**Approval Process for Clinical Trials at UMCNO:**

The **Principal Investigator (“PI”) or her/his designee** should take the following steps when the PI’s research involves University Medical Center New Orleans (UMCNO) patients, electronic medical record, equipment, or technology.

1. Submit IRB application to LSU IRB in Kuali for **UMCNO Office of Research** to review. All RRC related correspondence should be with [UMCOfficeofResearch@lcmchealth.org](mailto:UMCOfficeofResearch@lcmchealth.org)

The Kuali application **MUST** include the following at the time of submission-

1. UMCNO must be cited as the clinical site for the study.
2. UMCNO’s Research Review Committee application in Kuali must be completed
3. A complete protocol for all studies regardless of the IRB requirements must be attached
4. LCMC Report Request form (Empire form) if data will be requested from UMCNO IT

1. **Concurrently** in one email the following documents must be provided to **UMCNO- Sponsored Projects** at [UMC-SponsoredProjects@lcmchealth.org](mailto:UMC-SponsoredProjects@lcmchealth.org) (for all studies other than chart review/QI)
2. A completed MCA (UMCNO template with instructions), approved and signed by the **PI**
3. Draft budget (including CPT codes) using UMCNO’s shared research discount rate
4. Draft CTA/DUA after an initial review by LSUHSC legal department
5. UMCNO Legal will revise the CTA to include terms required by UMCNO and return CTA with markup to LSUHSC’s legal contact for the study for review and submission to the Sponsor. The process will be repeated as needed.
6. UMCNO will route the CTA and the subcontract **(together)** for signatures ONLY after the budget negotiations are complete and the budget is included in the routing documents.
7. UMCNO Office of Research sets the ancillary review status in Kuali, so the PI or designee can monitor UMCNO RRC’s review progress in Kuali. The following messages may appear.

* PENDING – The submission is awaiting UMCNO ancillary review prior to IRB review
* NOT APPROVED YET – Documents are missing. A comment in ancillary review will indicate which documents are outstanding.
* APPROVED – Conditionally approved by UMCNO pending IRB approval.

1. **UMCNO RRC** will not approve a study until it has reviewed the following;

* LSU IRB approval
* A fully executed three party contract and a subcontract as required for the study.
* The fully executed contract and subcontract must be received by UMCNO with a copy to the [UMCOfficeofResearch@lcmchealth.org](mailto:UMCOfficeofResearch@lcmchealth.org) . The RRC notification will be sent to the study team from [UMCOfficeofResearch@lcmchealth.org](mailto:UMCOfficeofResearch@lcmchealth.org) and will state the following:

**\*The study is fully approved. Research activities can begin at UMCNO\***