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| Single Patient Expanded Access Consent Form Template Version 1.0, 7/14/2023  **GENERAL INSTRUCTIONS** – delete this box from the submitted consent form  This template is for experimental treatment using an investigational device or drug as part of FDA- approved Expanded Access. In the template, the investigational product is referred to as a ‘drug’; however, edit for a device or biologic, as appropriate.  Use this template as follows:   * Red text represents instructions to you – to be deleted from the final version. For example, when a section starts with “[Include if…],” you should read the red bracketed phrase, and either delete the whole section if not applicable to this Expanded Access treatment, or delete just the red bracketed phrase and retain the section if applicable to this Expanded Access treatment. * Blue text represents guidance on suggested content – to be edited and changed to black or replaced with black in the final version. The language should be understandable at an 8th grade reading level. * Black text represents text that should ordinarily be incorporated as-is, if applicable   There are four signature pages at the end of this template; use the one that is applicable and delete the remaining four.  Please note that you must enter the project title and PI name in black in the header on the second page.  The submitted version should have no red or blue text (including instruction boxes like this one) |

**CONSENT TO PARTICIPATE IN EXPANDED ACCESS TREATMENT**

**Basic Information**

Title of Project: Title

IRB Number: the “H number” of your submission

Principal Investigator: PI name

PI/study email

PI/study mailing address

Related Phone Numbers:

* Regular business hours: phone number
* 24 hours: 24-hour number (if pager, please provide instructions)

**Introduction:**

The purpose of this form is to explain your options for treatment with the investigational drug name of investigational drug. The U.S. Food and Drug Administration (FDA) has not yet approved name of investigational drug for this use; however, the FDA has authorized the use of this drug to treat you. [Include if the investigational product is approved by the FDA but is being used outside of the FDA-approved indication; otherwise, delete] Name of investigational drug is also FDA-approved to treat a different condition called name of FDA-approved indication.

Participation in this Expanded Access treatment is voluntary. You are free to say yes or no and your decision will not impact the medical care you will receive from your doctor. Although research studies may be happening to see if this drug is safe and effective, you will be given this drug to treat your condition, and you will not be part of a clinical research study. This type of use of an investigational drug is known as Expanded Access. This allows a patient with a serious or life-threatening disease or condition to try an investigational medical product for treatment outside of clinical research studies when there are no comparable or satisfactory therapies available.

Before you can begin receiving name of investigational drug under this Expanded Access treatment (called “treatment” in this consent form), we want to give you some information to help you decide if you would like to receive this treatment. It provides important information about what you will be asked to do during the treatment, about the risks and benefits of the treatment, and about your rights.

[Use this language if this consent is seeking parental permission for participation of a child or if this Expanded Access treatment involves a participant with impaired decision-making capacity; otherwise, delete this sentence:] The term “you” refers to the person receiving this treatment throughout this document.

**What is the Purpose of this Treatment?**

The purpose of this treatment is insert patient-specific treatment purpose. It is the opinion of your treating doctor(s) that name of investigational drug is the best available option for your clinical care.

Your doctor(s) are advising you to receive this treatment because complete this sentence by describing why the patient is being asked to be treated with this investigational drug. For example, there is no drug approved by the FDA for use in routine medical care in the United States for this condition, or the FDA-approved drug(s) available for treatment of this condition did not work for the patient, or the patient cannot tolerate the side-effects of the drug(s) approved by the FDA for treatment of this condition.

**What Will Happen During This Treatment?**

[Include if there are clinical screening procedures that occur after consent is signed to determine eligibility to receive the treatment; otherwise delete] Prior to receiving the treatment, you will need to have explain tests that the patient will need to undergo to determine treatment eligibility. If you do not qualify to receive the treatment, you will not receive name of investigational drug. Your doctor will discuss other options with you. If you are able to receive name of investigational drug, begin discussion of treatment protocol by following instructions in next paragraph.

Provide a concise description of the procedures in enough detail to give a clear picture of what the patient will experience during the treatment protocol. Explain the overall arc of treatment in a chronological order, and describe procedures to be followed (including pregnancy testing if applicable), the location and length of time for the procedures, the frequency of procedures, the method, dose, and frequency of drug administration, and any specific tasks patients will be expected to complete on their own (if applicable). Technical language unfamiliar to the patient population should not be used. Subheadings may be inserted to make this section more readable.

