

Request for Research Outside Monitor Remote and “Read-Only” access to study records through Stanford Medicine Children’s Health EpicCare Link

APPLICATION INSTRUCTIONS AND FORM

PURPOSE:

To facilitate source verification of study participants who receive research-related care at Stanford Medicine Children’s Health (SMCH) and to ensure compliance with applicable patient privacy and security laws, SMCH has established the following procedures to permit outside Human Subject Research Study Monitors (OMs) to apply for access to remotely view study subjects’ records in Epic through SMCH’s EpicCare Link Portal.

SAFEGUARDS:

Study Monitor remote access to the EHR is strictly controlled as follows:

1. You are required to provide documentation that the device used to access EpicCare Link Portal meets the following SCH IT Security requirements. This information is captured in the application form.
 - a. Full disk encryption
 - b. Anti-Virus software is installed and running on the device
 - c. Access to secure home or office network or VPN
 - d. login ID and password is required to access the device
 - e. Device is issued and managed by employer
2. Study participants must sign the study’s Stanford University IRB approved informed consent form/HIPAA authorization form (ICF) prior to your access of study records, which authorizes your access to study-relevant contents of the study participant’s medical record.
3. You will be provided with a unique ID (SCH ID) for EpicCare Link Portal. You may not share this ID or your password with anyone else.
4. You will have “read-only” access to records of study participants.
5. You will have access only to the study participant’s study-related medical records through EpicCare Link Portal (EpicCare Link) and only for the specified remote monitoring dates (Fifteen (15) business days advance notice of a remote monitoring visit is required).
6. Access will be audited for compliance with this agreement and SMCH’s patient privacy/security and research policies.

DIRECTIONS:

Before SMCH may grant you access to EpicCare Link Portal for remote monitoring, you must complete the following request form, confidentiality statement, provide a description of the location where remote work will be performed and physical security measures in place to protect PHI, and provide documentation that your device meets SMCH IT Security requirements. A copy of the completed forms must be provided to the SoM MCHRI at least Fifteen (15) business days prior to your first remote monitoring access. Incomplete requests will not be processed and EpicCare Link Portal access will be denied until a complete request is submitted and approved.

APPLICATION AND TRAINING:

1. Application Form:
 - “Request for Remote Access to EpicCare Link Portal” (see page 3)
2. HIPAA Privacy & Security:
 - “Confidentiality Statement and Remote Access Guideline – Human Subject Research Study Monitors”

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(See pages 4 and 5)

3. EpicCare Link Portal training:
 - Once your application for access has been reviewed and approved, you will be provided with a SMCH ID that is your unique access to the EpicCare Link system and receive confirmation that access has been established and will be made available to you during the specified dates and times. Training is available for Research Monitors as needed. Please coordinate with your Research coordinator to arrange the training.
4. Advance Notice:
 - Fifteen (15) business days in advance of planned remote monitoring, you must provide the MCHRI with the MRN for the study participant(s) that will be reviewed during the remote monitoring visit.
5. Day of Remote Access:
 - You must check-in virtually with your MCHRI contact to verify you have the records requested and to pose any questions related to the remote access or the monitoring of the day.
 - If you need to step away from your laptop even for a short break, you must log-off from the session to prevent unauthorized access under your secure user ID (SMCH ID) code. You may be held responsible for any unauthorized access to the EHR using your user ID (SMCH ID) code.
 - You must access EpicCare Link from a secure location such as your home or office. You may not conduct your review in public spaces/locations such as libraries, Starbucks, or other locations where you are using a public network or unauthorized parties may be able to view your work.
 - You must connect from a secure internet connection such as a home or office network.
 - Downloading, storing, taking screenshots and printing Protected Health Information/Personally Identifiable Information from EpicCare Link is strictly prohibited.
6. Duration of Access:
 - The SMCH ID which is required for EpicCare Link is valid for 6 months from date of access control approval. If you leave the sponsor organization, your Supervisor is required to immediately notify the SoM MCHRI so that the SMCH ID and EpicCare Link access can be terminated immediately.
 - Access to individual patient records within EpicCare Link is limited to the specified dates and times of each remote monitoring review and access is only available between 5am – 8pm PST. Records provided for each scheduled review will expire and be removed from EpicCare Link at 8pm PST on the end date of the review.

For questions regarding this Application Form or any processes/issues related to SMCH Research Monitor Epic access, please submit a Help Ticket via the below RedCap form, and we will get back to you as soon as possible.

Help Ticket (RedCap form) link:

<https://redcap.stanford.edu/surveys/?s=8LD4MFADWD>

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APPLICATION FORM

You must submit a completed and signed copy of this form, the signed Confidentiality Statement, and a description of the location where remote monitoring will be performed to the MCHRI contact.

Requestor’s Information (to be completed by Monitor)

First and Last Name:

Name of Sponsor / CRO Company:

Sponsor / CRO Company Address:

City:

State:

Zip Code:

Date of Birth (Month/Day):

Email Address:

Phone Number where you can be reached on day(s) of remote access:

Today’s Date (x/x/xxxx):

Anticipated Date(s) of Visit:
to

My signature below indicates that I have read and understand the information on this form and agree to fully comply with the safeguards listed on pages 1 and 2, and with the application and training process described above.

