**Consent of an Adult to Receive [ Emergency Use or Expanded Access] of**

**[Name of drug, biologic or device]**

**Parents’ or Guardians’ Permission for Your Child to Receive Emergency Use or Expanded Access of [Name of drug, biologic or device]**

(for parent/Legal guardian to sign on behalf of Minor less than 7 years of age)

**Agreement of a Child to Receive [Emergency Use or Expanded Access] of**

**[Name of drug, biologic or device]**

(for use of Minor 15-17 years of age)

###### Participant’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Medical Record #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| Name of Physician ProvidingTreatment with [name of drug/biologic or device] | [Include Name, address, telephone] |

## What is the purpose of this form?

The purpose of this form is to explain your options for treatment with an investigational drug or device. Investigational means that the Food and Drug Administration (FDA) has not yet approved the drug or device. Although the safety and effectiveness of the drug or device are not yet proven through clinical trials, you will be given this drug or device to treat your condition. This type of use of an investigational drug or device is known as an Emergency Use or Expanded Access. You do not have to receive this treatment with [name of drug/biologic or device], if you do not want to. You should have all your questions answered before you agree to receive this treatment. Before you sign this form, be sure you understand how [name of drug/biologic or device] relates to your condition, as well as the risks and possible benefits. If you want to receive treatment, you will need to sign this form. You will be given a copy of this form.

**Who is providing the investigational treatment?**

The investigational [name of drug/biologic or device]is being provided by [list manufacturer] who makes the [name of drug/biologic or device].

[Name of drug/biologic or device] is an investigational agent. An investigational agent is one that researchers are still conducting research with to find out whether it is safe and effective. Because this [name of drug/biologic or device] is investigational, the Food and Drug Administration (FDA) has not yet approved it for general use.

**Why am I being asked to take part in treatment?**

You are being told about this treatment because [specify the patient’s condition and available treatments]. [name of drug/biologic or device] has not received approval for use in treating [indication] from the Food and Drug Administration (FDA). The Food and Drug Administration (FDA) has granted permission for [UV PI name] to provide this [name of drug/biologic or device] because you are not able to participate in a clinical treatment. The use of[name of drug/biologic or device] is for clinical purposes, not research.

You are being offered [name of drug/biologic or device] because your doctor believes that being treated with the [name of drug/biologic or device] is a good clinical option for you.

**How long will I be asked to participate in this treatment?**

[Describe the length of time treatment will be– include number of visits or treatments, as applicable.]

|  |
| --- |
| What are the procedures involved with receiving [name of drug/biologic or device]? |

[Describe the procedures in chronological order, what will happen at each visit, indicate if the patient must hold any current medications in order to receive the investigational agent, how will the patient receive the investigational agent -IV, surgery; include a table/schedule if valuable to the patient, when can the patient resume taking any held medication]

**What are your responsibilities if you receive this treatment?**

You and have certain responsibilities to help ensure your safety. These responsibilities are listed below:

* You must be completely truthful about your health history.
* Follow all instructions given.
* You or should tell the doctor about any changes in your health or the way you feel.

During the time you are receiving the [name of drug/biologic or device], Dr. [Name of UVA PI] will let you know of any test results that may be important to your health.  In addition, [Name of UVA PI] will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue receiving the investigational medication.

**What are the risks of taking Inotuzumab Ozogamicin?**

Because this treatment is considered investigational and has not received FDA approval, there may be risks that we do not know about at this time. The known risks/side effects are listed below.

[List reasonably foreseeable risks of the drug/biologic or device. Include frequency if known]

**Risks and side effects related to [name of drug/biologic or device]include:**

**Likely**

**Less Likely**

**Rare but Serious**

**Other unexpected risks:**

You may have side effects that we do not expect or know to watch for now. Call your doctor if you have any symptoms or problems.

**Could you be helped by participating in this treatment?**

You may or may not benefit from the [name of drug/biologic or device]. A possible benefit is that your health may improve. It is also possible that your health may not improve.

**What are your other choices if you do not take part in this expanded access program?**

You may choose not to receive the treatment or may stop treatment at any time. Your decision will not affect the quality of care you receive at the University of Virginia. Your doctor, as well, may discontinue treatment with [name of drug/biologic or device] if they feel it is in your best interest.

Will you be paid for taking [name of drug/biologic or device]?

You will not get any money for taking part in this expanded access program.

**Will receiving [name of drug/biologic or device] cost you any money?**

**[**The [name of drug/biologic or device] will be provided free of charge to you.]

Your insurance plan may or may not pay for treatment with this [name of drug/biologic or device]. If your insurance plan does not pay for this treatment, you will be billed for the cost of the [name of drug/biologic or device] and all related doctor and hospital costs, including drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.

