**Sample Only (revised 02/23/21)– Cannot be used without IRB Approval**

**TITLE:** [***The title of the expanded access plan must match the title in your application and on your master protocol, if applicable.***]

**PRINCIPAL INVESTIGATOR:** [*PI* *Name*]

 [*PI Address*]

**CO-INVESTIGATOR(S):** [*Name(s)*]

[***TAKE NOTE****:*

* *The consent form should be written to conform to the UTHSC IRB template in regard to headings, format, and content. Additional content from the sponsor is allowable for review in the event that it is not repetitive of template content, and this content should be placed at the end of each applicable section.*
* ***Lay terms*** *or explanations must be used for all medical terms (consult our lay term glossary at* [*http://www.uthsc.edu/research/compliance/irb/researchers/consent-forms.php*](http://www.uthsc.edu/research/compliance/irb/researchers/consent-forms.php) *). Sentence structure should be simple. Do not use abbreviations such as “e.g.” and “i.e.”, difficult-to-understand prepositions such as “via”*, or *symbols such as “+”.*

**1. KEY INFORMATION**

[*If the treatment/compassionate use includes ONLY children 7 years old and younger, simply write the consent form addressing the parent/legal guardian (ex: “your child”).*  In this consent form “your child” always refers to the patient receiving the investigational treatment.

[***OR***]

[*If the treatment/compassionate use includes any children 8 years of age and older, OR any adults who cannot consent for themselves, edit and include the following:*] In this consent form “you” refers to the patient receiving the investigational treatment [and/or] [*choose:* the parent/legal guardian and/or the legally authorized representative].

[***OR***]

[*If the expanded access treatment does not include either of the above populations, no statement is needed as the consent form should be written in the second person addressing the adult patient as “you”.*]

[*Any treatment/compassionate use should include the following:*]

You are being given the opportunity to receive an investigational [choose: drug, biologic, or device]. The purpose of this consent form is to help you decide if you want to receive this treatment. Please read the form carefully and discuss with others before making any decisions.

Please ask questions about anything you do not understand.

[ *State the name of the disease or condition for which the investigational treatment is being provided*. *Include a statement that, in the physician’s opinion, the patient does not have any alternative Food and Drug Administration (FDA)-approved medical product available to them that has as favorable a risk-benefit ratio.*]

You have been diagnosed with disease X. The Food and Drug Administration (FDA)-approved drug or drugs available for your treatment have not worked in treating your illness. **OR** You have not been able to tolerate the side-effects of the drug or drugs approved by the Food and Drug Administration (FDA) for treatment of your condition. **OR** For your condition, there is no drug approved by the Food and Drug Administration (FDA) for use in routine medical care in the United States.

[*Indicate the name of the investigational drug/biologic or device. Explain that the product is investigational, has not been approved by the FDA as safe and effective, and that its use is experimental. State that the use of the product may only proceed under the FDA’s expanded access program with FDA authorization.*]

Drug P is an investigational drug that may be useful in treating your disease. It is not currently approved by FDA as safe and effective for the treatment of your disease, and its use is considered experimental. However, the FDA has authorized your physician to treat you with the investigational drug P under FDA’s expanded access program because prior studies suggest that it may offer benefit in treating your condition.

**Procedures:**

[*Provide in lay terms a basic description of the design of the treatment plan. Describe the length of time the treatment will last (e.g., hours, days, weeks, months, years, or until a certain event), as well as long-term follow-up, if appropriate.*]

Drug P will be administered through an IV line twice a week for four weeks or until your liver enzymes return to normal. You will need to come to the clinic in the morning for the infusion. We will observe you for any reactions to the drug for three hours after infusion of the drug is completed. You will be able to leave the clinic after the observation period is completed.

[*All expanded access treatment consent forms should include the following:*]

For a detailed explanation of the procedures, refer to the section of this consent form entitled, DETAILED PROCEDURES TO BE FOLLLOWED.

**Risks:**

[*Describe in lay terms the most common (highest in frequency) physical risks of the treatment procedures (including drug/device administration) and the most serious physical risks (greatest in magnitude), even if the latter rarely occur. For example:*]

Some of the most common side effects from the investigational drug are dry mouth, itchiness, joint pain, nausea and fatigue. This drug could also cause heart damage and death, but these rarely occur.

**Benefits:**

[*In simple language, indicate the possible benefit for the patient in receiving the investigational product.*]

Your physician would like to provide you with the investigational treatment because she believes that it may result in improvement of your condition. However, there is no guarantee that you will benefit from this investigational treatment. It is possible that you will receive no benefit other than that associated with regular monitoring of your condition and your response to treatment.

**Alternatives:**

[*Explain that patients cannot receive the investigational treatment outside the expanded access program and that the doctor has determined that there is no comparable or satisfactory therapy to diagnose, monitor or treat the condition. However, note that medical treatment will be provided for the disease or condition whether or not the patient chooses to receive the investigational product. For example:*]

Because the [*choose*: drug, biologic, device] is an unapproved investigational treatment, it is only available through the FDA’s expanded access program. You will not be able to receive it outside this program. Your physician has determined that there is no comparable or satisfactory therapy available to treat your condition. However, if you decide that you do not want to receive it, your physician will discuss with you other options for managing your condition. You will receive medical treatment whether or not you participate in the expanded access program.

