

MUSC Hollings Cancer Center **CTO # _____**
Protocol Review Committee
Clinical Trials Office, Administrative Operations Unit
Phone: 792-6968
PROGRAM LEADER SIGNOFF/PROJECT SUBMISSION FORM

I. KEY PERSONNEL FOR THIS PROJECT

Principal Investigator: _____ Phone: _____
 Co-Principal Investigator: _____ Phone: _____
 Study Coordinator: _____ Phone: _____
 Regulatory Specialist: _____ Phone: _____
 Research Program(s): _____

A. I would like a radiologist involved/listed as **Co-PI** of this study. Yes No
 If yes, please circle the name of the radiologist(s). If other, please fill in name:
 _____ ; _____ ; Other: _____

B. I would like a radiologist involved/listed as **Sub-Investigator** of this study. Yes No
 If yes, please circle the name of the radiologist(s). If other, please fill in name:
 _____ ; _____ ; Other: _____

C. I would like a pathologist(s) involved/listed as **Sub-Investigator** of this study. Yes No
 If yes, please circle the name of the pathologist(s). If other, please fill in name:
 _____ ; Other: _____

D. Study Management Services Requested: CTO Program Resources

II. PROTOCOL INFORMATION

A. Title (or cover page of protocol):

B. Protocol Authorship: P.I. Sponsor

C. If Authorship = PI (investigator-initiated), would you like to list your protocol on Physician Data Query (PDQ*)?
 (*PDQ is a database produced by the NCI and includes a cancer clinical trials database) Yes No

D. If investigator-initiated, will this be offered to members of the HCC Research Network? Yes No

If investigator-initiated, is this a multi-center trial?: Yes No

If yes, please list other participating sites outside of HCC: _____ ; _____ ; _____

E. Co-Investigators: (include statistician when applicable)
 _____ ; _____ ; _____ ; _____

F. Does this study require filing an FDA/IND number for any study drugs? Yes No

G. Phase: Pilot I I/II II III IV N/A

H. Does this study involve the use of radioactive substances? Yes No

I. Does this study involve the use of bio-hazardous materials? Yes No

J. Patient Accrual*: 1. Total Projected Accrual for HCC : _____
2. Estimated Annual Accrual for HCC: _____

**Please be realistic in projecting accrual figures. These figures will be the basis for semi-annual scientific progress review, whereby those trials not meeting accrual projections will be closed to accrual or terminated. Please access the Protocol Monitoring Committee policy at: http://hcc.musc.edu/intranet/clinical_trials/#policy_procedure for further details.*

K. Complete for Grants: a. Will this project begin while awaiting funding notification? Yes No
b. Do you intend to perform this study if extramural funding is not awarded? Yes No

III. **FUNDING:** Investigator Initiated Unfunded (Please complete the non-sponsored study budget.)
 Investigator Initiated Supported (Please complete the non-sponsored study budget.)
 Pharmaceutical
 Co-operative Group
 Federal Grant
 Private Grant

IV. **THREE YEAR HISTORICAL TUMOR COUNT FOR THE DISEASE AREA:**

YEAR	# OF PATIENTS
2002	
2003	
2004	

V. **REQUIRED ELEMENTS OF A PROTOCOL:** When applicable, each of these elements is required in order for a protocol to be placed on the PRC agenda. In addition, the PRC can only review final versions of a protocol.

- | | |
|---|---|
| Title Page | Section 8.0: Dose Modification for Toxicity |
| Section 1.0: Objectives | Section 9.0: Monitoring of Patients |
| Section 2.0: Background and Rationale | Section 10.0: Off-Study Criteria |
| Section 3.0: Patient Inclusion/Exclusion Criteria | Section 11.0: Adverse Event Reporting |
| Section 4.0: Procedure for Patient Entry on Study | Section 12.0: Statistical Considerations |
| Section 5.0: Research Plan/Study Design | Section 13.0: Case Report Forms/Tools |
| Section 6.0: Drug Formulation and Procurement | Section 14.0: Records to be Kept |
| Section 7.0: Criteria for Response Assessments | Section 15.0: References |

VI. **PROGRAM LEADER SIGNOFF**

This sign-off also attests to agreement with the placement of the study on the program priority diagram. Use additional sheets if necessary.

Program Leader (Print or Type)

(Signature)

(Program Leader (Print or Type))

(Signature)