**UNIVERSITY MEDICAL CENTER NEW ORLEANS**

**INSTRUCTIONS FOR RESEARCH APPLICATION**

**Initial Submission and Approval Process**

**Purpose:** the UMC Research Review Committee (RRC) serves to assure compliance with human research subject protections and revenue compliance for all clinical research being conducted on UMCNO’s campus.

In order to ensure timely approval of a project, please submit the documentation listed below as early as possible during the startup phase of the trial. Any documents that are incomplete or inaccurate will not be reviewed.

Quality Improvement projects should also be submitted to the UMC Office of Research for review, along with your IRB determination letter.

**Required Documents:** the following documents should be submitted electronically to UMCOfficeofResearch@lcmchealth.org for review.

* UMCNO RRC application (signed by PI)
* IRB application documents (inclusive of a complete list of staff submitted to IRB for approval)
* Study protocol/grant proposal (inclusive of schedule of assessments)
* Investigator Brochure (INDs) or Device Instruction Sheet (IDEs)
* Proof of CMS/insurance coverage
* IRB determination of non-significant risk for devices
* ICF(s) and HIPAA forms
* Medicare Coverage Analysis (final approved copy signed by PI)
* CTA and internal budget for all studies (except chart reviews)

**Procedures and Guidelines:**

1. All documents should be submitted electronically. NO paper copies will be accepted.
2. The UMC Office of Research will determine whether and which credentialing is applicable to study staff. Submission of related documentation may be necessary in order to secure approval. The primary contact/PI will be notified if further information is required.
3. If the drug or device to be studied in the proposed project is available for commercial use, but not listed in the hospital formulary or central supply/stock, UMC Office of Research will present it to Finance to determine feasibility of establishing the manufacturer as a vendor.
4. All Informed Consent Forms should list the UMC Office of Research as an entity that may inspect the subject’s medical records for quality assurance purposes. For studies that have been approved to use an approved template that cannot be modified, please notify the UMC Office of Research, and we will work with you to find a solution.
5. The MCA is required for all studies that utilize routine inpatient or outpatient services at UMCNO, whether the charges will be billed to insurance or the sponsor. The PI/Study coordinator is responsible for obtaining the correct pricing for all procedures billable to the sponsor/funding agency. Failure to obtain correct pricing may result in study budget shortages and revenue noncompliance.
6. Upon approval of the MCA, the PI will sign the document to be kept on file to ensure appropriate routing of charges. If changes to the protocol necessitate changes to the MCA, it is the responsibility of the PI to provide a revised document to the Office of Research to ensure continued revenue compliance.
7. The UMC Office of Research will determine whether and with whom it will be necessary to execute additional agreements related to the conduct of the study at UMCNO. If such agreements are needed, the UMC Office of Research will facilitate this discussion through the Department Business Manager/Office of Sponsored Research. Research charges may be incorporated into these agreement/sub-contracts accordingly.
8. While the RRC and IRB review may be conducted concurrently, please be reminded that research projects will not be approved on UMCNO’s campus until IRB approval is obtained. Likewise, should contracts with UMCNO be appropriate, projects will not be approved by RRC until those agreements are executed.
9. Upon receipt of all required documentation, the RRC approval notification will be sent to the PI with a copy to the primary study coordinator and the UMCNO VP, Research. This communication should be kept in the study regulatory file.

\*Please note that beginning February 15, 2019 all IRB approvals of study amendments and change in personnel forms should be submitted to the UMC Office of Research. Forms and instructions for these will be available at the UMCNO Research Intranet page or by request through the UMCOfficeofResearch@lcmchealth.org email address.