**[If applicable]** You will be responsible for the cost of administering the investigational [drug/biologic]. You will be responsible for the cost of travel to come to the clinic at UVA and for any parking costs.

**What if you are hurt?**

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of participating in this expanded access program, you may contact the Doctor providing you with the treatment or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of participating in treatment, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

**What happens if you decide to stop taking the investigational medication?**

You can change your mind about receiving the [name of drug/biologic or device] any time. You can agree to take the investigational [name of drug/biologic or device] now and change your mind later. If you decide to stop, please tell us right away. You do not have to take this investigational [name of drug/biologic or device] to get services you can normally get at the University of Virginia. If you decide you no longer wish to receive the investigational [name of drug/biologic or device] we will ask you to please tell us that you want to withdraw.

**How will your personal information be shared?**

Your doctor is asking for your permission to gather, use and share information about you while you are receiving the investigational [name of drug/biologic or device]. If you decide not to give your permission, you cannot receive the investigational [name of drug/biologic or device], but you can continue to receive regular medical care at UVA.

**If you sign this form, we may collect any or, all of the following information about you:**

* Personal information such as name, address and date of birth
* Your health information if required for the medication administration. This may include a review of your medical records and test results from before, during and after you take the medication. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

**Who will see your private information?**

Some of your information, such as side effects from the [name of drug/biologic or device], will be shared with [list manufacturer] and the Food and Drug Administration (FDA). You will not be personally identified in any correspondence. We may also provide information to the UVA Institutional Review Board (IRB) if you experience any serious health related problems that occur when you are receiving the treatment.

**What if you sign the form but then decide you don't want your private information shared?**

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the UVA PI listed on this form. Your doctor will still use information about you that was collected before you ended your participation.

A copy of this consent form will be put in your medical record. This means that everyone who is allowed to see your medical records will be able to find out that you received this investigational [name of drug/biologic or device]. This is done so your regular doctors will know what you receive as part of your clinical care. If you have other health problems during your participation in this expanded access program, they will be able to treat you properly.

**Please contact your treating physician listed below to:**

* Obtain more information about the [name of drug/biologic or device].
* Report an illness, injury, or other problem (you may also need to tell your regular doctors)
* Stop the treatment before it is finished
* Express a concern about the [name of drug/biologic or device].

**Principal Investigator:**

**[Name, address, phone #]**

**What if you have a concern about this process?**

You may also report a concern about this process or ask questions about your rights by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research

PO Box 800483 Charlottesville, Virginia 22908

Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of your doctor, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials review your concern. When reporting a concern, you do not have to give your name.

**Signatures [Choose appropriate signature lines]**

*Note: Contact the IRB if you have questions about which signature sections are relevant for your treatment.*

**What does your signature mean?**

Before you sign this form, please ask questions about any part of this treatment that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to receive treatment with the treatment. You will receive a copy of this signed document.

**Consent from Adult**

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PARTICIPANT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PARTICIPANT (PRINT) |  | \_\_\_\_\_\_\_  DATE |  |  |

**To be completed by participant if 18 years of age or older.**

If an interpreter is involved in the consent process because the potential patient does not speak English well or at all, the participant should NOT sign on the line above – leave this line blank. Instead, the participant should sign the Short Form or full consent written in the language they can understand.

**Person Obtaining Consent**

By signing below, you confirm that you have fully explained this treatment to the potential patient, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING CONSENT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING CONSENT (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |

**Interpreter**

By signing below, you confirm that the treatment has been fully explained to the potential patient in a language they understand and have answered all their questions.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  INTERPRETER (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ INTERPRETER (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |

**If an interpreter was used to explain this treatment to a potential patient, the interpreter must sign and date the line above.**

**Assent from Child**

**Consent from the parent/guardian MUST be obtained before approaching the child for their assent.**

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARTICIPANT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PARTICIPANT (PRINT) |  | \_\_\_\_\_\_\_  DATE |  |  |
|  | | | | | | |

**Person Obtaining Assent of the Child (less than 18 years of age)**

**Consent from the parent/guardian MUST be obtained before approaching the child for their assent.**

By signing below, you confirm that the treatment has been explained to the child (less than 18 years of age), all questions have been answered and the child has voluntarily agreed to participate.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING ASSENT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PERSON OBTAINING ASSENT (PRINT) |  | \_\_\_\_\_\_\_  DATE |

**Interpreter**

By signing below, you confirm that the treatment has been fully explained to the potential patient in a language they understand and have answered all their questions.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  INTERPRETER (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ INTERPRETER (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |

**If an interpreter was used to explain this treatment to a potential patient who is a child, the interpreter must sign and date the line above**

**Parental/ Guardian Permission**

By signing below, you confirm you have the legal authority to sign for this child.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARENT/GUARDIAN (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PARENT/GUARDIAN (PRINT NAME) |  | \_\_\_\_\_\_ DATE |  |  |

