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)
- ☐ 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
	Select One
DEGREE	LICENSURE
☐ BSN ☐ BS ☐ MS ☐ PhD ☐ None ☐ Other:	☐ RN ☐ LPN ☐ MT ☐ None ☐ 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	☐	☐	☐	
Develops and/or implements study recruitment methods	☐	☐	☐	
Prepares study initiation program, materials and activities	☐	☐	☐	
Screens patients for study eligibility by reviewing patient health records or interviewing patients	☐	☐	☐	
Maintains screening logs	☐	☐	☐	
Provides education related to study, to patient, family, and UMCNO staff as necessary per protocol	☐	☐	☐	
Obtains informed consent from research subject	☐	☐	☐	
Checks and records vital signs		☐	☐	
Performs venipuncture to obtain study specific specimens		☐	☐	☐
Collects and/or processes human specimens (i.e. blood, urine, sputum etc.)	☐	☐	☐	☐
Ships biological materials **(Requires IATA training)** ☐ Attached	☐	☐	☐	☐
Maintains specimen inventory and ensures appropriate storage conditions and security	☐	☐	☐	☐
Investigational pharmacy: Once study drug is ordered by licensed provider and dispensed by pharmacist, delivers study drug to research subject.	☐	☐	☐	
Provides subject education/instruction on use of study medication/device, side effects and how to notify researcher of adverse drug reactions	☐	☐	☐	
Schedules research subject visits and study procedures	☐	☐	☐	
Documents research notes into electronic health record	☐	☐	☐	
Maintains complete and accurate records including data collection records, source documents, and case report forms	☐	☐	☐	☐
Prepares/manages payments to research subjects	☐	☐	☐	☐

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 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: _____

_____

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: _____

Revised: 4 /13/2015

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

UMC
UNIVERSITY
MEDICAL CENTER
NEW ORLEANS

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

Office of Research

Contact Information form

Full Name (Last, First, M.I.)				
Primary Address (Mailing)		City	State	Zip Code
Gender ☐ Male ☐ Female	Birth Date *(MM/DD/YYYY)* / /	Contact Number ( ) _____ Home ( ) _____ Cell		

School Affiliation

LSUHSC: ☐ Faculty ☐ Staff ☐ Student

TUHSC: ☐ Faculty ☐ Staff ☐ 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.