## I. SCOPE

This procedure applies to all clinicians, colleagues, and Research Non-Colleagues who access Loyola University Medical Center (LUMC) hospitals, clinics, or electronic medical record systems for research purposes.

Research Non-Colleagues are 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.

## II. PROCEDURES

A. Research Non-Colleagues are to be approved by LUMC Clinical Research before they may access LUMC facilities or electronic systems. See SOP ADM-002 Research Non-Colleague Access to LUMC.

B. Activities in LUMC space
   1. Researchers may access and perform research activities in LUMC space as specifically approved through the Research Non-Colleague process (if applicable), as approved for each study through the IRB, and in accordance with LUMC policy and state and federal regulations. Limitations include but are not limited to:
      a. Research Non-Colleagues may not perform patient care services that are to be billed to the patient or the patient's insurance.
      b. Research Non-Colleagues may only perform those services that are listed on the Research Non-Colleague's current approval document.
      c. Researchers may only perform those activities for which they were determined to be competent.
      d. Researchers follow the same scope of practice guidelines as apply to clinical colleagues in a similar role. This is especially pertinent for registered nurses.
   2. A research participant that has services performed by or in LUMC is also an LUMC patient.
      a. Patients must be registered before or upon presentation to LUMC for services.
      b. Patients must be checked in or admitted to the area in which services will be provided.

C. Use of the electronic medical record
   1. Copies of research consent forms are uploaded in to Epic as described in SOP Research Consents in Epic.
   2. The principal investigator and/or his/her designee ("Study Team") is encouraged to document research activities in Epic as they relate to the patient's clinical care within the following parameters:
      a. The Study Team is required to document the consent process and conversation with the patient in the patient's medical record.
      b. Research documentation is entered in a Research Encounter, a Research note type, or is otherwise clearly labeled as research.
      c. Data collected by research personnel is entered in notes and not in flowsheets.
      d. Data collected on research equipment is clearly labeled as research.
   3. Research laboratory results from a central laboratory may be scanned in to Epic if:
      a. The central lab is CLIA certified.
      b. The results are accompanied with a cover sheet signed by the treating physician that explains they are from a research central lab but are medically relevant.
   4. Research personnel may enter orders as permissible under LUMC policies and procedures for acceptable order entry by non-physicians.
      a. Research personnel may pend orders as needed.

b. Licensed registered nurses may utilize additional order modes in defined, rare circumstances.
   (1) Verbal Order w/ Read Back: Verbal orders shall be used infrequently and limited to the following situations:
      (a) urgent situations when immediate written or electronic communication is not feasible; or
      (b) when a pharmacist, nurse or respiratory therapist calls an LIP to clarify or correct a written order.

   Verbal orders must be counter signed by the ordering physician in Epic before the physician leaves the patient care area.
   (2) Ambulatory Protocol: An Ambulatory Protocol/Standing Orders SmartSets must be used for this order mode. The Ambulatory Protocol must be approved through the Medical Executive Committee (MEC).

5. Blood collection for research purposes requires an order. The order 'Research Study Lab' may be used when a venipuncture is needed for blood collection or when additional tubes are needed from a routine venipuncture. See Guidance Document: Blood collection for research for additional guidance.

## III. REFERENCES

A. Research SOP ADM-002 Research Non-Colleague Access to LUMC
B. Research SOP PAT-001 Consent documentation in Epic
C. Comprehensive Accreditation Manual, The Joint Commission
D. LUMC Patient Care Policy DOC 003 Diagnostic and Therapeutics Orders
E. Guidance Document: Blood collection for research

## IV. APPROVALS

11/2/21
LUHS Regional Chief Clinical Officer (or designee) Date

11/2/21
LUC Medical Director, Clinical Research Office (or designee) Date

**Revision History**

| Effective Date | Summary of Changes |
|---|---|
| 1/Jan/2020 | Initial version |
| 1/Oct/2021 | Incorporated reference to Guidance Document: Blood collection for research |