**If an interpreter is involved in the consent process because the parent/guardian does not speak English well or at all, the parent/guardian should NOT sign on the line(s) above – leave the line(s) above blank. Instead, the parent/guardian should sign the IRB approved Short Form written in the language they can understand.**

**Interpreter**

By signing below, you confirm that the treatment has been fully explained to the potential patient in a language they understand and have answered all their questions.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  INTERPRETER (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ INTERPRETER (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |

**If an interpreter was used to explain this treatment to a potential patient, the interpreter must sign and date the line above.**

**Person Obtaining Parental/Guardian Permission**

By signing below, you confirm that you have fully explained this treatment to the parent/guardian, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING PARENTAL/ GUARDIAN PERMISSION (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING PARENTAL/GUARDIAN PERMISSION (PRINT NAME) |  | \_\_\_\_\_\_\_\_ DATE |

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**Surrogate Consent**

In the event the adult participant is unable to give informed consent for participation in this treatment:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PERSON GIVING CONSENT FOR PARTICIPANT DATE

(Signature/ Printed)

RELATIONSHIP TO PARTICIPANT: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**If an interpreter is involved in the consent process because the surrogate does not speak English well or at all, the surrogate should NOT sign on the line above – leave this line blank. Instead, the surrogate should sign the Short Form written in the language they can understand.**

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**Person Obtaining Consent of the Surrogate**

By signing below, you confirm that you have fully explained this treatment to the potential patient’s surrogate, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

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| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING CONSENT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING CONSENT (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |

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**Attending Physician Approval**

I am the doctor that provides medical care for this patient. I believe that his/her health might be helped by receiving this treatment. I approve his/her participation in receiving this treatment.

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| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ATTENDING PHYSICIAN (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ATTENDING PHYSICIAN (PRINT NAME) |  | \_\_\_\_\_\_\_\_ DATE |

**Note: If the UVA investigator is also the attending physician for the patient, they may also sign here as the attending physician.**

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**Person Obtaining Assent of the Adult Patient**

The patient is unable to give assent due to the following reason: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**OR**

By signing below, you confirm that the treatment has been explained to the adult patient, all questions have been answered and the adult patient has not demonstrated resistance or dissent by word or gesture to continue receiving treatment. You also confirm that if the patient demonstrates resistance or dissent at any point while receiving treatment that they will not be patiented to any additional interventions.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PERSON OBTAINING ASSENT (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  PERSON OBTAINING ASSENT (PRINT) |  | \_\_\_\_\_\_\_  DATE |

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**Interpreter**

By signing below, you confirm that the treatment has been fully explained to the potential patient’s surrogate in a language they understand and have answered all their questions.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  INTERPRETER (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ INTERPRETER (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |

**If an interpreter was used to explain this treatment the interpreter must sign and date the line above.**

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**Consent of the Patient to Continue to receive treatment**

Your legal representative gave his/her permission for you to receive emergency treatment. This is because you were not able to make your own decision due to your illness. Your condition is now better. You are being asked to decide whether to continue to be in this treatment. The decision is up to you. Before you sign this form, please ask questions about any part of this treatment that is not clear to you. When you sign below, you are saying you understand the information we gave you about the treatment and in this form.

**If you sign this form it means that you agree to continue being in the treatment.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

PARTICIPANT PARTICIPANT DATE

(SIGNATURE) (PRINT)

**If an interpreter is involved in the consent process because the patient does not speak English well or at all, the patient should NOT sign on the line above – leave this line blank. Instead, the patient should sign the Short Form written in the language they can understand.**

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**Person Obtaining Consent of the Patient**

By signing below, you confirm that you have fully explained this treatment to the patient, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_

PERSON OBTAINING PERSON OBTAINING DATE

CONSENT CONSENT (PRINT)

(SIGNATURE)

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**Interpreter**

By signing below, you confirm that the treatment has been fully explained to the potential patient in a language they understand and have answered all their questions.

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| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  INTERPRETER (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ INTERPRETER (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |

**If an interpreter was used to explain this treatment to a potential patient, the interpreter must sign and date the line above.**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Impartial Witness**

**If this consent form is read to the patient because the patient is blind or illiterate, an impartial witness not affiliated with the treatment doctor must be present for the consenting process and sign the following statement. The patient may place an X on the Participant Signature line above.**

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the treatment.   I also agree that the **identified individual(s)** freely gave their informed consent to participate in this treatment.

**Please indicate with check box the identified individual(s):**

Patient  Parent(s)/Guardian of the patient  Patient’s surrogate

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ IMPARTIAL WITNESS (SIGNATURE) |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ IMPARTIAL WITNESS (PRINT) |  | \_\_\_\_\_\_\_\_ DATE |

**Notification of My Health Care Provider**

Your health care provider will be notified of your participation in this treatment.