**Voluntary Participation:**

[*Include the following statements:*]

Your participation in the expanded access program is voluntary. You may decide not to participate or you may decide to discontinue the investigational treatment at any time. Your decision will not change your other medical care in any way or otherwise result in any penalty or loss of benefits to which you are entitled. If your decision changes, you should contact the physician.

 **2. DETAILED PROCEDURES TO BE FOLLOWED:**

[*Include specific location(s) and the corresponding addresses at which the treatment will be performed.*]

Your treatment will take place at \_\_\_\_\_.

[*In simple language, using a bullet point format with headers or a table, explain the following:*

* *The tests and procedures that will be done (including medical record abstraction)*
* *Which procedures/drugs are standard of care and which are part of the protocol for expanded access to the investigational product*
* *If treatment procedures will occur at a standard of care visit, indicate how much additional time will be required to complete the investigational treatment procedures*
* *The amount of blood to be drawn at each visit (in teaspoons/tablespoons) and the total amount of blood to be drawn during the entire treatment period (in teaspoons/tablespoons)*
* *Estimate the time required of the patient for each visit*

*For example:*]

Day 1/Visit 1 (1 hour 30 minutes):

* Electrocardiogram (EKG), a tracing of the electrical activity of your heart
* 2 tablespoons of blood will be drawn from your arm by needle stick for [*kind of* *blood tests*]
* Information such as your age, weight, height, and medical history such as [previous heart attacks] will be copied from your medical record

Day 2/Visit 2 (2 hours 30 min.):

* Complete a questionnaire
* You will receive the investigational drug intravenously (into your vein) for 2 hours

**3. RISKS ASSOCIATED WITH TREATMENT:**

[*In simple language and in simple bullet format (whenever possible), explain the possible risks and discomforts, including:*

* *Potential risks of the investigational treatment, as well as known risks of other diagnostic and monitoring procedures that are part of the expanded access program;*
* *If applicable, psychological, social, or economic risks; and*
* *Only include the risks associated with procedures and/or treatments being performed solely because the patient is participating in this expanded access program. Risks of standard of care procedures that would normally be performed even if the subject were not participating in the expanded access treatment should not be included in the consent form.*]

[*Start with the potential side effects of the investigational treatment. To the extent possible, risks of harm or discomfort should be characterized as to their probabilities of occurrence, potential seriousness, duration, and reversibility. You may do this in 1 of the following 2 ways:*

* *If you can state the percentage of occurrence for each risk, the use of categories is not necessary. However, you should list the risks in bullet format and in descending order, with the most frequently occurring risks first and so on;* ***OR***
* *You may use categories of risk: The current UTHSC guidelines for risk categories include Very Rare, less than 1%; Rare, 1 to 5%; Occasional, 6 – 20%; Common, 21 – 50%; and Very Common, 51 to 100%. One of these categories should be used for each potential risk with the corresponding range of percentages. For example:*]

All drugs can have side effects. Although not all or none of these side effects may occur, if they do occur, they may need medical attention. You must notify your physician about all symptoms, side effects, complaints, illnesses, or injuries which you experience during the course of your treatment regardless of whether or not you think these are related to the investigational drug. You should discuss these with your study doctor as well as your regular health care provider, if you choose.

As a result of your participation in the expanded access program, you are at risk for the following side effects.

[***Investigational Product Name***] may cause some, all, or none of the side effects listed below.

Very Common (51-100%)

Occasional (6-20%)

[***Include the following 2 paragraphs for all expanded access treatments:***]

There is a risk that your private identifiable information may be seen by people not involved in your medical care (such as if the physician’s computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets and computer passwords) to minimize the chance that any unauthorized persons might see your confidential information.

Use of the investigational treatment may involve risks to you [*if applicable,* *add:* or to the embryo or fetus, if you are or may become pregnant,] which are currently unforeseeable. You will be told about any new information that might change your decision to receive the treatment. You may be asked to sign a new consent form if this occurs.

[***If any of the following procedures will be performed as part of the expanded access treatment, use the following template language:***]

**Blood Draw:**

Risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, lightheadedness, and/or fainting are also possible, although unlikely.

**Intravenous Line (IV):**

There is a slight chance that multiple needle-sticks will be necessary to make sure the IV is placed correctly. You might feel a small amount of pain when the IV is placed but it does not last very long. A bruise or a minor infection might develop where the IV is placed.

**Computed Tomography (CT) Scan:**

The treatment plan requires that you have computed tomography (CT) of your [*insert body part*]. The CT scan involves low doses of radiation.

