Yale NewHaven Health Bridgeport Hospital

Bridgeport Hospital
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: _____

Principal investigator: _____

INTRODUCTION:
You are invited to participate in this research study, the purpose of which is ...**< state purpose in 1 sentence >**..... You are eligible to participate in this study because...**<explain feature(s) of subject that make him/her eligible >.....**

In order to decide whether or not you wish to be a part of this research study, you should know enough about its risks and benefits in order to make an informed judgement. This consent document gives you information about the research study, which a member of the research team will discuss with you. Once you understand the study, you will be asked if you wish to participate; and if so, you will be asked to sign this form.

This paragraph is optional...
Approximately **..< # >.....** patients are expected to participate in this study at Bridgeport Hospital and that approximately **...< # >.....** patients are expected to participate at the **..< # >.....** medical centers at which this study is being conducted.

You **.....< explain background / rationale of study > .....**

STUDY PROCEDURE:
If you agree to participate in this study, you be will be asked .....**< Explain procedures to be followed, in lay terms, as outlined in Sections (3 & 4) of the research study outline. Explain randomization, blinded treatment, nature of placebo ("inactive substance"), what therapies/activities/foods will be withdrawn or prohibited during the study and medical terms using lay words. Outline in chronological order where patient will go and what will be done, during each phase of the study. Distinguish clearly between any procedures that are experimental and those that are part of the subject's standard of care.>.....**

Your participation in this study will last approximately ....**< # of days, weeks, months or years >.....**

RISKS AND INCONVENIENCES:
< Explain potential risks / discomforts as outlined in Section (5) of the research study outline >.... < name of experimental drug > ... may be associated with risks unknown and unforeseen. Thus, it is important that you notify study personnel if you experience any new symptoms while you are enrolled in this study. **If appropriate, include the following statement "Participation in this study may involve risks that are currently not known."**
In order to minimize potential risks, **..... < Specify safeguards as outlined in Section (7) of the research study outline. Include specific information about pregnancy, contraception,**

potential fetal risks of medications when applicable>

BENEFITS:
< Describe potential benefit(s) from participation in the study, as well as benefits (i.e. improved health outcomes) to the population the subjects represents, or to society at large (i.e., general advancement of scientific knowledge. If there is no likelihood that the subject will benefit directly from their participation this should be stated> .....

ECONOMIC CONSIDERATIONS:
You will receive **.... < Describe payments, reimbursements, gifts, medications supplied as part of the study. If payment is prorated for subjects who do not complete the study, please explain. > .....**

The cost of all routine tests and treatments performed during the time you participate in this study will be billed to you or to your insurance company. If you are injured because you take part in this study, medical care will be made available to you at Bridgeport Hospital. No other form of compensation is available. Financial compensation for such things as lost wages, discomfort or disability due to an injury is not available. By signing this form, you do not give up any legal rights.

INVESTIGATOR COMPENSATION
<Sponsor of the study > is paying your study doctor and/or Bridgeport Hospital to conduct this study. The amount of this payment is sufficient to cover the study doctor's and/or Bridgeport Hospital's expenses to perform the study but provides minimal personal financial benefit to your study doctor and/or Bridgeport Hospital.

ALTERNATIVES:
Your alternative to participating in this study is **... < Specify alternative therapeutic, diagnostic or preventive procedures that should be considered before the subject decides whether to participate (even if it's as simple as "not to participate,") noting especially what procedures and treatments the patient would receive as part of routine clinical care, which might be so provided and which would not be available outside of the study protocol > ....** You can discuss these alternatives with the study personnel and/or your personal physician.

CONFIDENTIALITY:
The portion of your medical records relevant to this study may be reviewed by the health care professionals caring for you, the study investigators, the U.S. Food and Drug Administration (FDA) **if FDA sponsored study,** members of the Institutional Review Board of Bridgeport Hospital and representatives of**....< insert name of study sponsor >...,** the sponsor of this study. Otherwise, all information obtained from your participation in this study will be held strictly confidential and will be disclosed only with your permission or as required by U.S. or State law. Your identity will be removed from any medical record information used for publication or educational purposes.

REFUSAL AND WITHDRAWAL:
You may refuse to take part in or may withdraw from this study at any time without affecting your present or future care at this hospital and without penalty or loss of benefits to which you may otherwise be entitled.

Your participation may also be terminated by the investigator or the study sponsor for administrative reasons, if you fail to follow the study plan, if you experience any study-related injury or adverse effects of medications or procedures or if the study personnel or your own doctor(s) determine that it is in your best medical interest not to remain in the study.

If you choose to withdraw from the study, you will inform the study personnel of your intent. When your participation in the study ends, for any reason, you will return all unused medication and supplies and receive instructions as to how to resume your routine medical care.

< Subjects should be informed whether they will have the ability to withdraw their data from the research once it is collected. If data cannot be withdrawn (for example, if they have been anonymized), subjects should be apprised of this >

RIGHTS:

Should you have any questions about the study, or in the event of study-related injury, you may call Dr**. .. < insert name of P.I. >.....** at Bridgeport Hospital (203-384-....**< P.I . phone ext. >....**). If you have additional questions about your rights as a research subject, you may contact the office of the Bridgeport Hospital Institutional Review Board at 203 384-4549.

You will be informed of any significant new findings obtained during the course of this study which may relate to your willingness to continue participating in it.

I have read and fully understand the information provided in this consent form. Known risks and potential benefits, as well as the procedures, complications and alternatives to my participating in it, have been explained to me. I have had ample opportunity to ask questions and all my questions have been answered to my satisfaction. I believe that I have adequate knowledge upon which to base an informed consent. I will receive a copy of this consent form.

I HEREBY VOLUNTARILY AGREE TO PARTICIPATE IN THIS STUDY.

____ / ____ / ____ **Name:** _____

___ : ___ AM/PM **Signature:** _____

***** **OR** *****

AS A LEGALLY AUTHORIZED REPRESENTATIVE OF _____
_____,
I HEREBY AUTHORIZE HIS/HER PARTICIPATION IN THIS STUDY.

____ / ____ / ____ **Name:** _____

___ : ___ AM/PM **Signature:** _____

Relationship to participant: _____

The participant's consent could not be obtained because:
_____
_____

INVESTIGATOR'S (OR DESIGNEE'S) STATEMENT: I have fully explained to the participant (or his/her legally authorized representative) the purpose, procedures, alternatives to and the potential risks and benefits of participating in this study. I have offered to answer any questions of the participant and/or legally authorized representative acting on his/her behalf, and have answered, to the best of my ability, all questions posed. I believe the participant (or his/her legally authorized representative) understands the explanations and answers which I have provided.

____ / ____ / ____ **Name:** _____

Signature: _____

***** THIS FORM IS NOT VALID UNLESS IT BEARS IRB STAMP *****