**University of North Carolina at Chapel Hill**  
**Consent to Participate in an Experimental Treatment**  
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**Consent Form Version Date:**   
**IRB #**   
**Title of Protocol**:   
**Principal Physician**:   
**Department**:   
**Phone number**:   
**Email Address**:   
**Protocol Personnel:**  
**Funding Source and/or Sponsor:**   
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**What are some general things you should know about compassionate use protocols?**You are being asked to take part in an expanded access (“compassionate use”) protocol. The Food and Drug Administration (FDA) allows patients with serious medical conditions who do not have any other options for treatment to receive experimental treatments on a case-by-case basis. To take part is voluntary.

You may refuse or you may withdraw your consent to participate, for any reason, without penalty.   
  
Details about this protocol are discussed below.  It is important that you understand this information so that you both can make an informed choice about being in this protocol.   
  
You will be given a copy of this consent form.  You and should ask the personnel named above, or staff members who may assist them, any questions either of you have about this protocol at any time.

**What is the purpose of this protocol?**  
The purpose of this protocol is to provide you treatment for [disease/condition]. Until now, your condition has not improved with typical therapies used for this [disease/condition]. We will use a drug known as [drug/treatment] to treat you. [In layman’s terms, provide an explanation as to why you think this treatment might work and may benefit the patient.]

**Are there any reasons you should not be in this protocol?**  
You should not be in this protocol if:

* [list reasons they should not receive this treatment]

**How many people will take part in this protocol?**

[if for a single subject] The FDA’s permission to use this therapy is specific for you. You are the only person receiving this treatment under this protocol.

[if for a small group] This protocol is approved for up to [X] patients.

**How long will your part in this protocol last?**  
Your involvement will last [Indicate the length of time of the individual participant’s active involvement.  Include expected time needed for visits as well as the overall length of time. Tell participants whether there is any follow-up.]. This includes the treatment itself, as well as regular scheduled clinic follow-up visits to make sure they are improving and experiencing no side effects from the therapy.   
  
**What will happen if you take part in the investigational treatment?**

Describe in lay language, step-by-step, what will be required of or done to the patient. Be concise. Avoid describing study procedures in lengthy narrative form. If there are multiple steps, use headers, bullets, tables, pictures whenever available.

**What are the possible benefits from being in this protocol?**

The benefits to you may [describe potential benefit]. There is no guarantee that [drug/treatment] will be more useful than other treatments for your illness.

**What are the possible risks or discomforts involved from being in this protocol?**

For each procedure, describe immediate and long-term physical, psychological, and social risks/discomforts. Describe how the researchers are minimizing the risks/discomforts.  If there are no known risks state this fact.  
There may be uncommon or previously unknown risks. You should report any problems to the personnel listed on the top of this page.  
  
**If you choose not to be in the protocol, what other treatment options do you have?**  
You do not have to be in this protocol in order to receive treatment. The other treatments that are available include: [Describe other treatment alternatives.]  
  
**What if we learn about new findings or information during the treatment?**

You will be given any new information gained during the course of the treatment that might affect your willingness to continue participation in the protocol.   
  
**How will information about you be protected?**

You will not be identified in any report or publication about this protocol. Although every effort will be made to keep records private, there may be times when federal or state law requires the disclosure of such records, including personal information.  This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the confidentiality of personal information.  In some cases, your information in this protocol could be reviewed by representatives of the University, the drug manufacturer, or government agencies (for example, the FDA) for purposes such as quality control or safety.

As part of this compassionate use protocol, UNC personnel will report to the FDA your experience with this treatment.   
  
Your treatment information under this protocol will be part of your medical record.

**What will happen if you are injured by this treatment?**  
All experimental treatment involves a chance that something bad might happen to you.  This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this protocol. If such problems occur, the protocol personnel will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

**What if you want to stop before your part in the protocol is complete?**

You can withdraw from this protocol at any time, without penalty. The project personnel also have the right to stop your participation at any time. This could be because you have had an unexpected reaction or because the entire protocol has been stopped.  
  
**Will you receive anything for being in this protocol?**

You will not be paid for taking part in this protocol or for any discovery, invention, development or method of treatment that may result from taking part in this protocol. You will not be paid royalties if a commercial product is developed from blood or tissue obtained from you during this protocol.

**Will it cost you anything to be in this protocol?**

Some of the medical care you will receive in this protocol is considered routine care for your disease and would be recommended whether or not you participate in this protocol. Costs related to such routine medical care will be billed to your insurance provider. You will be responsible for any co-payments, deductibles and/or other out of packet expenses required by your insurance provider.

Standard of care costs for which you or your insurance provider will be expected to pay include the following:

* [Describe/list standard of cost care]

The following procedures/tests are study related and will be paid for by the sponsor:

* [Describe/list sponsor paid costs]

**What if you have questions about this protocol?**   
You have the right to ask, and have answered, any questions you may have about this protocol. If there are questions about the protocol (including payments), complaints, concerns, or if a protocol-related injury occurs, contact the personnel listed on the first page of this form**.  
  
What if there are questions about your rights as a participant?**

All compassionate use protocols with human volunteers is reviewed by a committee that works to protect your rights and welfare. If there are questions or concerns about your rights as a compassionate use protocol participant, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB\_subjects@unc.edu.

**Participant’s Agreement:**

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily give permission to participate in this compassionate use protocol.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of Participant | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date |
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