[*Indicate the amount of radiation to which patients may be exposed by comparing it to the level of radiation that people experience on a regular basis, such as daily exposure to the background radiation in nature. For more information about radiation dose assessments go to* [*http://www.doseinfo-radar.com/RADARDoseRiskCalc.html*](http://www.doseinfo-radar.com/RADARDoseRiskCalc.html)*. For example:*]

The total amount of radiation per scan is 5mSv (millisievert). A millisievert is a unit of measure of radiation dose. This amount is less than the radiation exposure from 2 mammograms.

[*If appropriate, include the potential risks and discomforts of contrast agents and sedation. For example*:]

You may be given an injection of a contrast liquid in your vein to allow the radiologist to obtain clearer images of your organs. The contrast dye may cause nausea or vomiting, sneezing, itching, or hives.

You may hear a slight buzzing, clicking, and/or whirring sound as the CT scanner moves around your body.

If you wear or have an electronic medical device, such as a pacemaker or a drug pump, please make sure you tell your doctor and health care staff. The Food and Drug Administration (FDA) has reported that CT scans may interfere with electronic medical devices such as pacemakers, defibrillators, neurostimulators, and implanted or externally worn drug infusion pumps. In the reports received by the FDA, CT scans may have caused unintended “shocks” from the neurostimulators, errors in insulin infusion pumps, and brief changes in pacemaker output pulse rate.

**DEXA:**

The treatment plan involves exposure to radiation from a DEXA whole body scan. This procedure involves minimal risk. The radiation dose from the whole body scan that will be performed during the your treatment is approximately 2 to 10 microsieverts. A microsievert is a unit of measure of radiation dose.  This scan provides about the same amount of radiation exposure as you would receive from exposure to natural sources of radiation in one day.

**Drug Screening:**

You will undergo screening for illicit (street) drug(s). If others find out you have tested positive for illegal drugs, it may cause mental stress, unfair treatment from other people, problems with getting insurance or finding a job, legal difficulties, or other unknown problems. It is important to seek medical care if you have a drug abuse problem. [*Edit the following sentence according to your current procedure; i.e., indicate whether results will or will not be placed in the medical record.*] The information about your test result will be placed in your medical record.

[*If the subject is a minor and the result of the drug test will be shared with the parent/LAR, include a statement using simple terms regarding the potential psychological distress and familial conflict that may occur as a result of receiving the results of a positive drug test, and if applicable, indicate that referrals for counseling will be provided.*]

You will undergo screening for illicit (street) drug(s). A positive test result will be shared with your parents/LAR. This may cause you psychological distress and create familial tension and conflicts. It is important to seek medical care if you have a drug abuse problem.

**ECG:**

The pads placed on your chest for the ECG may cause a mild allergic reaction.

**Fasting:**

The potential discomforts associated with fasting are minor and include dizziness, headache, stomachache, or fainting.

**HIV/Sexually Transmitted Disease Testing:**

You will be tested for HIV (AIDS virus) [or Hepatitis, etc.] during your treatment. If the test results are positive, you will be informed and referred for appropriate counseling.  You may experience some psychological distress (become sad, angry, anxious) if you test positive and did not know you had this disease. [*Edit the following sentence according to your current procedure; i.e., indicate whether results will or will not be placed in the medical record.*] The information about your test result will be placed in your medical record.  In accord with state law, a positive result for a sexually transmitted disease must be reported to the Tennessee Department of Health.

[**If the investigational product is taken home, insert this or similar language:**]

Only you should take the investigational drug. It must be kept out of reach of children or anyone else who may not be able to read or understand the label.

**MRI:**

There are no known major risks with an MRI scan. But it is possible that harmful effects could be found in the future. Even though the tunnel is open, it may bother you to be placed in a tight space (claustrophobia), and to hear the noise made by the magnet during the scan. You will be given earplugs to reduce the noise. You may also feel the table vibrate and/or move slightly during the scan. It may be hard to lie on the table during the scan. You are at risk for injury from the MRI magnet if you have a pacemaker or other implanted electrical devices, brain stimulators, dental implants, aneurysm clips (metal clips on the wall of a large artery), metallic prostheses (including metal pins and rods, heart valves, and cochlear implants), permanent eyeliner, implanted delivery pump, or shrapnel fragments. Welders and metal workers are also at risk for injury because of possible small metal fragments in the eye of which they may be unaware. You will be screened for these conditions prior to the procedure, and if you have any of these conditions, you will not receive an MRI scan. If you have any metal pieces in your body, they could move during the scan and damage nearby tissues or organs, so you must tell your doctor before the scan if you have any metal pieces in your body.

**Pregnancy Risks for Females:** [*The following paragraphs should be included if there is a risk to either the mother or fetus sufficient to exclude pregnant females from the investigational treatment or to avoid pregnancy during the course of treatment*.]

Females who are pregnant or nursing a child may not receive the investigational treatment.  If you are a female and are able to become pregnant, you will have a [*insert the appropriate method:* blood *or* urine] test to make sure that you are not pregnant before you receive treatment.

