



UMCNO Office of Research Credentialing Instructions and Process

Clinical research coordinators employed/appointed to assist investigators must be credentialed by the Office of Research to perform their specific duties. The research affiliate may not be involved in the conduct of research at UMCNO until all credentialing requirements have been satisfied and approval is granted by the Office of Research.

Process

1. The research affiliate will complete the checklist and provide **DO** required documentation to the Office of Research via a single email. Incomplete submissions will delay credentialing.
 - a. Submitted information must be current and accurate.
 - b. On the Scope of Practice, check off only the duties associated with your designated role.
 - c. Please type required information in the attached documents including drop-down selections and checkboxes and print for required signatures.
2. Office of Research will contact research affiliate to notify of credentialing approval and provide details regarding steps for gaining access to the electronic health record and other UMCNO systems including required training.
3. Full credentialing will be renewed every two years by submission of renewal checklist and accompanying documentation to the Office of Research.
4. The Office of Research will track credentialing expiration dates and notify research affiliates at 60 and 30 days prior to credentialing expiration.
5. Once the research affiliate credentialing is re-approved, the research affiliate and PI will be notified of re-approval via email.
6. In addition to the full credentialing renewal, some licensure and certification documentation must be collected annually. The Office of Research will track expiration dates and notify the research affiliate of expiring licensure/certification.



DEPARTMENT OF CLINICAL RESEARCH RESEARCH AFFILIATE REQUIREMENTS CHECKLIST

Name: _____

- Student Coordinator Nurse
- Current Personnel Performance Evaluation (N/A for new hires <1 year and students)
- Curriculum Vitae
- Job Description (N/A for students/volunteers)
- Professional License Verification
- Photo Identification (driver's license, passport, student ID)
- CPR/BLS Certification
- Scope of Practice
- Immunization records
 - MMR [Measles, Mumps/Rubella] Titer Results or MMR X 2 Vaccinations
 - Hepatitis B Antibody & Antigen Titers or Hepatitis B X 3 Vaccinations
 - Varicella Titer or Vaccination
 - Flu Vaccination
- TB Skin Test/X-ray (required annually)
- Documentation of Background Screening & Drug Screening
- GCP/Human Subject Protection Training (CITI Program, NIH, etc.)
- Computer Access Request Form *Complete Employee Portion*
- Non-Employee HR Packet
- Clinical Research Contact Form

The checklist and accompanying documentation should be emailed to umcofficeofresearch@lcmchealth.org.

For credentialing questions, contact the Office of Research at 504-702-5005 or 504-702-3149.

University Medical Center New Orleans

Scope of Practice for Licensed /Non-licensed Research Personnel Involved in Clinical Research

NAME (Type Last name, First name)	RESEARCH ROLE
	Choose an item.
DEGREE	LICENSURE
<input type="checkbox"/> BSN <input type="checkbox"/> BS <input type="checkbox"/> MS <input type="checkbox"/> PhD <input type="checkbox"/> None <input type="checkbox"/> Other:	<input type="checkbox"/> RN <input type="checkbox"/> LPN <input type="checkbox"/> MT <input type="checkbox"/> None <input type="checkbox"/> Other:
SUPERVISOR/SUPERVISING INVESTIGATOR	DEPARTMENT/DIVISION

The Scope of Practice is specific to the duties and responsibilities of each research affiliate. The affiliate is authorized to conduct research involving human subjects with the responsibilities approved below in conjunction with approved research protocols. This Scope of Practice does not substitute for the requirement of obtaining clinical privileges, credentialing, or board processing for all licensed independent providers. The Principal Investigator associated with the study is responsible for the conduct of the employee and must sign the Scope of Practice.

PROCEDURES:

Affiliates are authorized to perform the following duties and procedures on a regular and ongoing basis on protocols approved by an IRB and UMCNO’s Research Review Committee. A signed copy of this document will be maintained in the affiliates’ s file in the UMCNO Office of Research.

Non-licensed affiliate includes research coordinators who are not credentialed, research assistants, biostatisticians, administrative assistants, and students. Foreign medical graduates that are not licensed in the U.S. are considered non-licensed personnel.

Check the appropriate boxes for routine duties that apply to the research employee’s designated credential affiliation

Note: Any documentation that supports your ability to perform these duties should be submitted.