**How Long Will the Treatment Last?**

[Include if the specific schedule for administration of the investigator drug is known; otherwise delete] If you agree to receive this treatment, the treatment is expected to last for includeexpected length of treatment. Discuss the specific schedule for the administration of the investigational drug, describing the length of time the treatment will last (e.g., hours, days, weeks, months, years, or until a certain event such as the drug is no longer effective), as well as long-term follow-up, if appropriate. Include number of visits or treatments as applicable. [Include if the specific schedule for administration of the investigator drug is not known; otherwise delete] The total duration of treatment will depend on the clinical response of your disease. We do not know with certainty how long your treatment will last.

**What are The Potential Risks of This Treatment?**

You may have side effects from name of investigational drug. You will be watched carefully for any side effects. However, doctors don’t know all the side effects that could possibly happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects may be temporary. In some cases, side effects can be serious, long lasting, may never go away, or possibly result in death. If you have any questions about any of the possible risks listed below, you should talk to your doctor.

The list of side effects below contains the most common or serious side effects of the drug. Please notify your doctor if you experience any of the described side effects. This treatment is experimental, so there may be risks that are currently not known. Please tell your doctor if you are experiencing any problems.

Provide a list of reasonably foreseeable risks or side effects of the investigational drug and their likelihood of occurrence (when appropriate or known). Include frequency, if known. Include information on risks that are more likely to occur and those that are serious. Discuss any potential risks from the medical procedures necessary to administer the investigational drug/biologic/device, if appropriate. Provide specific instructions for whom the patient should contact if experiencing serious side effects. Whenever possible, include the risks of drugs in a table organized by frequency such as below. If the specific frequency of risks is not known, please describe known risks and organize by likelihood as accurately as possible.

Very Common (greater than 10 out of 100 patients)

List risks

Common (from 1-10 out of 100 patients)

List risks

Less Common (from 1 out of 1000 to 1 out of 100 patients)

List risks

Rare (less than 1 out of 1000 patients)

List risks

[Include and edit if patients should not become pregnant because of risks to the fetus; otherwise, delete paragraph] Reproductive Risks:

If you get pregnant while you are receiving this treatment, it could be bad for the fetus/baby. You must use birth control if you are able to get pregnant and will have sex while you are receiving this treatment. [Include or modify time frame if applicable; otherwise, delete] You should also keep using birth control for three months after your treatment ends. Only some birth control methods work well enough to be safe while you are receiving this treatment. These methods are oral contraceptives (the pill), intrauterine devices (IUDs), contraceptive implants under the skin, contraceptive rings or patches or injections, diaphragms with spermicide, and condoms with foam. You should not receive this treatment if you are able to get pregnant and cannot use one of these birth control methods if you have sex.

[Include and edit if this procedure is part of the treatment plan; otherwise, delete this paragraph] Risks associated with blood draws:

Taking blood may cause some pain, bleeding or bruising at the spot where the needle enters your body. Rarely, taking blood may cause fainting or infection.

[Include if there are any consequences of a decision to withdraw from the Expanded Access treatment or any necessary procedures for withdrawing; otherwise, delete paragraph] If you decide that you want to stop receiving the name of investigational drug, we ask that you let us know. If you stop early, list risks of withdrawing. You are free to stop at any time, but if you tell us, we can do some things to help keep you safe. These things include list procedures for orderly withdrawal.

**Potential Benefits**

Your doctor(s) would like to treat you with the investigational drug because they believe that it may benefit you; however, no one knows if name of investigational drug will help you. Your condition may get better, stay the same, or get worse.

**What Other Treatment Options are Available?**

Your doctor(s) have decided that there are no other satisfactory alternatives available to you, other than to receive this treatment. You always have the option of deciding not to seek treatment, continue with your current treatment plan, or seek other care for comfort only. You should discuss these options with your doctor(s).

**Costs**

[Include if the investigational drug will be provided free of charge by the manufacturer; otherwise delete] The Expanded Access treatment name of investigational drug will be provided free of charge by the manufacturer.