If you choose to receive the investigational treatment, you must use birth control such as:

* sexual abstinence;
* birth control pills, birth control shots, IUD, birth control implants (placed under the skin by a health care provider), or patches (placed on the skin);
* sexual activity with a male partner who has had a vasectomy (surgery to become sterile); OR
* 2 forms of birth control, such as condom/diaphragm AND spermicidal foam or gel.

You must also use this birth control for at least \_\_ days after your last dose of the investigational treatment.

[*If the patient is a minor and the result of the pregnancy test will be shared with the parent/LAR, include a statement using simple terms regarding the potential psychological distress and familial conflict that may occur as a result of having a positive pregnancy test, and if applicable, indicate that referrals for counseling and/or obstetric services will be provided.*]

You may experience some psychological distress (become sad, angry, anxious) if you have a positive pregnancy test and did not know you were pregnant. A positive test might also cause stress and conflict within your family. Referrals for counseling and/or obstetric services will be provided if you need them.

[*The following paragraph should also be included if there is a risk of reducing the effectiveness of hormonal birth control due to the investigational product*.]

Taking \_\_\_\_ may reduce the effectiveness of your oral hormonal birth control (in other words, birth control pills). If you use oral hormonal birth control, you must use an additional, non-hormonal form of birth control, such as condom/diaphragm AND spermicidal foam or gel, while you are taking \_\_\_\_\_, and for \_\_\_\_ days after you stop taking \_\_\_\_.

If you think that you have become pregnant while receiving the investigational treatment, you should tell your physician immediately.

**Pregnancy Risks for Males**: [*The following paragraph should be included if there is a risk to either the mother or fetus sufficient to avoid fathering a child during the course of expanded access treatment.*]

Males should not get a sexual partner pregnant while taking the investigational treatment [*If applicable also add the following:*] and for [*specify amount of time*] after the last dose. In addition, you must also avoid sperm donation while being treated and for at least [*specify amount of time*] after your last dose. The effect of the drug on sperm is not known.

If you decide to take the investigational treatment, you must agree to use birth control such as sexual abstinence, vasectomy, or two methods of birth control (for example, condom or diaphragm AND spermicidal foam or gel) during treatment and for at least \_*\_\_\_* days after your last dose. You should tell your partner of the potential for harm to an unborn child. She should know that if pregnancy occurs, you will need to report it to your doctor, and she should also promptly notify her physician.

**Questionnaires/Surveys:** [*If the expanded access protocol includes questionnaires/surveys with sensitive questions, then include the following:*]

Completion of the \_\_\_\_\_\_\_\_\_ may make you feel uncomfortable or cause troublesome feelings or emotions. You may refuse to answer any of the questions and you may take a break at any time while completing the questionnaires.

**Radiological Procedures:**

A part of the plan for using the investigational treatment requires you to have [*name of procedure, e.g., a chest x-ray*] performed. [*Indicate the amount of radiation to which patients may be exposed by comparing it to the level of radiation that people experience on a regular basis, such as daily exposure to the background radiation in nature. For more information about radiation dose assessments go to* [*http://www.doseinfo-radar.com/RADARDoseRiskCalc.html*](http://www.doseinfo-radar.com/RADARDoseRiskCalc.html)*. For example:*]

The total amount of radiation you will receive is about the same as you would receive from exposure to about 1 day of natural sources of radiation.

**Videotaping/Photography/Audio Recording:** [*Edit the following sentence according to which procedure(s) you will include in the expanded access treatment:*]

Having your photograph taken, your voice recorded, and being videotaped may make you feel uncomfortable. You may take a break any time. There is also a potential risk of loss of confidentiality if someone who views your video and photograph or listens to your audio recording identifies you.

**Previously Unknown Medical Conditions or Genetic Risk Susceptibilities:**

[*If results of tests using the specimens are relevant to the health of patients and may be returned to them, then indicate that disclosure of the results may have adverse psychological and social consequences. For example*:]

If test results show that you are positive for \_\_\_\_\_ and you are made aware of this result, it may cause mental stress, unfair treatment from other people, or other unanticipated problems.

[*OR*]

Genetic testing may reveal that you are at increased risk for [breast cancer] compared to the general population.

 **4. CONFIDENTIALITY:**

**Treatment records/specimens**

[*Explain how paper treatment records will be maintained. For example:*]

All your paper treatment records will be stored in locked file cabinets and will be accessible only to health care personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

[*Explain how electronic treatment records will be maintained. For example:*]

All your electronic treatment records will be computer password protected and accessible only to health care personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

[***OR***]

All your electronic treatment records will be kept on an encrypted computer where your information is replaced with a code and password only known to health care personnel, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

[*If the expanded access treatment plan includes collection of specimens that will be maintained at the local site, explain whether or not the specimens will be labeled with a code. For example:*]

Your [tissue, blood, etc.] sample will be labeled with a code.

[***OR***]

Your [tissue, blood, etc.] sample will be labeled with your [name, social security number, etc.].

