so, any personal identifiers will be removed so that the information or samples cannot be linked back to you. As a result, we will no longer be able to identify and destroy them.

Investigators, including investigators from collaborating institutions, can request this data and samples for new research. Samples and data may also be shared with outside non-profit academic investigators as well as with for-profit pharmaceutical investigators or commercial entities, with whom we collaborate.

You will not be asked to provide additional informed consent for the use of your de-identified information or samples in future research.

Future research studies may include genetic research. Your genes are unique to you. At this time, you cannot be identified through this research. There is a risk that you might be reidentified in the future as genetic research progresses

P. PRIVACY OF PROTECTED HEALTH INFORMATION

Federal law requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions (“protected health information”). If you enroll in this research study, your “protected health information” will be used and shared with others as explained below.

1. What protected health information about me will be used or shared with others during this research?

- Existing medical records, including mental health records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires

2. Why will protected information about me be used or shared with others?

The main reasons include the following:

- To conduct and oversee the research described earlier in this form;
- To ensure the research meets legal, institutional, and accreditation requirements;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the drug(s) used in the study and for the purpose of this or other research relating the study drug(s) and their use in cancer;
- To better understand the diseases being studied and to improve the design of future studies; and,
- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, its subcontractors, representatives, business partners, and its agent(s): Merck Dohme & Sharp
- Other research doctors and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

5. For how long will protected health information about me be used or shared with others?

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. Statement of privacy rights:

- You have the right to withdraw your permission for the research doctors and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as

oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: "Whom do I contact if I have questions about the research study?"

- You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: "Whom do I contact if I have questions about the research study?"

Q. DOCUMENTATION OF ASSENT

Signature of participant between age of 10 and 18: The person doing this research study has explained what will happen to me if I take part in this research study. My signature below means that I want to be in this research study. I can

decide not to take part in this research study if I do not want to and nothing will happen to me if I decide I do not want to participate.

_____ _____
Signature of Participant Date

To be completed by person obtaining assent:

The assent discussion was initiated on _____ (date).

☐ The information was presented in age-appropriate terms. The minor:
- ☐ Agreed to take part in the study
- ☐ Did not agree to take part in the study

☐ An assent discussion was not initiated with the minor for the following reason(s):
- ☐ Minor is incapacitated
- ☐ Minor is under 10 years of age
- ☐ Other_____

_____

Signature of Individual obtaining assent: _____

Printed name of above: _____

Date: _____

R. DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

Signature of Participant or Legally Authorized Representative

Date

Relationship of Legally Authorized Representative to Participant

To be completed by person obtaining consent:

Adult Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative.

☐ 1) The participant is an adult and provided consent to participate.

☐ 1a) Participant (or legally authorized representative) is a non-English speaker and signed the translated Short Form in lieu of English consent document:

As someone who understands both English and the language spoken by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

☐ 1b) Participant is physically unable to sign the consent form because:

☐ The participant is illiterate.

☐ The participant has a physical disability.

☐ Other (please describe): _____

The consent form was presented to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

- ☐ 2a) gave permission for the adult participant to participate
- ☐ 2b) did not give permission for the adult participant to participate

To be completed by person obtaining consent:

Minor Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative, or, where the participant is a minor, the participant's parent or legal guardian.

☐ 1) The parent or legally authorized representative gave permission for the minor to participate.

☐ 1a) Parent or legally authorized representative is a non-English speaker and signed the translated Short Form in lieu of English consent document

As someone who understands both English and the language spoken by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.

Signature of Interpreter/Witness: _____

Printed name of Interpreter/Witness: _____

Date: _____

☐ 1b) Parent or legally authorized representative is physically unable to sign the consent form because:

- ☐ The participant is illiterate.
- ☐ The participant has a physical disability.
- ☐ Other (please describe): _____

The consent form was presented to the parent or legally authorized representative who was given the opportunity to ask questions and who communicated agreement for the minor to participate in the research.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 1c) The parent or legally authorized representative did not give permission for the minor to participate

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