



I. SCOPE

This procedure applies to Loyola University of Chicago (LUC) employees and school of medicine, school of nursing, and graduate school students that request access to Loyola University Medical Center (LUMC) facilities or resources for research purposes only ("Research Non-Colleagues").

Other LUC students and employees who will be involved in the clinical care of LUMC patients unrelated to or in addition to research or complete clinical rotations at LUMC fall under other departmental procedures.

Research monitors follow research SOP PRO-004 External monitor access to Epic.

II. INITIAL SUBMISSION

- A. The Research Non-Colleague requests access to LUMC facilities or resources and identifies that the access is related to research activities.
- B. The Research Non-Colleague is referred to LUMC Clinical Research (LUMC CR) at (708) 216-4412 or luhsresearch@luhs.org.
- C. LUMC CR confirms the Research Non-Colleague's access to LUMC is for research purposes only. If there is any other purpose, LUMC CR refers the user to the appropriate party:
 1. LUC Employee: referral will depend on the individual situation
 2. School of Medicine Student: Office of Research Services
 3. School of Nursing Student: Center for Professional Practice and Development
 4. Graduate Student: referral will depend on the individual situation
- D. Under the guidance of a supervisor, the Research Non-Colleague completes the Research Non-Colleague Initial Application and sends to LUMC CR.
- E. LUMC CR determines which requirements are applicable for the Research Non-Colleague. The LUC- and LUMC- facilitated requirements should proceed in parallel for efficiency.
- F. LUMC CR informs the supervisor of the requirements facilitated by LUC.
 1. LUC-facilitated requirements may include:
 - a. A background check.
 - b. Occupational health requirements for those who may enter LUMC patient care areas.
 - c. Documentation of competency for each clinical activity to be performed in LUMC for those who may intervene with patients. Competency documentation must include the same level of detail as the LUMC competency documentation for the unit or service area.
 - d. Current licensure and BLS training for nurses who may intervene with patients.
 - e. Listed on at least one IRB-approved protocol.
 2. The supervisor informs LUMC CR when the LUC-facilitated requirements are completed.
- G. LUMC CR requests a non-colleague Workday ID for the Research Non-Colleague.
- H. Once the Workday ID is granted, LUMC CR assigns required modules to the Research Non-Colleague in HealthStream.
 1. Modules may include:
 - a. Trinity Code of Conduct training.
 - b. Trinity Confidentiality and Information Security Agreement.
 - c. HIPAA training for those who may have access to protected health information.
 - d. Infection Prevention Annual Competency and Environment of Care training for those who may enter LUMC patient care areas.
 2. LUMC CR provides the Research Non-Colleague with their log in information and instructions for completing HealthStream modules.
 3. If the assigned modules are not completed within 4 weeks, the Workday ID will be terminated. The Research Non-Colleague will need to be re-submit a Research Non-Colleague Application.



- I. For those requesting access to the electronic health record, LUMC CR provides upcoming training times to the Research Non-Colleague and facilitates scheduling the training.
- J. For those requesting access to secure patient care areas, LUMC CR facilitates approval for badge access to the area(s) from the manager of the patient care area.
- K. Once all LUC- and LUMC-facilitated requirements are met, LUMC CR completes the Research Non-Colleague Initial Approval document. LUMC CR, the Research Non-Colleague, and the supervisor sign the document. The Research Non-Colleague is then approved to access LUMC for research for a period of one year.
- L. LUMC CR submits requests for systems access for each system noted in the Initial Approval document.
 1. The user will be granted view only, research clinical protocol coordinator, research nurse, or research oncology nurse Epic access according to the scope of approved research activities and Epic training.

III. ANNUAL RENEWAL

- A. LUMC CR tracks Research Non-Colleague approval statuses.
- B. Two months before the Research Non-Colleague's approval is due to expire, LUMC emails the Research Non-Colleague and his/her supervisor. The email contains:
 1. A copy of the current approval letter
 2. A copy of the Renewal Application
 3. The expiration date for the current approval.
- C. Under the guidance of a supervisor, the Research Non-Colleague completes the Research Non-Colleague Renewal Application and sends to LUMC CR.
- D. LUMC CR determines which requirements are applicable for the Research Non-Colleague's renewal. The LUC- and LUMC- facilitated requirements should proceed in parallel for efficiency.
- E. Requirements for any new activities are as noted in Section II. F-J.
- F. The following items require completion annually:
 1. Infection Prevention Annual Competency if entering patient care areas.
 2. Occupational health requirements, including annual influenza vaccinations, if entering patient care areas.
 3. Competency documentation for each clinical activity to be performed within LUMC, if intervening with patients in LUMC.
- G. Once all LUC- and LUMC-facilitated requirements are met, LUMC CR completes the Research Non-Colleague Renewal Approval document. LUMC CR, the Research Non-Colleague, and the supervisor sign the document. The Research Non-Colleague is then approved to access LUMC for research for a period of one year.

IV. TERMINATION

- A. The supervisor is responsible for notifying LUMC CR when a Research Non-Colleague leaves his/her position at LUC. The notification is provided as soon as possible after learning of the termination and no later than the individual's last day at LUC.
- B. LUMC CR terminates the Research Non-Colleague's access to the LUMC network, including the electronic medical record.
- C. The supervisor returns the Research Non-Colleague's badge to the parking office.

V. REFERENCES

- A. Comprehensive Accreditation Manual, The Joint Commission
- B. COMP-002 Access to and release of patient information- Students, trainees, agency staff, and volunteers
- C. RH-2 Reference and background check
- D. G-19 Verification of employee current licensure/registration/certification



- E. OPER 010 Occupational Health and Safety Requirements
- F. SOP PRO-004 External Monitor Access to Research

VI. ASSOCIATED DOCUMENTS AND FORMS

- A. Research Non-Colleague Initial Application
- B. Research Non-Colleague Renewal Application

VII. APPROVALS


 _____ 10-29-19
 LUMC EVP, Clinical Affairs (or designee) Date


 _____ 10/24/19
 LUC Senior Director, Clinical Research Office (or designee) Date