[*If any individual records or specimens will be transmitted during the expanded access treatment, explain whether or not the data and/or specimens will contain identifiers, be sent using an encrypted method, or be labeled with a code. For example:*]

Your identifiable treatment records will be transmitted to [name of the sponsor of the expanded access program] using an encrypted method (not regular email), where your information is replaced with a code and password only known to the entities below). [***OR***] Your treatment records will be transmitted to [name of the sponsor of the expanded access program] and will be labeled with a code (will not contain any identifiable information about you).

Your [tissue, blood, etc.] will be transmitted to [name of the sponsor of the expanded access program] and will be labeled with a code. [***OR***] Your identifiable [tissue, blood, etc.] will be transmitted to [name of the sponsor of the expanded access program].

[*If coded treatment records or specimens will be sent to an external site(s), explain whether or not the master key/list that links the patient’s name with the code will be maintained at the local treatment site.*]

A master key/list which links your name with the code on your [treatment record and/or specimen] will be maintained at [name of the local treatment site].

**Medical Records**

[*Explain whether documentation of participation in the expanded access program, such as a copy of the consent form or other notation, will be placed in the patient’s medical record.* ***Note****: If the treatment will take place at Regional One Health, University Clinical Health, or Methodist/Le Bonheur facilities, these institutions require that a copy of the consent form be filed in the patient’s medical record. For example:*]

Information about your treatment with the investigational drug or the results of procedures performed will be placed in your medical record.  As such, it may be available to your insurer.  However, it will not be available to your employer, except with your explicit authorization and/or as permitted by law.

 [***OR***]

Information about your treatment with the investigational drug or the results of procedures will not be placed in your medical record.

**GINA**

[*For expanded access treatment that requires genetic analysis that may reveal the genetic susceptibility of patients or others to health problems of which they are currently unaware or from which they do not presently suffer, add the following paragraph.*]

A federal law, called the Genetic Information Nondiscrimination Act (GINA), provides additional protections for the genetic information about you that may be discovered during your treatment. GINA makes it illegal for a health insurer to request or use any genetic information about you to make decisions about your eligibility for coverage or your premiums. The law also prevents employers with 15 or more employees from using genetic information to make decisions about hiring, promoting, or firing you. The protections of the law do not apply to insurers providing life, disability, or long-term care insurance.

**Presentations/Publications**

[*Explain whether or not individual patients will be identified in any presentations or publications based on the expanded access program. For example:*]

While individual details about your case might be provided in publications or presentations about the use of the investigational treatment, they will not be discussed in a way that would allow you to be individually identified as a patient.

[*For industry-sponsored expanded access programs, include the following:*]

A description of the sponsor’s expanded access program may be available on <http://www.ClinicalTrials.gov> or the Expanded Access Navigator website at https://navigator.reaganudall.org/expanded-access-navigator or on the sponsor’s website.

**Limits to Confidentiality**

[*Explain any limits to confidentiality. For example:*]

Information obtained during the course of your treatment which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others, may be reported to a third party to protect the rights and welfare of those at potential risk.

**Authorization to Use and Disclose Protected Health Information for Investigational Purposes**

[*NOTE: This must* ***not*** *be altered with sponsor language, as sponsors are not covered under the HIPAA regulations.*]

Under federal privacy regulations, you have the right to decide who can review and copy your identifiable health information (called “protected health information” or PHI). PHI collected during your treatment may include information such as:

* Past and present medical records
* Records about your treatment visits
* Records about phone calls made as part of your treatment
* Records about your treatment with the investigational product

By signing this consent form, you are giving your permission for your doctor and the health care staff to get your PHI from doctors and/or facilities where you have received health care. They may also share your PHI with:

[*Edit this list as it applies to the expanded access treatment program:*]

* The Institutional Review Board (IRB) at the University of Tennessee Health Science Center
* [*because the treatment/compassionate use involves an FDA-regulated drug/device/biologic, add*] The US Food and Drug Administration (FDA)
* [*if treatment procedures will be billed to the subject’s insurance, add*] Your medical insurance provider
* [*if treatment procedures are taking place at both Methodist and Le Bonheur, add*] Methodist Le Bonheur Healthcare
* [*if treatment procedures are taking place at Le Bonheur Children’s Hospital add*] Le Bonheur Children’s Hospital
* [*if treatment procedures are taking place at Methodist Hospitals, add*] Methodist Healthcare-Memphis Hospitals
* [*if treatment procedures are taking place at Regional One Health, add*] Regional One Health
* [*if treatment procedures are taking place at University Clinical Health, add*] University Clinical Health
* [*if treatment procedures are taking place at a UT Le Bonheur Pediatric Specialists facility, add*] UT Le Bonheur Pediatric Specialists, Inc.
* [*if the expanded access program has a sponsor other than the physician-investigator, add*] [name of sponsor], which sponsors and provides funds for your treatment

[*If you included a commercial sponsor above you must add:*] However, the sponsor listed above does not have the same obligations to protect your PHI.

