**University of North Carolina at Chapel Hill**
**Consent to Receive an Experimental Treatment**
**Adult Participants**
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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:**
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 **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 to join, or you may withdraw your consent to participate, for any reason, without penalty.

The [name of device] is not currently approved by the FDA. In order to receive this device, the manufacturer has obtained the FDA’s permission for the personnel listed on the top of this form to use this device and provide you management and care under this compassionate use protocol.

Details about management of and care for the use of the device are discussed below.  It is important that you understand this information so that you can make an informed choice about receiving the management and care under this protocol.

You will be given a copy of this consent form.  You should ask the protocol personnel named above, or staff members who may assist them, any questions you have about this the device or your care at any time.

**What is the purpose of this protocol?**
The purpose of this protocol is to provide you treatment for \_\_\_\_\_\_\_\_\_\_. Also, describe in layman terms why the patient is being selected for this compassionate use protocol. Describe relevant information on safety and/or efficacy.
 **Are there any reasons you should not be in this protocol?**
You should not receive treatment under this protocol if you do not wish to receive treatment from this experimental device or if you are unwilling to attend the follow-up clinic visits required.
**How many people will take part in this protocol?**
[if for a single subject] The FDA’s permission to use this device is specific for you. You are the only person receiving this device 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.

**What will happen if you take part in the protocol?**
This is the procedures section.  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 this protocol, what other treatment options do you have?**
You do not have to be in this protocol in order to receive treatment. [describe any other treatment options]

**What if we learn about new findings or information during your treatment?**
You will be given any new information gained during the course of the protocol that might affect your willingness to continue your participation.

**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 device 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 and the device manufacturer will report to the FDA your experience with the device.
Your treatment information under this protocol will be part of your medical record.

**What will happen if you are injured by the management and care as part of this protocol?**
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 you 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 participating in the protocol?**
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 have failed to follow instructions, 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 any tissue obtained from you during this protocol. [remove if n/a]

**Will it cost you anything receive this treatment?**
If you enroll in this protocol, you will have costs which include:

[List the additional costs that are specific to use of this device. If you have received approval from the FDA and will charge for an investigational device clearly state this.]

**What if you have questions about this treatment?**
You have the right to ask, and have answered, any questions you may have about this protocol. If you have questions about the treatment, complaints, concerns, or if a treatment-related injury occurs, you should contact the project personnel listed on the first page of this form.

**What if you have questions about your rights as a protocol participant?**
All compassionate use protocols, are reviewed by a committee that works to protect your rights and welfare.  If you have questions or concerns about your rights as under this protocol, 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 agree to participate in this compassionate use protocol.

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Printed Name of Participant |   |

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| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Printed Name of Protocol Personnel Obtaining Consent |   |