You and/or your health insurance may be billed for the costs of medical care while you are receiving name of investigational drug. You have the right to ask what it may cost you to take part in this Expanded Access treatment. Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn’t pay for if you take part in this Expanded Access treatment. Also, find out if you need approval from your insurance plan before you can take part in the Expanded Access treatment.

If you would like assistance, financial counseling is available through the BMC Financial Counseling Department at 617-414-5155. The Expanded Access staff can help you contact this program. You can ask any questions now about insurance coverage for this Expanded Access Treatment. You can also ask the investigator later, using the number on the first page of this form.

**Payment**

You will not be paid for taking part in this treatment.

**Confidentiality**

We must use information that shows your identity to administer this treatment. Information already collected about you will remain in the record even if you later withdraw from receiving name of investigational drug.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. Only the people listed later in this section will be given access to your information. However, we cannot guarantee complete confidentiality.

If you agree to receive this treatment and sign this form, we will share information that may show your identity with the following groups of people:

* People who are involved in the Expanded Access or help oversee the Expanded Access, including safety monitoring.
* People from Federal and state agencies who audit or review the Expanded Access treatment, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
* People who see your medical records. Please ask us if you have any questions about what information will be included in your medical records.
* [Include if appropriate] Name of manufacturer of the drug, the manufacturer of the drug.
* Any people who you give us separate permission to share your information.

[Include without editing if this Expanded Access treatment is registered on ClinicalTrials.gov; otherwise, delete paragraph] A description of this Expanded Access treatment will be available on <http://www.ClinicalTrials.gov>. 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.

**Use and Sharing of Your Health Information**

The clinical team has to use and share your health information to do this Expanded Access treatment, including information that may identify you. By agreeing to receive this treatment and signing this form, you are giving us your permission where needed to use and share your health information as described in this form.

Health information that might be used or shared during this treatment includes:

* Information that is in your hospital or office health records. The records we will use or share are those related to the aims, conduct, and monitoring of the Expanded Access treatment.
* Health information from tests, procedures, visits, interviews, or forms filled out as part of this Expanded Access treatment.
* [Include this closed bullet and all applicable open bullet(s) if the study involves any of the following types of information; otherwise, delete this closed bullet and all open bullets] The health information specifically includes:
* Mental health communications (with a psychiatrist, psychologist, clinical nurse specialist, marriage-, family-, rehabilitation-, or mental-health-counselor, or educational psychologist)
* Domestic violence counseling
* Social work communications
* Rape victim counseling
* HIV/AIDS information
* Sexually transmitted disease information
* Communicable disease information
* [IMPORTANT NOTE: Please consult with BMC or BU counsel about the need for specific written consent if the study intends to further disclose alcohol or drug use information] Alcohol or drug use disorder treatment records about list specific data to be used and shared
* Genetic testing

The reasons that your health information might be used or shared with others are:

* To do the Expanded Access treatment described here.
* To make sure we do the Expanded Access treatment according to certain standards set by ethics, law, and quality groups.
* To comply with laws and regulations. This includes safety-related information. [Include if the study DOES gather information that requires mandatory reporting; otherwise, delete sentence] As we explained above, we also have to share any information from you about list information such as child abuse or neglect; elder abuse; specific reportable diseases; harm to others.
* [Include if the study DOES gather information about self-harm; otherwise, delete entire bullet] To protect you. As we explained above, if you are in immediate danger of hurting yourself, it is possible that your information will be shared with others as part of a plan for safety.

The people and groups that may use or share your health information are:

* Individuals involved in this Expanded Access treatment from Boston Medical Center, Boston University, and/or other organizations
* Other people within Boston Medical Center and Boston University who may need to access your health information to do their jobs such as for treatment, research administration, payment, billing, or health care operations
  + People or groups that the clinical team use to help conduct the Expanded Access treatment or to provide oversight for the treatment
  + The Institutional Review Board that oversees the Expanded Access treatment and other people or groups that are part of the Human Research Protection Program that oversees the Expanded Access treatment
  + Research monitors, reviewers, or accreditation agencies and other people or groups that oversee research information and the safety of the Expanded Access treatment
  + [Include if applicable; otherwise delete bullet] The manufacturer(s) of the Expanded Access treatment, and people or groups they hire to help them do the Expanded Access treatment
  + [Include if applicable; otherwise delete bullet] Government agencies in other countries that are involved in the Expanded Access treatment
  + [Include if the study DOES gather information that requires mandatory reporting; otherwise, delete bullet] Public health and safety authorities who receive our reports about list information such as child abuse or neglect; elder abuse; specific reportable diseases; harm to others.
  + [Include if the study DOES gather information about self-harm; otherwise, delete entire bullet] Other care providers and public safety authorities who may be involved in helping to protect you if you express thoughts about hurting yourself.
  + [Include if applicable; otherwise delete bullet] list other group(s) that will have access to the patient’s health information