Your PHI will only be used and/or given to others:

* To provide you with the investigational treatment
* To study the results of your treatment
* To see if the treatment was provided correctly

[*Provide an expiration date for the authorization:*]

Your PHI will be used for as long as the sponsor reports information about the investigational treatment to the FDA.

You may withdraw or take away your permission to use and disclose your PHI at any time. You do this by sending written notice to the investigator listed above. If you withdraw your permission, you may not be able to continue to receive the investigational treatment.

When you withdraw your permission, no new PHI will be gathered after that date. However, information that has already been gathered may still be used and given to others. The federal regulations allow you to review or copy your PHI that is gathered during your treatment.

**Certificate of Confidentiality**

[*If your expanded access treatment includes a Certificate of Confidentiality issued by the FDA, add the following:*]

This treatment is covered by a Certificate of Confidentiality from FDA. This means that the health care team may not disclose or use information [*if using or collecting them as part of the treatment plan, add:* or biospecimens] that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. The health care team may disclose information, documents [*if using or collecting them as part of the treatment plan, add:* or biospecimens] protected by this Certificate when: (1) disclosure is required under federal, state or local laws, for example, to report elder abuse, some communicable diseases, or threats of harm to yourself or others, (2) disclosure is necessary for FDA oversight of the expanded access program, (3) the information will be used in medical research allowed under federal regulations, or (4) it is necessary for the medical treatment to which you are consenting. The Certificate of Confidentiality also does not prevent you from voluntarily releasing information about yourself or your involvement in this expanded access treatment. If you want your information released to an insurer, medical care provider, or any other person not connected with the treatment program, you must provide consent to allow the health care team to release it.

 **5. COMPENSATION AND TREATMENT FOR INJURY:**

[*All expanded access treatment MUST include the statements in this section. If sponsors have different liability or reimbursement language, this can be added after all of UTHSC’s required liability language and can be separated by subheaders if preferable (e.g., “UTHSC’s statements”; “Sponsor X’s statements”.*]

[*All consent forms must include 1 of the 2 following paragraphs. If you are providing the expanded access treatment at any of the additional sites/organizations in the list below, you must name all of them in each of the 3 sentences of the template paragraph, using only one paragraph. This language should NOT be edited otherwise.*

* *when both Methodist & Le Bonheur are involved, also include:* Methodist Le Bonheur Healthcare
* *when only Methodist hospitals are involved, also include:* Methodist Healthcare-Memphis Hospitals
* *when only Le Bonheur Children’s hospital is involved, also include:* Le Bonheur Children’s Hospital
* Regional One Health
* University Clinical Health
* UT Regional One Physicians
* UT Le Bonheur Pediatric Specialists, Inc.
* UT Methodist Physicians Group
* Methodist Medical Group

[*Use when NONE of the additional institutions in the above list is involved*:]

You are not waiving any legal rights or releasing the University of Tennessee or its agents from liability for negligence. In the event of physical injury resulting from treatment procedures, the University of Tennessee does not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee does not provide for treatment or reimbursement for such injuries.

***OR***

[*Use when ONE or MORE institutions in the above list is involved*]

You are not waiving any legal rights or releasing the University of Tennessee, [*name each additional institution*], or the agents thereof, from liability for negligence. In the event of physical injury resulting from treatment procedures, the University of Tennessee and [*name each additional institution again*] do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and [*name each additional institution again*] do not provide for treatment or reimbursement for such injuries.

[*Edit the 2nd statement below to indicate whether the doctor will provide the medical treatment to patients in case of an injury related to the investigational treatment, provide acute treatment and refer, or just provide a referral. For example*:]

If you are injured or get sick as a result of receiving the investigational treatment, call your doctor immediately. The doctor will provide acute medical treatment, and will provide you with a subsequent referral to appropriate health care facilities.

[*For all expanded access treatment, include the following sentence. This language should NOT be edited.*:]

If you are injured or get sick as a result of receiving this investigational treatment, you and/or your insurance will be billed for the costs associated with treatment for your injury or illness.

[*For all expanded access treatments, include the following sentence. This language should NOT be edited.*]

No compensation will be available to you for any extra expenses that you may have as the result of physical injuries from the investigational treatment, such as additional hospital bills, lost wages, travel expenses, etc*.*

[*For all expanded access treatments, include the following sentence. This language should NOT be edited.*]

No compensation will be available to you for any non-physical injuries that you may have as a result of receiving the investigational treatment, such as legal problems, problems with your finances or job, or damage to your reputation.

[*In addition to the UTHSC statements above, if the sponsor may reimburse part or all of these costs associated with the treatment of an injury related to the investigational treatment, indicate this and any exceptions/limitations. (You may use a separate subheader above the sponsor statements if preferable.) For example*:]

If you have followed the instructions of the doctor providing the investigational treatment, [name of the sponsor] will reimburse you, your insurance company, and/or the hospital for any costs of the treatment of your injury or illness related to the investigational treatment.

