I. SCOPE

This SOP applies to all external users who have a need to review Loyola University Medical Center (LUMC) medical records for purposes of monitoring a clinical research study ("monitors"). External users are those who are not employed by Loyola University Health System or Loyola University of Chicago (LUC).

Monitors may only access the medical record, Epic, if acceptable under the study agreement and each patient's HIPAA authorization or IRB-approved HIPAA waiver.

Monitors access Epic through LoyolaConnect, a web-based portal. Their access is limited to the patients identified by the Study Team as consented to the study they are monitoring. There are 3 requirements for this functionality: 1) each study have a current patient group in Loyola Connect, and each monitor have 2) an active Workday ID and 3) LoyolaConnect access.

This SOP does not address the requirements for access to the Loyola University of Chicago network or systems, such as obtaining a NAP ID.

II. PROCEDURES

1. The PI or his/her designee ("Study Team") receives notification of an upcoming monitor visit.
2. **Patient Group:** The Study Team initiates and maintains the study patient group in LoyolaConnect. IT requests for a patient group are submitted when a new group is needed or when there are changes (additions or removals) to the patients in the group. A new request is not necessarily needed for each monitor visit. A new request is not needed if there is a new monitor for the study.
    a. To create a new patient group:
        (1) the Study Team completes the 'LoyolaConnect research patient group request'. It is acceptable to provide a list in a different format as long as the same information is present (i.e. oncology research patient lists may be generated from Velos).
        (2) The Study Team submits a Generic Service Request through Trinity Health's ServiceNow to request a new patient group in LoyolaConnect and attaches the request form as confidential.
            (a) A LUMC manager or above must be listed as the request approver in ServiceNow. Enter Katherine van Meurs (LUMC Manager, Clinical Research Operations).
        (3) The LoyolaConnect team builds a new patient group for each study. The name for the patient group follows the convention 'Research Patients LU[LU#]'.
    b. To maintain a patient group:
        (1) Before each monitor visit, the Study Team reviews the most recent 'LoyolaConnect research patient group request' to ensure the list remains accurate.
        (2) If patients need to be added or removed, the Study Team submits a updated patient group list through ServiceNow, Generic Service Request.
3. **Workday ID:** The Study Team initiates and maintains the monitor's Workday ID. A Workday ID is needed before Epic access may be requested. Requests for a Workday ID are submitted when a monitor is new to Loyola. The Workday ID must be reactivated annually. A Workday ID request is not necessarily needed for each monitor visit.
    a. The monitor and Study Team complete the Non-Colleague Workday Request Form for the monitor. The form's fields should be completed with the following exceptions/additional guidance:

(1) Social Security Number: the last 4 digits are required
(2) Position (Job Title): Research Monitor
(3) Department: enter the LUC department that is hosting the monitor
(4) Department code: leave blank
(5) Contract Pay Rate: leave blank
(6) Contract Start Date: enter the first date the monitor is expected to access Epic
(7) Termination Date: enter one year from the first day of the monitor visit. Note: the termination cannot be more than one year from the start date.
(8) Scheduled weekly hours: leave blank
(9) Work shift: leave blank
(10) Has this Agency Non-Colleague been approved by LRT?: leave blank
(11) Supervisor Information: list the LUMC Manager, Clinical Research Operations
    (a) Supervisor/Requestor/Sponsor: Katherine van Meurs
    (b) Supervisor Department: 9999 Clinical Research
    (c) Supervisor Title: Manager, Research Operations
    (d) Supervisor Phone Number: 708-216-4412
    (e) Supervisor's Email Address: Katherine.vanmeurs@lumc.edu
(12) Is there a Business Associate Agreement (BAA) on file?: Enter 'N/A, user's access falls under a research agreement'
(13) Is the BAA current?: enter N/A
(14) Is there a service agreement on file?: enter 'N/A. Contact Katie van Meurs at 6-4412 with questions about research agreements'.
(15) Is the service agreement current?: enter N/A
(16) Is there an Epic 3rd party agreement?: enter N/A

  b. The Study Team emails the completed form to LUMC Manager, Clinical Research Operations (Katherine.vanmeurs@lumc.edu). She signs and returns.