We ask anyone who gets your health information from us to protect the privacy of your information. However, we cannot control how they may use or share your health information. We cannot promise that they will keep it completely private.

The time period for using or sharing your health information:

* The time period is not known, because Expanded Access treatment is an ongoing process. We cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Your privacy rights are:

* You have the right not to sign this form that allows us to use and share your health information for this Expanded Access treatment. If you do not sign this form, you cannot receive the treatment. This is because we need to use the health information to do the Expanded Access treatment. Your decision not to sign the form will not affect any other treatment, health care, enrollment in health plans, or eligibility for benefits.
* You have the right to withdraw your permission to use or share your health information in this Expanded Access treatment. If you want to withdraw your permission, you must write a letter to the Principal Investigator at the address listed on the first page of this form. If you withdraw your permission, you will not be able to take back information that has already been used or shared with others. This includes information used or shared to do the Expanded Access treatment or to be sure the Expanded Access treatment is safe and of high quality. If you withdraw your permission, you cannot continue to receive the Expanded Access treatment.
* When your treatment has been completed, you have the right to request access to the health information that we used or shared to make your treatment or payment decisions. If you ask for Expanded Access treatment information that is not in your medical record, we might not give it to you, but we will explain why not. You may use the contact information on the first page of this form to find out how to get your health information. You may also contact the HIPAA Privacy Officer at [choose applicable privacy contact] Boston Medical Center at [privacyofficer@bmc.org](mailto:DG-privacyofficer@bmc.org) / Boston University at [HIPAA@BU.EDU](mailto:HIPAA@BU.EDU).

[End of Use and Sharing section]

**Compensation for Injury**

Insert language approved by the manufacturer and BMC Clinical Trial Office or BU Industry Engagement Office if available; otherwise use and edit the following:

If you think that you have been injured by receiving this Expanded Access treatment, please let the Principal Investigator know right away. Use the phone number on the first page of this form. If you have a health emergency, get care first. You can seek treatment for the injury at Boston Medical Center, the BU School of Dental Medicine, or at any healthcare facility you choose. Tell the doctors that you are receiving this treatment.

There is no program to provide compensation for the cost of care for injury related to the Expanded Access treatment or for other expenses. Other expenses might be lost wages, disability, pain, or discomfort. You or your insurance will be billed for the medical care you receive for an injury. You are not giving up any of your legal rights by signing this form.

**Patient’s Rights**

By consenting to receive this treatment you do not waive any of your legal rights. Consenting means that you have been given information about this treatment and that you agree to receive this treatment. You will be given a copy of this form to keep.

If you do not agree to receive this treatment or if at any time you withdraw from receiving this treatment you will not suffer any penalty or lose any benefits to which you are entitled. Your decision to receive the treatment is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

During the course of this treatment, we may find out something that might make you not want to continue receiving this treatment. If this happens, we will tell you as soon as possible. You should also tell us if you ever have concerns about receiving this treatment.

We may decide to have you stop receiving this treatment even if you want to continue to receive it. Some reasons this could happen include your condition getting worse, the drug no longer being safe for you, the FDA tells your doctor(s) to stop, or the drug is no longer available from the manufacturer. If your doctor(s) stop your treatment, we will tell you as soon as possible.

**Questions**

The investigator or a member of the clinical team will try to answer all of your questions. If you have questions or concerns at any time, contact name at phone number. Also call if you need to report an injury while being in this Expanded Access treatment. Contact name at phone number if there is no answer at that phone number or if you are calling after normal business hours.