 **6. QUESTIONS:**

Contact [name] at [number(s)] if you have questions about your participation in this expanded access program, or if you have questions, concerns, or complaints about your treatment.

If you feel you have had an injury or a reaction to the investigational treatment, contact [name of the principal or co-investigator] at [must be a 24-hour/7-day telephone number(s)]. [***Note****: explain whether the 24-hour/7-day telephone number is an answering service, office number, pager, etc.*]

You may contact Cameron Barclay, MSA, UTHSC IRB Director, at 901-448-4824, or visit the IRB website at <http://www.uthsc.edu/research/compliance/irb/> if you have any questions about your rights as a patient in the expanded access program, or if you have questions, concerns, or complaints about your treatment.

 **7. COSTS OF PARTICIPATION:**

[*Explain whether there are any costs to the patient or his/her parent/legal guardian or his/her legally authorized representative. If there are, explain whether insurance will be billed and who will pay if insurance does not.*]

There are no costs to you for receiving the investigational treatment. [*If applicable, include the following statements:*] [Sponsor Name] will provide the investigational [drug/biologic/device] free of charge. Tests and procedures that are done only as part of the treatment with the investigational product will not be billed to you or your insurance company.

[***OR***]

You or your insurance company may be billed for:

* [list costs as necessary]

[*If some or all of the costs associated with procedures being performed only as part of the treatment with the investigational agent will be billed to insurance, add:*]

You may want to talk with your insurance company about its payment policy for medical care or procedures performed as part of your treatment with the investigational product. If your insurance company does not pay, you may be billed for those charges.

 **8. CONFLICT OF INTEREST:**

[*Include this section in the consent form only if, with respect to the sponsor of the expanded access program, one of the individuals among the investigators (including their spouses, parents, or children) has:*

* *Received remuneration from a publicly traded entity in the previous 12 months preceding the disclosure, and/or possesses any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000; or*
* *Received remuneration from a non-publicly traded entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000, or when any individual among the key personnel holds any equity interest in that entity; or*
* *Held intellectual property rights and interests (patents, trademarks, or copyrights) in the drug, device, or other article being provided, and income related to such rights and interest has been received.*

***If no conflict of interest exists, do not include this section in your consent form****.*

*If a conflict of interest exists, insert the following statement:*]

Some patients want to know whether the investigators or other persons involved in providing the investigational treatment have a financial interest in the product or the company sponsoring the expanded access treatment. You should know that [name(s) of key personnel with conflict of interest] [*insert a brief description of the financial interest: e.g*., receives consulting fees from or holds the patent on the investigational product, or owns stock in *(insert name of company)*]which provides funds for this expanded access program.

 **9. FUTURE CONTACT:** [***Change this section to “8.” if you have no Conflict of Interest section***]

[*Include and edit the following paragraph if you wish to attempt to find patients lost to follow up.*]

If we lose contact with you during your treatment for any reason (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about your continued treatment; etc.), we will attempt to find you or make contact with you in the following ways:

* The phone number(s) you provided to us will be called, but if you are not the person who answers, we will not discuss the expanded access treatment or the fact that you are/were receiving it.
* Certified mail will be sent to you requesting that you call us.
* A letter will be sent to the address(es) you provided to us, but neither the return address nor any markings on the envelope will identify the expanded access treatment or the fact that you are/were receiving it.
* [*list any other ways that you stated in your application*]

Put your initials on one of the lines below:

\_\_\_\_\_\_\_We CAN attempt to find/contact you in the above ways.

\_\_\_\_\_\_\_We MAY NOT attempt to find/contact you in the above ways.

[*Include and edit the following paragraph if applicable to the expanded access treatment program.*]

Please note that if we lose contact with you and there is new information about the investigational treatment that could affect your safety, we will attempt to find you or make contact with you in any way possible.

[*Include and edit the following paragraph if you wish to retain patients’ contact information and PHI, including screening results, in order to contact them in the future regarding participation in research studies.*]

Sometimes we wish to keep your contact information, medical diagnosis, and other health information in order to contact you in the future and tell you about research studies in which you might be eligible to participate.

Put your initials on one of the lines below:

\_\_\_\_\_\_\_We CAN keep your contact information and health information to ask you about participating in future studies.

\_\_\_\_\_\_\_We MAY NOT keep your contact information and health information to ask you about participating in future studies.

 **10. CONSENT OF PATIENT:** [***Change this section to “9.” if you have no Conflict of Interest section***]

You have read or have had read to you a description of the investigational treatment as outlined above. The investigator or his/her representative has explained the treatment to you and has answered all the questions you have at this time. You knowingly and freely choose to receive the investigational treatment. A copy of this consent form will be given to you for your records.