Signature:

Requestor’s Supervisor Information (To be completed by Supervisor)

Name of Requestor’s Supervisor:

Email Address:

Business Phone Number:

Stanford Medicine Children’s Health (SMCH) requires the device used by the monitor to access EpicCare Link Portal to be encrypted, have anti-virus software installed and running, and require a login and password. The monitor must also have access to a secure home or office internet connection. You agree that the device provided to and used by the person listed above has been is encrypted, has anti-virus software installed and running, and the device requires a login and password and you will keep a written record indicating computer(s) used and how they

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are compliant. You also agree that the person listed above has access to a secure home, office or VPN connection.

My signature below indicates that I currently supervise the person listed above, have verified their device meets SMCH’s security requirements, and commit to immediately notify the Stanford MCHRI if that person’s employment status changes or other assignment changes relevant to this agreement prior to one year from date of agreement approval.

Supervisor’s Signature:

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CONFIDENTIALITY STATEMENT HUMAN SUBJECT RESEARCH STUDY MONITORS

I, _____, (PLEASE PRINT NAME) as a Human Subject Research Study Monitor (“Monitor”) at Stanford Medicine Children's Health (“SMCH”):

- Understand for purposes of this engagement, my remote access to the SMCH EPICCARE LINK Portal is restricted to human subject research monitor-related activities.
- Understand that my remote access to SMCH EPICCARE LINK is restricted to monitors located within the United States.
- **Understand that it is my legal and ethical responsibility to maintain the confidentiality of all patient identity, patient information, patient medical records, personally identifiable information, employee information, financial information, proprietary information, confidential information used in research, and other confidential information arising from or pertaining to SMCH (collectively, “Confidential Information”). This includes patient information (“PHI”) in any form, whether observed, spoken, written, or electronically maintained.**
- Understand for purposes of remote monitoring-related activities, I am restricted from accessing EPICCARE LINK Portal in public sites. I agree to establish and maintain a dedicated, safe, secure and confidential work space in the home free from distractions, have adequate physical protections to the home and dedicated work area to properly protect proprietary and confidential information, including Protected Health Information, from accidental, inadvertent, or intentional unauthorized access, use or disclosure that could result from overheard work telephone calls, over the shoulder viewing, shared access to office file cabinets, access to use IDs and passwords, inadequate locking mechanisms or other types of inadequate safeguards.
- Agree not to disclose any information or records to any person outside SMCH without proper authorization from SCH or to anyone inside SCH who does not have a need to know for a research purpose. Information accessed and used for research, including outside presentations and publications, requires appropriate Stanford IRB review and approval as well as a signed HIPAA compliant authorization signed by the study subject prior to access, use or disclosure.
- Understand that I may not download, copy, screenshot, or print confidential information and/or patient information from EPICCARE LINK or any other remote non-hospital storage facilities such as DropBox, SalesForce, GoogleDocs, etc.
- Understand that each time I access protected health information (PHI) or personally identifiable information (PII) I will only use the computer approved by SMCH and will only access the minimum necessary PHI/PII required to do tasks associated with Monitor-related activities.
- Understand that I am not to download or copy confidential data from EPICCARE LINK (to store on my computer hard drive, any mobile device or any removable device such as a USB/thumb drive).
- Agree to discuss confidential information only with the Study Coordinator or PI as appropriate, and only for Monitor-related purposes, and will not discuss within the hearing of other people who do not have a need to know about that information. Any communication with the Study Coordinator or PI that contains PHI will be conducted over the phone or through encrypted email.
- Understand that unauthorized disclosure of confidential information shall make me subject to legal action and/or ineligible to be a Monitor at SMCH.
- Understand that any and all references to HIV testing that may be included in a progress note, such as any clinical test, laboratory or otherwise used to identify HIV, a component of HIV, or antibodies or antigens to HIV, are specially protected and that unauthorized disclosure shall make me subject to legal action and/or ineligible to be a Monitor at SMCH.
- Understand that the law especially protects mental health, psychiatric, fertility, certain genetic, and drug/alcohol abuse records, and that unauthorized disclosure of such information may make me subject to legal action and/or ineligible to be a Monitor SMCH. SMCH will not provide access to these records; however, reference to these conditions may be included in physician documentation specific to the subject’s treatment in the clinical trial.
- Understand that access to EPICCARE LINK is audited regularly, and that any inappropriate access to information shall make me subject to legal action and/or ineligible to be a Monitor at SMCH.

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- Understand that I am responsible for protecting PHI/PII that is sent by me electronically such as through encrypted e-mail, and I am responsible for following the applicable SMCH policies with respect to the transmission of PHI/PII and that any inappropriate disclosure of information shall make me subject to legal action and/or ineligible to be a Monitor at SMCH.
- Understand that violation of any portion of the SMCH policies and procedures related to confidentiality of PHI/PII, patient records, the SCH Code of Conduct or any violation of federal or state regulations governing the patient’s right to privacy may result in immediate termination of my Monitor relationship with SMCH.

I acknowledge that I have read and understand the above statements and will discuss them with my designated SMCH host should I have any questions.

Signature: _____ Date (x/x/xxxx): _____

Printed Name: _____ Host Department: _ MCHRI _____