Yale NewHaven Health Bridgeport Hospital

OUTLINE OF RESEARCH STUDY

Title: [ ]

Principal Investigator:

1. **Purpose of study**: State the specific aim(s) of the study.

2. **Background**: Describe the background information that led to the plan for this project.

   a. **Previous data / information**: Include previous data/information which led to project.

   b. **Hypotheses to be tested in this study**: Describe the hypotheses to be tested.

3. **Study subjects**: Provide a description of the targeted involvement of human subjects. Will subjects who require additional safeguards or other considerations be enrolled in the study (i.e., children, decisionally impaired, prisoners, non-English speaking,)? If so, identify and provide a justification for their involvement.

   a. **Number**: At Bridgeport Hospital: _____ At all centers: _____.

   b. **Inclusion criteria**: What are the criteria used to determine subject inclusion. How will eligibility be determined and by whom?

   c. **Exclusion criteria**: What are the criteria used to determine subject exclusion. How will eligibility be determined and by whom?

   d. **Randomization procedure(s)**: Describe how subjects will be randomized; including justification for blinding or not blinding the trial, if applicable. Clarify any changes in the participant's care as he/she shifts from standard clinical care to the study intervention.

4. **Study methods**:

   a. **Study site(s)**: List locations where subjects will be consented and treated.

   b. **Subject recruitment method(s)**: State how potential subjects will be identified, contacted and recruited; i.e. patients referred to study personnel; review of medical/laboratory records. Attach a copy of all recruitment materials.

   c. **State baseline, active, follow-up and data analysis activities.**

      1) Include the sequence and timing/duration of study procedures (distinguish research procedures from those that are part of routine care).

      2) Study duration and number of study visits required of research participants.

      3) Definition of treatment failure or participant removal criteria.

      4) Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.

   d. **Withdrawal of subjects** (end points):

5. **Potential risks**: Describe the reasonably foreseeable risks, including risks to subject privacy, discomforts or inconveniences with subjects participating in the research.

   a. **Therapy withdrawn/withheld**: Include any treatment which needs to be discontinued to participate in the study as well as the use of placebos. Justification of why participants will not receive routine care or will have current therapy stopped.

   b. **Phlebotomy** required: List any blood work required during the study and whether it is the standard of practice or if additional episodes are required. Blood draw measurements should be provided in teaspoons/tablespoons, ounces.

      1) Number / frequency of phlebotomy episodes:

      2) Total blood required for sampling during protocol: _____.

   c. **Tests / procedures requiring radiation exposure**: List any radiation exposure required during the study and whether it is the standard of practice or if additional exposures are required.

   d. **Risks of study procedure(s)**: Describe the reasonably foreseeable risks of

the procedure.

e. **Risk(s) of study medication(s)**: What is the name of the drug, device or biologic being used? Indicate whether FDA approval been granted and for what indication. Describe the reasonably foreseeable risks. Include IND Number if appropriate

1) Investigational agent(s):

2) Standard agent(s):

6. **Potential Benefits:** Identify any benefits that may be reasonable expected to result from the research, either to the subject or society at large. Do no include payment to subjects in this section.

7. **Alternatives:** What other alternatives are available to the subject outside of the research

8. **Safeguards / procedures to reduce risk**: Describe the manner in which the above risks will be minimized.

9. **Data collection and analysis**: Describe what data and protected health information will be collected and used for research. State how the data will be collected, recorded and stored.

10. **Confidentiality and Security of Data:** Describe the methods and procedures that will be used to safeguard the confidentiality and security of the subject's protected health information.

11. **Financial considerations**:

a. Funding source(s): List Sponsor and contact person of the Study.

b. Direct remuneration to subjects: List amount and reason, i.e., payment for participation; reimbursement for travel, parking, etc.

c. Indirect remuneration to subjects: Describe any indirect payments that will be provided to the subjects and the conditions for receiving such, i.e., waiver of professional fees for procedures/clinic visits; payment for hospitalization, outpatient medications provided by the study.

d. Direct remuneration to investigator/institution: List payment for each enrolled subject.

e. Indirect remuneration to investigator/institution: List any equipment provided by the study; medications provided by the study, etc.

12. **Waiver of Consent:** Will you request a waiver of consent, for this study? If so, please indicate the following:

a. Does the research present greater than minimal risk to the subject?

b. Will the waiver adversely affect the subject's rights and welfare

c. Why would the research be impracticable to conduct without the waiver

d. Where appropriate, how will pertinent information be shared with the subjects at a later date?

13. **Waiver of Documentation of Consent:** If requesting waiver of signed consent (verbal consent will be obtained from the subject): Indicate the following:

a. Would the signed consent be the only record linking the subject and the research?

b. Does a breach of confidentiality constitute the principal risk to subjects, OR

c. Does the research pose greater than minimal risk? AND

d. Does the research include any activities that would require signed consent in a non-research context?

14. **Required HIPAA Authorization:** If the research involves the creation, use or disclosure of protected health information, include a completed HIPAA Research Authorization Form

15. **Request for Waiver of HIPAA Authorization:** Describe why it would be impracticable to obtain the subject's authorization for use/disclosure of the data.