HOUSATONIC COMMUNITY COLLEGE

Institutional Review Board

IRB Project Summary

A. SUMMARIZE THE GOALS AND PURPOSE OF THE PROJECT

Describe the general purpose of the study and include relevant background information. Describe in layman terms why the study is being done, what is the background on the agent or device, if none, state that there is none. Describe what the known information on efficacy is. What are the main aims of the study and how will these be determined.

B. LIST YOUR EXACT METHODS OF:

i. Finding research participants

ii. Obtaining informed consent (if applicable)

iii. Methodology with respect to participants (i.e., what will they be asked to do?)

This is the procedures section. Describe in lay language, step-by-step, what will be required of or done to the research subject. Please avoid describing study procedures in lengthy narrative form. If there are multiple steps, use headers, bullets, tables, pictures whenever available. This may include, but need not be limited to:

- *Overall design: Procedures to be performed, including frequency and follow-up.*
  - *Describe diary cards, questionnaires, surveys, if any.*
  - *For studies that involve questionnaires, include a statement informing the subject they may choose not to answer a question for any reason.*
  - *For any procedures indicate whether they are a requirement of participation in the study.*
  - *In research involving patients as subjects, provide the name of the physician responsible for the patient's welfare during the study.*
- *For Randomization: Explain to the subjects that they will be assigned by chance, like flipping a coin, to a study group. Explain the study groups.*

C. MATERIALS OR EQUIPMENT

Clearly describe the tests, questionnaires, subject recruitment ads, and other materials and equipment that will be used in your study.

Include samples of aforementioned documents with your application.

D. HOW WILL YOUR PRIVACY BE PROTECTED?

Describe how data will be stored and subjects' privacy protected.

Indicate how privacy and confidentiality will be protected. Briefly but as clearly as possible

describe the key procedures for protecting the privacy and confidentiality of the individual's data, such as:

- *How research records will be secured.*
- *Who will have access to individually identifiable data (e.g. research collaborators, sponsors, etc.).*
- *Whether names or ID numbers will be used (if codes or numbers are assigned, describe how the linkage file will be secured).*

E. HOW LONG WILL YOUR PARTICIPATION IN THIS STUDY LAST?

Indicate the length of time of the individual subject's active involvement. Include expected time needed for visits as well as the overall length of time. Tell subjects whether there is any follow-up.

F. WHAT ARE THE POSSIBLE BENEFITS OF PARTICIPATING IN THIS STUDY?

*Insert **ONE** of the following paragraphs or modify one as appropriate to the specific study:*

"Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study."

"Research is designed to benefit society by gaining new knowledge. There is little chance you will benefit from being in this research study."

"Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be _____."

G. WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS INVOLVED WITH PARTICIPATING IN THIS STUDY?

For each research procedure/intervention, describe immediate and long-term physical, psychological, and social risks/discomforts related to the research components. If frequency of such risks or discomforts is known from previous studies, provide estimates of frequency. It may be more meaningful for subjects to see risks grouped as Common, Uncommon, Rare, etc. If the information is complex, you may use a table format to list the risks.

If applicable, include the risk of being assigned to a control group (e.g. placebo or observation arm).

H. WILL YOU RECEIVE ANYTHING FOR PARTICIPATING IN THIS STUDY?

*Insert **ONE** of the following sentences.*

"You will not receive anything for taking part in this study."

"You will be receiving _____for taking part in this study."

Describe payment or gift and schedule for their receipt. Address how payment will be

prorated in the event the subject withdraws from the study prior to completion. Include information about any reimbursement for parking, transportation, etc.

I. WHAT IF YOU WANT TO STOP BEFORE YOUR PART IN THE STUDY IS COMPLETE?

Modify the paragraph below, if necessary, to fit the study. Explain the consequences of a subject's decision to withdraw and the procedures that will be followed for the orderly termination of participation.

"You can withdraw from this study at any time, without penalty. The investigators 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 study has been stopped. "

J. WHO IS SPONSORING THIS STUDY?

When appropriate, the last sentence should be modified/expanded to disclose the nature of any potential conflicts of interest relating to this study, financial or otherwise.

"This research is funded by (name of Drug Company, the National Institutes of Health, etc.). This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study."