  c. The Study Team submits a Generic Service Request to request a Workday ID. See ServiceNow Non-Colleague Access Request instructions.

  d. IT emails the monitor's Workday ID to the LUMC Manager, Clinical Research Operations who forwards it to the Study Team.

  e. The Study Team submits an Access Request to re-activate Workday annually for each monitor.
    (1) See Instruction Sheet 2 - Access Request - Colleague and Non-Colleague for guidance on submitting an Access Request.
    (2) Select 'Reactivation' as the system.

4. **LoyolaConnect Access:** The Study Team initiates and re-activates the monitor's access to LoyolaConnect. The monitor's access to LoyolaConnect is limited to when he/she is known to be actively monitoring the study. A new request is submitted for each monitor visit.
  a. The Study Team requests LoyolaConnect access for the monitor.
    (1) The Study Team confirms the monitor has a Workday ID by reviewing emails from the LUMC Manager, Clinical Research or within the Access Request form itself (see below).
    (2) The Study Team submits a Trinity Health Access Request for the monitor's access to LoyolaConnect. See Instruction Sheet 2 - Access Request - Colleague and Non-Colleague.
      (a) If the monitor has multiple entries, select the entry that lists kvanmeurs (LUMC Manager, Clinical Research) as the supervisor.
      (b) When prompted, enter the Effective Date to be the first day the monitor needs Epic access and the End Date to be the day after the monitor is expected to no longer need Epic access.
        1. Requests for >5 day time frame will be queried to confirm accuracy.

          2.   if the monitor is expected to access Epic for more than 5 days, enter a note on the Epic page with an explanation.

    (c)   Specify in the request which patient group(s) the monitor needs access to.

    (d)   Submit the request.

(3) LUMC Manager, Clinical Research Operations approves the request.

(4) IT emails the monitor's username and password to the LUMC Manager, Clinical Research who forwards it to the Study Team.

    (a)   if the monitor's username and password has not been provided within 5 business days of the monitor visit, the Study Team calls the Trinity Helpdesk at 708-216-2160 and requests the ticket is escalated.

(5) The monitor accesses LoyolaConnect at: https://myloyolapro.iuhs.org/EpicWeb/common/epic_login.asp

(6) The Study Team submits a new request for LoyolaConnect access for each monitor visit.

b.   if the monitor requires a password reset, he/she uses the Trinity Self Help Password Reset system.

    (1) if the monitor is remote (not on the LUMC network), he/she accesses this through: https://remotepss.trinity-health.org. Note: the LUC network is remote.

    (2) if the monitor is on the LUMC network, he/she accesses this through https://pss.trinity-health.org

    (3) if the monitor is unable to access either site, he/she calls the Trinity Health helpdesk at 708-216-2160.

III.   REFERENCES

A.   LUMC Spirit information Technology page: http://luhs.che.org/Departments/hm/ITS/ (accessed 8/31/2018)

IV.   ASSOCIATED DOCUMENTS AND FORMS

1. Non-Colleague Workday Request Form
2. ServiceNow Non-Colleague Access Request Instructions
3. Instruction Sheet 2 - Access Request - Colleague and Non-Colleague
4. LoyolaConnect research patient group request

V.   APPROVALS

_____   3/29/19

LUMC EVP, Clinical Affairs (or designee)   Date

_____   3/25/19

LUC Senior Director, Clinical Research Office (or designee)   Date

**External Monitor Access
to Epic
PRO-004
Effective date: 01/Apr/2019**

LOYOLA
UNIVERSITY
HEALTH SYSTEM

LOYOLA
UNIVERSITY
CHICAGO

Revision History

Effective Date	Summary of Changes
1/Nov/2018	Initial version
1/Apr/2019	Clarified the types of tickets to be submitted; incorporated LUMC Manager, Clinical Research Operations as the non-colleague supervisor