Yale NewHaven Health Bridgeport Hospital

Institutional Review Board
203-384-4549

CONTINUING REVIEW / TERMINATION OF RESEARCH INVOLVING HUMAN SUBJECTS

Title: _____

Principal Investigator: _____ **IRB #** _____

Department: _____ Telephone: _____ Email: _____

Associate Investigators: _____

(list only ***if changed*** since last report) _____

Study subjects:

_____ Total number of subjects/records originally approved by the IRB
_____ Number of subjects/records enrolled since the last report to the IRB
_____ Number of subjects/records enrolled since initial study approval
_____ Number of subjects that have died
_____ Number of subjects/ that have completed the study
_____ Number of subjects that voluntarily withdrew from the study
_____ Number of subjects withdrawn by the PI from the study
_____ Number of subjects/records that remain actively involved in the study

Unforeseen / Adverse developments (since last report to IRB):

____ No unforeseen / adverse developments have occurred.
____ Adverse events affecting the risk/benefit ratio of the study have occurred, either from the literature or from the Investigator's findings ***(please detail below or on separate sheet).***

Status of study:

____ The study is **terminated** as of _____.
Reason for termination:

____ **Permission to continue the study** is requested because:
_____ Subject/record enrollment has not yet begun.
_____ Subject/record enrollment will continue.
_____ Enrollment is complete but subjects/records continue to be followed.
_____ Other: _____

Comments: _____

_____

_____

As the Principal Investigator of this research project, I certify the following:

- That the information provided in this application is complete and accurate.
- That I assume full responsibility for the protection of human subjects and the proper conduct of the research.
- That the research is performed according to ethical principles and in compliance with all federal, state and local laws, as well as Bridgeport Hospital policies regarding the protection of human subjects.

_____ _____

Signature of PI Date