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

**Signature of the Patient (18 years +)** **Date Time**

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

**Printed Name of Adult Patient**

[***If you are utilizing a Legally Authorized Representative for an incompetent adult patient, then the following 3 lines must be included here, above the Person Obtaining Consent lines:***]

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

**Signature of Legally Authorized Representative Date Time**

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

**Printed Name of Legally Authorized Representative**

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

**Relationship of Legally Authorized Representative**

[***If the investigational treatment involves adolescents as patients between the ages of 14-17, then the 5 following lines must be included here, above the Person Obtaining Consent lines:***]

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

**Assent of Minor (Ages 14-17) Date Time**

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

**Printed Name of Minor Patient (Ages 14-17)**

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

**Printed Name of Minor Patient (Ages 0-7)**

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

**Signature of Parent/Legal Guardian Date Time**

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

**Printed Name of Parent/Legal Guardian**

**Check Relationship to Minor:**

**[ ]  Parent**

**[ ]  Court-Appointed Legal Guardian**

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

**Signature of Person Obtaining Consent** **Date Time**

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

**Printed Name of Person Obtaining Consent**

In my judgment, the patient [*or parent/legal guardian or the legally authorized representative*] has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to receive the investigational treatment.

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

**Signature of Investigator** **Date Time**

[***Note****:* ***If the expanded access program includes children between the ages of 8-13, include the following Assent Discussion page as the last page of the consent form. You MUST retain the Assent header on that page which identifies its use with children ages 8-13. If your lower age limit for patients is greater than 8 and less than 13, please change both instances of “8-13” on the assent discussion page to your lower limit; for instance, “11-13.”***

***If the investigational treatment involves adults who do not have the ability to consent but may be able to provide assent, include the Adult Assent Discussion page as the last page of the consent form.***

***Delete the following pages if the expanded access treatment does not involve children between the ages of 8-13 or adults who do not have the ability to consent but may be able to provide assent.***]

**A. Assent Obtained:**

The assent discussion was initiated on \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (date) at \_\_\_\_\_\_\_\_\_\_ (time).

The information was presented in age-appropriate terms.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Minor Patient’s Printed Name (8-13 years) Minor Subject’s Date of Birth**

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

**Minor Patient’s Signature (8-13 years) Date Time**

**\* Please note that the parent/legal guardian must sign the consent signature page above.**

I hereby certify that I have discussed the investigational treatment with the minor patient and/or his/her parent/legal guardian. I have explained all the information contained in the informed consent document, including any risks that may be reasonably expected to occur. I further certify that the patient was encouraged to ask questions and that all questions were answered.

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

**Printed Name of Person Obtaining Assent**

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

**Signature of Person Obtaining Assent** **Date Time**

**B. Assent Not Obtained, but Minor Subject was Enrolled:**

Assent of the minor subject was NOT obtained for the following reason:

[ ]  Minor is cognitively or emotionally unable to participate in an assent discussion (e.g., minor has either a psychiatric or developmental disorder; minor received narcotics within the last 4 hours; minor is sedated; etc.). [*delete if option does not apply to the investigational treatment*]

[ ]  Minor refused to provide assent; however, the investigational treatment holds out a prospect of direct benefit that is important to the health or well-being of the minor and is available only in the context of the expanded access program [45 CFR 46.408(a)]. [*delete if option does not apply to the investigational treatment*]

**C. Assent Was Obtained, but Minor Subject was Unable to Sign:**

[ ]  The minor assented to participation, but has an incapacity that prevents applying a signature (e.g., the patient’s dominant hand is incapacitated, the patient is illiterate, etc.). The assenting patient’s inability to sign the assent document has been duly noted in the treatment record.

**A. Assent Obtained:**

The assent discussion was initiated on \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (date) at \_\_\_\_\_\_\_\_\_\_ (time).

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

**Adult Patient’s Printed Name**

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

**Adult Patient’s Signature Date Time**

**\* Please note that the legally authorized representative(s) must sign the consent signature page above.**

I hereby certify that I have discussed the investigational treatment with the adult patient and/or his/her legally authorized representative(s). I have explained all the information contained in the informed consent document, including any risks that may be reasonably expected to occur. I further certify that the patient was encouraged to ask questions and that all questions were answered.

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

**Printed Name of Person Obtaining Assent**

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

**Signature of Person Obtaining Assent Date Time**

**B. Assent Not Obtained, but Adult Patient was Enrolled**

Assent of the adult subject was NOT obtained for the following reason(s):

[ ]  Adult patient is cognitively or emotionally unable to participate in an assent discussion (e.g., patient has a psychiatric, medical, or developmental disorder; patient received narcotics within the last 4 hours; patient is sedated; etc.). [*delete if option does not apply to your expanded access treatment*]

[ ]  Adult patient refused to provide assent; however, the intervention or procedure involved in the expanded access treatment holds out a prospect of direct benefit that is important to the health or well-being of the adult patient and is available only in the context of the expanded access program. [*delete if option does not apply to your study*]

**C. Assent Was Obtained, but Adult Patient was Unable to Sign:**

[ ]  The patient assented to participation, but has an incapacity that prevents applying a signature (e.g., the patient’s dominant hand is incapacitated, the patient is illiterate, etc.). The assenting patient’s inability to sign the assent document has been duly noted in the treatment record.