You may also call 617-358-5372 or email [medirb@bu.edu](mailto:medirb@bu.edu). You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research and Expanded Access treatment. You should call or email the IRB if you want to find out about your rights. You should also call or email if you want to talk to someone who is not part of the Expanded Access treatment about your questions, concerns, or problems.

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| **1. SIGNATURE OF PATIENT – NO LARs** – delete this box from submitted consent form |

**Patient:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of patient

By signing this consent form, you are indicating that

* you have read this form (or it has been read to you)
* your questions have been answered to your satisfaction
* you voluntarily agree to participate in this Expanded Access treatment
* you permit the use and sharing of information that may identify you as described including your health information.

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

Signature of patient Date

**Person Conducting Consent Discussion:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person conducting consent discussion

I have personally explained the Expanded Access treatment to the above-named patient and answered all questions. I believe that the patient understands what is involved in the Expanded Access treatment and freely agrees to participate.

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

Signature of person conducting consent discussion Date

[For the enrollment of limited- and non-readers, studies that are greater than minimal risk must either include a plan to have an impartial witness who is present throughout the consent process, or propose some other method, such as a quiz or a “teach-back” process, to ensure comprehension. Include if a witness is the method that will be used to ensure comprehension by limited- and non-readers; otherwise, delete all text below] *To be completed by witness if person conducting consent discussion reads this form to the patient*

This consent form was read to and apparently understood by the patient in my presence.

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

Printed name of witness (a person not otherwise associated with the Expanded Access treatment)

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

Signature of witness Date

NOTE: THE PRINCIPAL INVESTIGATOR MUST KEEP THE ORIGINAL SIGNED, DATED CONSENT FORM [Include unless the requirement to provide the patient with a copy of the consent form is specifically waived or modified by the IRB; if this requirement has been waived or modified, please delete] AND MUST DOCUMENT THAT A COPY OF THE CONSENT FORM WAS GIVEN OR OFFERED TO THE PARTICIPANT

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| **2. SIGNATURE WITH LARs** – edit depending on whether all signatures are by LARs or whether some signatures are by patients – delete this box from submitted consent form |

**Patient:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of patient

By signing this consent form, you are indicating that

* you have read this form (or it has been read to you)
* your questions have been answered to your satisfaction
* you voluntarily agree to participate in this Expanded Access treatment
* you permit the use and sharing of information that may identify you as described, including your health information.

[Include if some patients may consent for themselves; otherwise, delete through *To be completed by LAR if patient does not personally sign*] *To be completed by patient if personally signing*

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

Signature of patient Date

*To be completed by LAR if patient does not personally sign*

I am providing consent on behalf of the patient.

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

Printed name of Legally Authorized Representative (LAR) Relationship to Patient

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

Signature of Legally Authorized Representative Date

**Person Conducting Consent Discussion:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person conducting consent discussion

[Include if some patients may consent for themselves; otherwise, delete through “*To be completed by person conducting consent discussion if person conducting consent discussion does not personally sign”*] *To be completed by person conducting consent discussion if patient personally signs*

I have personally explained the Expanded Access treatment to the above-named patient and answered all questions. I believe that the patient understands what is involved in the Expanded Access treatment and freely agrees to participate.

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

Signature of person conducting consent discussion Date

*To be completed by person conducting consent discussion if patient does not personally sign*

I have personally explained the Expanded Access treatment to the above-named patient’s Legally Authorized Representative and answered all questions. I believe that the Legally Authorized Representative understands what is involved in the Expanded Access treatment and freely agrees to have the patient participate. [Include if some patients are capable of providing assent; otherwise delete sentence and two checkboxes – retain signature of person conducting consent discussion] I consider that the above-named patient (check one):

 is capable of understanding what is involved in the Expanded Access treatment and freely agrees to participate.

 is not capable of understanding what is involved in the Expanded Access treatment.

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

Signature of person conducting consent discussion Date

[For the enrollment of limited- and non-readers, studies that are greater than minimal risk must either include a plan to have an impartial witness who is present throughout the consent process, or propose some other method, such as a quiz or a “teach-back” process, to ensure comprehension. Include if a witness is the method that will be used to ensure comprehension by limited- and non-readers; otherwise, delete all text below] *To be completed by witness if person conducting the consent discussion reads this form to the patient/LAR*

This consent form was read to and apparently understood by the patient/Legally Authorized Representative in my presence.

