# UMCNO/WJMC Submission Process

Instructions for submission of clinical research, biospecimen collection, and quality improvement studies at UMCNO/WJMC

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# Purpose:

**The UMC Research Review Committee determines compliance with the regulations, policies, and laws which govern the conduct of clinical research.**

**Our goal is to ensure adequate human subjects research protection, revenue integrity, data protection, intellectual property assignment, and alignment with institutionally-approved best practices.**

# Administrative Workflow for RRC submission:
## Process overview for industry sponsored studies

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| Affiliate submits initial email to UMC Office of Research with the following documents:<br>CTA/DUA, draft MCA, protocol with schedule of assessments* | UMC produces subcontract with corresponding budget to include UMC startup fees and prices for protocol-related services inclusive of overhead |
| Affiliate includes UMC subcontract/pricing in its negotiation with Sponsor | Affiliate submits application to IRB of Record; the UMC RRC application should be submitted as soon as possible thereafter to avoid delays in startup should questions arise. |
| Affiliate Department submits CTA/DUA to UMC Office of Research for full legal review; any terms required by UMC will be inserted at this time | UMC Office of Research will submit contract with markup to Affiliate Office of Research Services for affiliate review |
| After completion of contract/budget negotiation, affiliate will return final Draft to UMC. CTA/DUA and subcontract will be routed for signatures. | UMC Office of Research returns partially executed agreements to Affiliate Department |
| Affiliate Department routes agreements for signature at Affiliate Institution. Fully executed copies of prime and sub-agreements returned to UMC, either by sponsor or Affiliate | Affiliate IRB approval submitted to UMC Office of Research.<br>RRC approval released upon receipt of IRB approval and full execution of all agreements. |

*If UMC regulatory, nursing, specimen processing, or other research services are needed, feasibility will be assessed upon initial submission of the project.

# Administrative Workflow for RRC submission:
## Process overview for grant-funded studies

Affiliate submits initial email to UMC Office of Research with the following documents:
grant proposal, list of services to be performed by/at UMC

UMC produces subcontract with corresponding budget to include UMC startup fees (if allowable) and prices for grant-related services inclusive of overhead

Affiliate obtains a Letter of Support from UMC to be included in the grant application along with the UMC subcontract

Affiliate receives notice of award.

Affiliate submits application to IRB of Record; the UMC RRC application should be submitted as soon as possible thereafter to avoid delays in startup should questions arise.

IRB approval obtained. RRC approval released upon submission of IRB approval and grant award.

# Initiating a Study at UMCNO/WJMC

## Send an email to the UMC Office of Research with the following as soon as possible:

- Subject line: Study Startup Request: Department/PI Name/Sponsor/IRB Number if available, Protocol # if not
- Scope of work: include a list of any UMC services you are asking us to perform - administrative services, clinical services, facility use, and procedures.
- Questions to consider:
  1. Am I using UMC Contracting and Regulatory Staff?
  2. Am I using the CTU clinic, procedure, or infusion space?
  3. Am I using UMC Nursing, Data Coordination, or Lab Services?
  4. What is my funding source (Grant or Commercial)?
- Attach the Protocol including Schedule of Assessments for your study and a draft MCA including the CPT codes for procedures to be performed at UMCNO/WJMC

# Required Documents:

**The following must be submitted to the UMC Office of Research in order to secure a conditional approval pending IRB approval**

***No paper copies will be accepted**

1. UMCNO RRC application (signed by PI – electronic signature accepted)
2. Application to IRB of Record, including complete list of staff
3. Study protocol/grant proposal, including schedule of assessments
4. Investigator Brochure (drugs) or Instructions for Use (devices)
5. Proof of CMS/insurance coverage for approved drugs and devices
6. IRB determination of non-significant risk for devices
7. ICF(s) and HIPAA forms
8. Medicare Coverage Analysis (draft version)
9. Clinical Trial Agreement (CTA), Facility Use Agreement, or Data Use Agreement (as applicable)

# Administrative Startup - All Studies: the following must be done regardless of whether UMCNO/WJMC staff are performing research tasks

1. Generation of subcontract: UMC Office of Research will create a subcontract to be reviewed by affiliate Office of Sponsored Research inclusive of a draft budget based on scope of work and requested pricing. The subcontract outlines the responsibilities of UMC Staff and services/pricing for which UMC will be reimbursed.

2. Review of necessary prime agreement(s): UMC Office of Research will review any agreements that will govern the project to ensure inclusion of UMCNO/WJMC's institutionally agreed upon terms.

3. Review policies and credentialing requirements for all affiliate staff conducting research at UMCNO/WJMC.

# RRC Workflow once full application is submitted:

**RRC initial application**

- Submit application and supporting documents electronically to UMCOfficeofResearch@lcmchealth.org.
- We recommend that submission follows IRB application as soon as possible.

**Processing of application**

- All forms are submitted and signed as required.
- All staff should be credentialed or have credentialing in process.
- Submissions will not be reviewed until all documentation received.

**RRC review**

- RRC meets weekly on Friday mornings (with some exceptions).
- All documents will be reviewed to determine feasibility and compliance with ethics and billing regulations.

**RRC pending approval**

- After RRC review, request for clarification/revisions will be sent to study team.
- All requested corrections and updated documents should be submitted to the UMCOfficeofResearch@lcmchealth.org inbox.

**RRC chair review**

- Requested clarification/revisions will be reviewed by the RRC chair upon submission of all outstanding items.
- If further clarifications/revisions are needed, the study team will be notified.

**RRC approval**

- Conditions required to secure approval:
  - All requested clarifications/revisions accepted
  - All study staff credentialed at UMCNO
  - All documents signed by PI
  - IRB approval submitted to UMC Office of Research
  - All necessary agreements fully executed and on file

# Ethics Compliance Functions

- Confirms appropriate IRB approval for the study type is being obtained
- Approves participation of all study staff listed on the IRB application
- Ensures UMCNO is listed as a performance site on IRB applications/study documents
- Ensures partial HIPAA waiver for PHI preparatory to research is requested for screening of potential participants (where applicable)
- Ensures studies which require use of data under a full HIPAA waiver and waiver of consent are consistent with federal regulations as applicable
- As appropriate, verifies that necessary agreements are being reviewed/ drafted.

# Billing Compliance Functions

- CMS Compliance
  - Billing Coverage Analysis (BCA) assistance
  - Verify Local/National Coverage Determinations, where applicable
  - Ensure adherence to BCA during conduct of the project
- Billing Compliance
  - Provide fair market value for research services
  - Study billing outline generation in Epic
  - Review of all charges dropped for routing determination according to BCA
  - Invoicing of affiliate for research-related charges
  - Appropriate crediting of payments received from investigators

# Other Compliance Functions

- Credentialing of all study team members per UMCNO/LCMC policy
- Oversight of study teams documentation in EMR per UMCNO policy
- Ensuring performance of study procedures per scope of practice
- Ensuring requests for data will be limited to UMCNO/WJMC records and will not include other LCMC institutions
- Ensuring adherence to all research policies at UMCNO during the conduct of research studies

# UMC Office of Research Staff

**Jyotsna Fuloria, MD – VP, Research**
**504-702-3661**
**jyotsna.Fuloria@lcmchealth.org**

**Jeannine Ascani, Research Compliance Manager**
**504-702-3141**
**jeannine.ascani@lcmchealth.org**

**Mitch Carter, Research Billing/Budget Contact**
**504-702-5005**
**Mitchell.carter@lcmchealth.org**

**Sara Pettit, Research Contract/Data Use Contact**
**504-702-3622**
**sara.pettit@lcmchealth.org**