Research Duties	Students & Other Non-Licensed	Licensed R.N.	Other Licensed & Credentialed	Lab/Bench Staff
Regulatory document preparation/submission to IRB, UMC Office of Research, Sponsor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Develops and/or implements study recruitment methods	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Prepares study initiation program, materials and activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Screens patients for study eligibility by reviewing patient health records or interviewing patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Maintains screening logs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Provides education related to study, to patient, family, and UMCNO staff as necessary per protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Obtains informed consent from research subject	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Checks and records vital signs		<input type="checkbox"/>	<input type="checkbox"/>	
Performs venipuncture to obtain study specific specimens		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Collects and/or processes human specimens (i.e. blood, urine, sputum etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ships biological materials (Requires IATA training) <small>Attached</small>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Maintains specimen inventory and ensures appropriate storage conditions and security	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Investigational pharmacy: Once study drug is ordered by licensed provider and dispensed by pharmacist, delivers study drug to research subject.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Provides subject education/instruction on use of study medication/device, side effects and how to notify researcher of adverse drug reactions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Schedules research subject visits and study procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Documents research notes into electronic health record	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Maintains complete and accurate records including data collection records, source documents, and case report forms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Prepares/manages payments to research subjects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Research Affiliate's Statement

This Scope of Practice outlines research duties I am permitted to undertake in conjunction with approved protocols. I understand that all research performed at UMCNO must be approved by the IRB and UMCNO's Research Review Committee. If I have questions or concerns, I will to contact UMCNO's Office of Research. I also understand that performing tasks beyond my scope of practice, without specific authorization, will lead to disciplinary action. I agree to abide by all applicable hospital policies.

Signature of Research Affiliate

Date

I certify that this affiliate possesses the skills to safely perform the aforementioned research duties. Both the affiliate and I acknowledge this Scope of Practice. I agree to abide by all applicable hospital policies.

Printed Name of PI

Signature of PI

Date

*****For Office Use Only*****

VP of Office of Research Signature/Designee

Date

Coordinator of Office of Research Signature

Date



University Medical Center New Orleans

Computer Account Application

All applicants *must* complete the following: (please print)

Last Name: _____ First Name: _____ Middle Initial: _____ Prefix: _____

Place of Birth: (City, State if U.S. City, Country if not U.S.): _____

Date of Birth: ____ / ____ / ____ Sex: _____ Social Security Number: _____

Home Street: _____ Home Phone Number: _____

Home City, State, Zip: _____

School / Department / Hospital / Agency: _____ Job Title: _____

Section: _____ Phone Number: _____

Address: _____ City, Zip: _____

By signing this application, I agree to the following:

- I acknowledge that I am accountable for all activity attributable to my logon ID. Accordingly, I will not share my logon ID and I will guard my password.
- I will use my logon ID to perform authorized activities only (i.e., to carry out employment, contract, or school-related responsibilities).
- If I abuse or gain unauthorized access to computer resources, I understand that UMC may immediately revoke my computer privileges and report my conduct to law enforcement authorities.
- I understand that, upon significant change in relationship with UMC (e.g., change of department/agency, job function, etc.), my access to computer resources will be subject to review and appropriate modification.
- I understand that, upon termination of employment, non-renewal of contract, or loss of active student status, UMC may delete my logon ID and my data.
- I understand the importance of privacy and confidentiality of information and in particular patient information, student records, and employee personal data. I pledge to access and handle all sensitive data with the appropriate care and precautions.
- I understand that UMC does not guarantee the privacy of e-mail.

Signature of Applicant: _____

Date of Application: _____

Applicant's computer supporter must complete the following:

Network

Login Script: _____, Home Directory: _____

Global Groups: _____

Supervisor Signature: _____ Print Name/Title: _____

Authorizing Signature: _____ Print Name/Title: _____

Computer Supporter's Signature: _____ Support Group: _____



University Medical Center New Orleans
Corporate Compliance Attestation Statement

I have attended the mandatory Corporate Compliance training for all new employees of University Medical Center New Orleans. I understand that I am responsible for being familiar with the Corporate Compliance Program as it relates to my position and to the facility as a whole. I understand that I am responsible for following the Corporate Compliance policies and procedures as well as other policies and procedures of the facility.

I understand that I am responsible to conduct myself in the manner consistent with the Code of Ethical Behavior and the Core Values of the University Medical Center New Orleans.

I understand that I am responsible for reporting any suspected Fraud and Abuse practices within this facility.

If I have any questions regarding compliance, I am to contact my supervisor or the University Medical Center New Orleans Corporate Compliance Department as soon as possible.