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

Printed name of witness (a person not otherwise associated with the Expanded Access treatment)

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

Signature of witness Date

NOTE: THE PRINCIPAL INVESTIGATOR MUST KEEP THE ORIGINAL SIGNED, DATED CONSENT FORM [Include unless the requirement to provide the patient with a copy of the consent form is specifically waived or modified by the IRB; if this requirement has been waived or modified, please delete] AND MUST DOCUMENT THAT A COPY OF THE CONSENT FORM WAS GIVEN OR OFFERED TO THE PARTICIPANT

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| **3. SIGNATURE OF PATIENT – NO LARs – LIMITED- AND NON-READERS EXCLUDED** – delete this box from submitted consent form |

**Patient:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of patient

By signing this consent form, you are indicating that

* you have read this form
* your questions have been answered to your satisfaction
* you voluntarily agree to participate in this Expanded Access treatment
* you permit the use and sharing of information that may identify you as described, including your health information.

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

Signature of patient Date

**Person Conducting Consent Discussion:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person conducting consent discussion

I have personally explained the Expanded Access treatment to the above-named patient (who has read this consent form) and answered all questions. I believe that the patient understands what is involved in the Expanded Access treatment and freely agrees to participate.

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

Signature of person conducting consent discussion Date

NOTE: THE PRINCIPAL INVESTIGATOR MUST KEEP THE ORIGINAL SIGNED, DATED CONSENT FORM [Include unless the requirement to provide the patient with a copy of the consent form is specifically waived or modified by the IRB; if this requirement has been waived or modified, please delete] AND MUST DOCUMENT THAT A COPY OF THE CONSENT FORM WAS GIVEN OR OFFERED TO THE PARTICIPANT

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| --- |
| **4. SIGNATURE WITH LARs – LIMITED- AND NON-READERS EXCLUDED** – edit depending on whether all signatures are by LARs or whether some signatures are by patients – delete this box from submitted consent form |

**Patient:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of patient

By signing this consent form, you are indicating that

* you have read this form
* your questions have been answered to your satisfaction
* you voluntarily agree to participate in this Expanded Access treatment
* you permit the use and sharing of information that may identify you as described, including your health information.

[Include if some patients may consent for themselves; otherwise, delete through “*To be completed by LAR if patient* ***does not personally sign****”*] *To be completed by patient if personally signing*

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

Signature of patient Date

*To be completed by LAR if patient does not personally sign*

I am providing consent on behalf of the patient.

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

Printed name of Legally Authorized Representative (LAR) Relationship to Patient

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

Signature of Legally Authorized Representative Date

**Person Conducting Consent Discussion:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person conducting consent discussion

[Include if some patients may consent for themselves; otherwise, delete through “*To be completed by person conducting consent discussion if patient does not personally sign”*] *To be completed by person conducting consent discussion if patient personally signs*

I have personally explained the Expanded Access treatment to the above-named patient (who has read this consent form) and answered all questions. I believe that the patient understands what is involved in the Expanded Access treatment and freely agrees to participate.

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

Signature of person conducting consent discussion Date

*To be completed by person conducting consent discussion if patient does not personally sign*

I have personally explained the Expanded Access treatment to the above-named patient’s Legally Authorized Representative (who has read this consent form) and answered all questions. I believe that the Legally Authorized Representative understands what is involved in the Expanded Access treatment and freely agrees to have the patient participate. [Include if some patients are capable of providing assent; otherwise delete sentence and two checkboxes – retain signature of person conducting consent discussion] I consider that the above-named patient (check one):

 is capable of understanding what is involved in the Expanded Access treatment and freely agrees to participate.

 is not capable of understanding what is involved in the Expanded Access treatment.

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

Signature of person conducting consent discussion Date

NOTE: THE PRINCIPAL INVESTIGATOR MUST KEEP THE ORIGINAL SIGNED, DATED CONSENT FORM [Include unless the requirement to provide the patient with a copy of the consent form is specifically waived or modified by the IRB; if this requirement has been waived or modified, please delete] AND MUST DOCUMENT THAT A COPY OF THE CONSENT FORM WAS GIVEN OR OFFERED TO THE PARTICIPANT