Stanford Medicine Children's Health Epic Access for Monitors (Research Only)

Effective June 18, 2020, this SOP is used for both **remote and on-site monitor access** to Stanford Medicine Children's Health Epic.

A Study Coordinator, Research Manager, or PI must complete the following instructions for any monitor (i.e., Industry Sponsor, FDA) who requires LPCH Epic access for research auditing purposes.

Limitations of Access: For each request, please provide a date range corresponding to the <u>minimum</u> number of days that your monitor will need Epic access. For patient privacy concerns, we limit the monitor's access to a *maximum of two weeks (or 14 calendar days)* per request. If your monitor requires Epic access for a subsequent occasion/visit, *a new submission is required.* For hours of operation, monitor access is restricted to 5am-8pm Pacific Time. *However, access assistance will only be available from 8am-5pm Pacific Time.* **Please note we are not permitted at this time to provide Epic access to monitors located outside the United States.**

Timeline of your Submission: Submit a request by completing the Online Request Form (REDCap Questionnaire) below *at least 15 business days prior to your monitor's requested first day of access.* If the requester does not receive a notification within 5 business days of your monitor's first day of access, please submit a Help Ticket HERE to get an update.
** Do not submit a request any earlier than 20 business days prior to your monitor's requested first day of access.**

Complete the Online Request Form (REDCap questionnaire):

I. Go to: https://med.stanford.edu/mchri/crso/epic/stanford-children-s-health-epic-access-for-monitors-research-onl.html

II. Click on RED button: ***EPIC Access for Research Monitors*** to access the Online Request Form (SUNet ID is required)

III. **IMPORTANT:** Prior to completing form, ensure you have **ALL** the following information and documents available to upload:

   1. PDF of the completed and signed Stanford Children's Health Remote Monitor Agreement
   2. PDF of your IRB Approval Letter (https://eprotocol.stanford.edu)
   3. List of all Medical Record Numbers (MRNs) to which the monitor will need access
   4. <u>For each MRN</u>, the following will be required:
      a. PDF of the *entire* Informed Consent Form (ICF) with signature(s) along with the corresponding PDF of the *entire* Assent Form (AF) with signature(s) as required by regulation. **Access request will not be processed if any of the ICFs and AFs are missing.** (ICFs and AFs can be downloaded from the Scanned Documents tab in Epic.) (HINT: use 'print to PDF'.)

<u>Important notes:</u>

- Requests missing any of the above required documents will not be processed.
- Access request will not be processed if any of the ICFs and AFs are missing.
   o For unique requests, such as in a case where a research study has a waiver of consent, please contact MCHRI/Stanford Children's Health personnel at lpchresearchepic@stanford.edu. We will review each case and provide guidance as appropriate. Please note additional approvals may be required based on what the unique circumstances of each request.

- Due to the backlog of studies that require monitor visits during shelter-in-place, requests may take longer than usual to process.
- This is the only process by which monitors may access SCH Epic remotely.

You are DONE.

Termination: Supervisors must submit a termination request here when an employee with access to Stanford Children's Health Epic leaves their position. Please be advised that MCHRI must be notified immediately of any termination or leave from the position in which SCH Epic access is currently enabled. This includes leaves of absence, internal Stanford University transfers, transfers to Stanford Children's Health or Stanford Healthcare, as well as employment separation from Stanford University. MCHRI will also perform regular monitoring of access. Should we identify an inactive user, we will send a status confirmation request to the PI/Manager that most recently attested to the individual's access. Should a response not be received from the PI/Manager within 48 hours, access to Epic will be terminated.

Please submit a Help Ticket HERE for any questions or issues regarding SCH Epic Access for Monitors.