

**TULANE UNIVERSITY HOSPITAL & CLINIC
INVESTIGATIONAL STUDY QUESTIONNAIRE**

STUDY TITLE: _____

PRINCIPAL INVESTIGATOR: _____ Department: _____

STUDY COORDINATOR: _____ SPONSOR: _____

e-mail: _____ Mail Code: _____

Phone: _____ Beeper: _____ Fax: _____

- **All submissions must include the IRB approval letter before they will be considered.**

PLEASE COMPLETE THE FOLLOWING QUESTIONS (leave no blank spaces & be specific):

1. Indicate the date you anticipate the study to begin: _____
and how long it will run/end date: _____
2. Anticipated number enrolled each month? _____ Total? _____
3. Gender and age range _____
4. Do you plan to enroll any Medicare patients? _____
5. Is this a qualifying trial according to the Medicare National Coverage Decision? _____
<http://www.cms.hhs.gov/coverage/8d2.asp>
6. Where will this study be conducted?
 - TUHC inpatient TUHC outpatient DePaul Uptown Square
 - Tulane Comprehensive Cancer Clinic Metairie Clinic TISM
 - Other (specify) _____
 - Requesting ancillary testing only – Research activities will not occur on TUHC premises
7. Which TUHC Departments/Units will be utilized? Please specify.
 - Clinic(s)(specify) _____
 - Inpatient Unit(s)(specify) _____
 - Pharmacy
 - Lab Who will draw/collect specimen? (TUHC staff, study staff?) _____
Where will specimen be resulted? (TUHC, outside?) _____
 - Other Diagnostic Dept (Specify) _____
 - Other Ancillary (Medical Records, etc.) _____
8. What type of space will be utilized? _____
(i.e.: exam room, consultation/procedure room, hospital bed, recovery room, etc) (All costs/charges not billed to patient/insurance as medically necessary must be documented on the Meditech Charge Form)
9. What additional TUHC assistance/services will be needed?
 - Pulling charts
 - Generation of a list
 - Specimen prep
 - Anatomic Pathology (specify) _____
 - Other _____
10. Names of Department Director(s)/Manager(s) you have discussed requirements with?
You must coordinate your research requirements with all involved departments to ensure that staffing/supply/cost issues are resolved. All costs/charges not billed to patient/insurance must be documented on the Meditech Charge Form.

11. Does this study require any professional (TUMG/physician) services? Please specify.

12. List the names & titles of all persons who will be involved in performing the study (please identify physicians, nurses, research coordinators, fellows, etc who are not TUHC employees).
**Any individual providing patient care/education, dispensing medications, documenting in the medical record must be credentialed at TUH&C (contact Ann Morgott 988-4762)*

13. Will investigational drugs be used? Placebo? Specify _____

Will the sponsor provide any of the study drugs/placebo? Specify. _____

Is drug commercially available? _____ Should patient insurance/patient be billed? _____

Where will the drugs be stored? _____

Costs for set-up, storing, mixing dispensing of drugs not charged to patient/insurance must be listed on Meditech Charge Form.

14. Will any electrical or battery medical equipment not belonging to TUHC be utilized? _____

In accordance with JCAHO Environment of Care Standard EC.1.6, all medical equipment entering TUHC (this includes satellite clinics), regardless of ownership (physician owned, sponsor owned, loaner, etc.) must have an incoming safety inspection and evaluation. Notify TUHC dept. manager to assist you in contacting TUHC BioMed.

Who will be using this equipment? _____

What type of equipment? (EKG, Spiro, etc.) _____

Make _____ Model _____ Serial # _____

15. What hospital/clinic supplies will be required? _____

How will the cost for these be covered? _____

16. Will investigational devices, instruments, machines be utilized? Specify.

Who will provide device/instrument/machine? _____

Device category _____ IDE# _____

17. Identify Protocol Induced costs and Routine Care costs. You may use the Schedule of Events in the protocol if it is in table format and includes a timeline. Otherwise use the form on the next page. If using the Schedule of Events from the protocol, indicate services by:

- Circle those that are protocol induced and will be provided at TUHC – will be billed to study account
- Place a triangle around those that are protocol induced but not provided at TUHC
- Highlight routine services that should be billed to the study account
- Items not indicated as above are considered routine and billable to a third party payor.

18. Do you need any special emergency equipment/drugs on standby other than those routinely available in the hospital & clinic? If yes, list below:

19. How will TUHC be reimbursed for treatment of an adverse reaction?

20. Any other pertinent information?

21. _____

PI Signature

SCHEDULE OF EVENTS/PROCEDURES

Service/Procedure	Study Arm	Study Timeline										
		Screen	Day/Wk	Day/Wk	Day/Wk	Day/Wk	Day/Wk	Day/Wk	Day/Wk	Day/Wk	Day/Wk	Day/Wk
		0										
CLINIC:												
INPATIENT:												
LAB:												
RAD/CARD/OTHER:												
PROFESSIONAL:												

KEY: RC = ROUTINE CARE WHICH WOULD OCCUR REGARDLESS OF PROTOCOL (insurance may be billed)
 RCS = ROUTINE CARE BILLED TO STUDY ACCOUNT
 PIC = PROTOCOL INDUCED CARE BILLED TO STUDY ACCOUNT
 NF = PROTOCOL INDUCED CARE THAT WILL BE PROVIDED BY STUDY (personnel/equipment) DO NOT BILL
 COPY AND ATTACH ADDITIONAL PAGES OF THIS TABLE IF NECESSARY