Employee's Signature

Date

Employee's Name (Printed)

Department



**HIPAA TRAINING EMPLOYEE CONFIDENTIALITY AGREEMENT
EMPLOYEE ACKNOWLEDGMENT**

I agree to comply with the UMCNO HIPAA policies which include procedures for proper handling of Personal Health Information (PHI), computer passwords and access, and confidentiality. I acknowledge that my violation of these policies by me may lead to immediate disciplinary action, up to and including the termination of my employment. I also acknowledge that my obligation of confidentiality continues to exist even when I leave the employ of the LCMC system facility.

Employee Name (print)

Employee Signature

Department

Date



SERVICE BEHAVIORS

ACKNOWLEDGMENT

I have reviewed the University Medical Center New Orleans Service Behaviors as presented in the General Orientation Key Elements presentation and Employee Information Guide. I have also been informed how to access further information related to service behaviors and other policies via UMCNO Policies & Documents website.

Employee Name (Print)

Employee Signature

Date

Department



**EMPLOYEE MEDICARE / MEDICAID
CUMULATIVE SANCTIONS ACKNOWLEDGEMENT**

Applicant Name: _____

Social Security Number: _____

Date of Birth: _____

Do you currently have or ever had HCFA / Medicare / Medicaid sanctions imposed against you under the name indicated above or any other name?

_____ YES _____ NO

If yes, please explain:

I certify that I understand that I am expected and obligated to inform my employer should I incur any type of HCFA / Medicare / Medicaid sanction against me at any time during my employment with University Medical Center New Orleans.

Applicant / Employee Signature

Date

Human Resources Designee Signature

Date

*Original retained in HR

General Orientation Key Elements Check List

Initial each space in the left column.

Initial	Service Excellence/Serving With Spirit
	Health Literacy
	Mission, Vision & Core Values (UMCNO Specific)
	AIDET: Customer Satisfaction
	E-Mail Etiquette
	Telephone Etiquette
	Cultural Diversity/Team Building
	American with Disabilities Act
	Ethics
	Offenders/Hospital Police
	Prisoner Care
	Key Elements: Common Policies
	Attendance, Tardiness, Paid Time Off, Extended Illness Time
	Appearance/Dress Code
	Performance Improvement
	Employee Information Guide
	Employee Health/Infection Control & Prevention
	Hand & Respiratory Hygiene
	Bloodborne Pathogens & Exposure Control
	Standard Precautions & PPE
	Biohazard Disposal, Sharps Disposal, Cleaning/Disinfection/Sterilization
	Isolation Precautions
	TB & Viral Screenings
	Safety
	Security
	UMC SAFE/Incident Reports
	Ergonomics, Back Safety
	Compliance
	Compliance Overview (including Code of Conduct)
	Security, Privacy (HIPAA Regulations)
	Federal False Claims Act & EMTALA
	Advocacy in Healthcare/Patient's Rights
	Healthcare Advocacy
	Patient's Rights & Responsibilities (including Pain Management & Population Specific Care)
	Stroke Awareness
	Risk Management
	National Patient Safety Goals

I have completed UMCNO General Orientation where the above content was presented along with information about how to access updated policies via Policies & Documents. I will complete the remaining orientation topics within my first 30 days of employment via the UMCNO learning management system, WILMA. I was given the opportunity to ask questions about these materials and I understand all key elements. I will abide by this institution's rules and policies.

Print Name

Signature

Department

Date



Office of Research

Contact Information form

Full Name (Last, First, M.I.)				
Primary Address (Mailing)		City	State	Zip Code
Gender	Birth Date (MM/DD/YYYY)	Contact Number		
<input type="checkbox"/> Male		() _____ Home		
<input type="checkbox"/> Female		() _____ Cell		
School Affiliation				
LSUHSC:		TUHSC:		
Faculty		Faculty		
Staff		Staff		
Student		Student		
Other: Facility name				
Faculty				
Staff				
Student				
Department Name				
Department Section				
Job Title		Office Number		
Email Address				

Signature

Date

EPIC TRAINING REQUEST FORM for Research

Name & Last 4 of SS#: _____

Contact Email (personal/work email): _____

Job Title/Role/Specialty: _____

IRB #: _____

Start Date: _____

Outpatient Inpatient

I am a clinician and will be completing clinical documentation within the patient record (i.e. Progress/Nursing Note, med admin, etc.)

I will be associating patients with research studies within the medical record.

I will be reviewing and splitting charges in the medical record to ensure study charges are attributed to the research grant, rather than the patient's insurance provider.

If the coordinator has been trained in EPIC applications elsewhere, please list below, including at what facility. He/she may qualify for an abbreviated training.

EPIC Courses Completed

Name of Facility

1. _____

2. _____

3. _____

NOTE: This form should only be completed if you will be documenting in the patient record as part of the IRB Study you have been credentialed to participate in.