UNIVERSITY MEDICAL CENTER NEW ORLEANS
RESEARCH REVIEW APPLICATION

Submission and Approval Process

1. Submit complete RRC application to Office of Research as early as possible in study process.

2. Quality Improvement projects must also be submitted to the RRC, but do not require attachments other than the protocol/description of project.

3. Required Attachments with RRC Application:
    - Current version of protocol
    - Schedule of Events (if not part of protocol)
    - Informed consent forms (draft acceptable)
    - HIPAA authorization
    - Draft Medicare Coverage Analysis (MCA)

4. Submit all documents electronically to umcofficeofresearch@lcmchealth.org.

5. The Office of Research will review the submitted draft MCA and work with PI/Coordinator to finalize the document.

6. The Office of Research will perform analysis of required research-related items and services to determine the need for execution of subsequent contracts.

7. In the absence of a UMCNO-executed contract with sponsor, the Office of Research will provide pricing for research-related items and services identified in the finalized MCA.

8. The RRC will meet weekly to review research projects that have completed the preceding steps.

9. IRB Approval: Submit IRB approval to Office of Research when available. The IRB approval is not required with initial submission.

10. Final RRC approval will be issued once all above requirements have been met.

11. Investigational Pharmacy: Once RRC approval is issued, the Office of Research will provide notification to designated research pharmacist.

Title of Protocol:

IRB #:

NCT#:

Sponsor Name/Contact Information:

Funding Source (Check ALL that apply and specify)

- ☐ Intramural Sources:
- ☐ National Institute of Health (NIH):
- ☐ Industry Sponsors:
- ☐ Other:

Study Staff (Please list all study staff including sub-investigators and their roles. All affiliates involved in research must be credentialed. Please contact the Office of Research for specifics at (504)-702-5005 or email umcofficeofresearch@lcmchealth.org.)

Principal Investigator:

Department/School:

Email:

Phone #:

Billing Address/Contact:

Primary Study Coordinator:

Email:

Phone #:

Anticipated Study Start Date (MM/YYYY):

Estimated Study Completion Date (MM/YYYY):

Please indicate if this study is a Medical Chart Review ONLY:

- ☐ **Yes**
- ☐ **No**

If YES, please skip subsequent sections, and have the Principal Investigator sign the form. After the Research Review Committee approves the study, the approval should be taken to Information Security to access Health Records.

Protocol Type (Check ALL that apply to Protocol):

- ☐ Audio/Images/Videotaping
- ☐ Biospecimen/Phlebotomy
- ☐ Diagnostic Test
- ☐ Investigational Drug/Device
- ☐ Interview/Questionnaire/Survey
- ☐ HIM Reports

Anticipated number of subjects to be enrolled:

Recruitment

Location:

UMCNO Inpatient Area:

UMCNO Outpatient Area**:**

Methods (Check ALL that apply):

- ☐ Investigator's Patients
- ☐ Inpatients
- ☐ Professional Referrals
- ☐ Emergency Room
- ☐ HIM Reports
- ☐ Advertising- media, electronic etc. (Please Specify)
- ☐ Other (Please Specify)

Trial Logistics

Subject treatment location:

Utilized Space (e.g. exam room, consultation/procedure, hospital bed, recovery room, etc.):

Additional UMC assistance/services (e.g. blood collection, pathology, other biospecimens, processing, storage, etc.):

Will UMC staff require protocol specific training?

- ☐ Yes
- ☐ No
- ☐ Not Applicable

Are any outside of UMC services diagnostic or therapeutic being used? ☐ Yes ☐ NO

(If YES, please provide detailed plans to have the diagnostic and therapeutic results entered into UMC's Electronic Health Record)

Name of investigational Drug/Device/Intervention:

Research Pharmacy Involvement?

- ☐ Yes
- ☐ No

PI Statement

I agree to abide by all UMCNO policies and procedures during the conduct of this research project**.**

Signatures:

_____	_____
Principal Investigator Signature	Research Review Committee Chair
_____	_____
Date	Date