

MEDICAL CENTER OF LOUISIANA  
RESEARCH PROTOCOL REVIEW APPLICATION

Research Review Committee (RRC)  
Nursing Research Committee (NRC)  
General Clinical Research Center (GCRC)  
HIV Outpatient Program (HOP) Research Committee

IRB Approved: \_\_\_\_\_  
Signed Budget Attached: \_\_\_\_\_

TITLE OF STUDY:

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PRINCIPAL

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AFFILIATION/DEPT: \_\_\_\_\_ FAX: \_\_\_\_\_

STUDY COORDINATOR: \_\_\_\_\_ PHONE: \_\_\_\_\_

SUMMARY OF RISKS:

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SUMMARY OF ANTICIPATED BENEFITS FOR SUBJECTS AND

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SPECIFY THE AREA(S) OF MCL WHERE SUBJECTS WILL BE RECRUITED:

SPECIFY THE AREA(S) OF MCL WHERE SUBJECTS WILL BE SEEN OR CARED

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SPECIFY BEGINNING DATE OF STUDY: \_\_\_\_\_

SPECIFY ESTIMATED COMPLETION \_\_\_\_\_

SPECIFY THE NAMES AND THE RELATED ACTIVITIES OF ALL PERSONNEL WHO WILL BE WORKING ON THIS STUDY AT MCL:

PERSONNEL AND CREDENTIALS

RESEARCH RELATED ACTIVITIES

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FOR A PHARMACEUTICAL STUDY:

A. Specify the study medications furnished by pharmaceutical company:

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B. Specify the study medications expected to be furnished by MCL:

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SPECIFY LABORATORY TESTS TO BE DONE BY AN OUTSIDE LABORATORY. (PI IS RESPONSIBLE FOR ANY SPECIAL TREATMENT OF SPECIMENS FOR LABORATORY OUTSIDE MCL.)

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SPECIFY FUNDING SOURCES (NIH, PHARMACEUTICAL GRANT, ETC.)

DATE OF IRB SUBMISSION: \_\_\_\_\_ DATE OF IRB APPROVAL: \_\_\_\_\_

AS PRINCIPAL INVESTIGATOR, I AGREE TO THE FOLLOWING:

1. A signed consent form will be placed in the subject's MCL chart immediately upon enrollment into the study.
2. There is to be no deviation from the protocol without additional approval of the respective research committee.
3. I will provide any additional information and will complete the study initiation pharmacy forms required to assure optimal patient care by the MCL department's personnel (i.e. Pathology, Medicine, Nursing, Pharmacy).
4. I will be responsible for any special treatment of specimens for laboratories outside MCL.
5. I will be responsible for assuring that any personnel employed to assist in the implementation of this study, will submit to the respective professional credentialing process (i.e. nurses, phlebotomists) as stipulated by MCL. -
6. I will be responsible for assuring that all associate personnel will wear picture identification badges in the clinical areas.
7. I will be responsible for assuring that all associate personnel will respect patient confidentiality and record integrity.
8. I will provide a notation for the medical record of any adverse event a particular subject should suffer as an in-patient or during follow-up .
9. I will forward a copy of the IRB re-approval form or notification of research completion to the respective research committee.
10. I will submit a monthly report of patients/subjects enrolled.
11. I may be responsible for patient charges for research only related costs.
12. I understand that I may not begin any aspect of this research until I have received an approval letter from the appropriate MCL committee.
13. I have attached a signed study budget which will serve as a contract with MCL.

**SIGNATURE** \_\_\_\_\_

**DATE** \_\_\_\_\_

\*\*\*\*\*WHEN STUDY RESULTS ARE PUBLISHED, MEDICAL CENTER OF LOUISIANA SHALL BE ACKNOWLEDGE FOR PARTIAL SUPPORT OF THE RESEARCH.



## PART IV

### TULANE - LSU - CHARITY HOSPITAL GENERAL CLINICAL RESEARCH CENTER

#### Timetable for Receipt and Review of Protocols

1. The GCRC Advisory Committee is scheduled to meet during the last week of every month, on Wednesday at 4:00 p.m.
2. Protocols (including appendix materials) are due in the Administrator's Office on the 10th. of the month for inclusion in the review agenda.
3. The GCRC will consider the expedited review of a protocol at any time if the investigator has identified a unique research subject whose timely cooperation needs to be secured and who would not otherwise be available, and untimely delay in enrolling the subject on-study would significantly jeopardize the investigator's research. The GCRC Advisory Committee Chairman assigns two Committee members to review the protocol and temporary approval may be given until full review by the Committee at the next scheduled meeting. This procedure will be used only in exceptional circumstances as defined above. IRB approval must be obtained before the study is initiated.
4. All protocols submitted for consideration should be prepared according to the instructions provided (**Applications must be typed**). **Applications that do not comply with the requirements outlined for protocol submission will be promptly returned to the principle investigator for revision.** Please send **7 copies of the application** and **4 copies of the research protocol** to Bob Sullivan, GCRC, 1430 Tulane Avenue, New Orleans, LA 70112, phone no. 585-4000. Questions related to admission and special nursing procedures should be directed to the Virginia Garrison, BSN, Nurse Manager, phone no. 585-4000.

**PRINCIPAL  
INVESTIGATOR:  
SIGNATURE**

I agree to cite GCRC support or resources utilized in all publications as follows:  
**"Supported in whole or in part by NIH Grant #5M01RR05096 from the  
Division of Research Resources, National Institutes of Health".**

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