



**Center for Clinical and
Translational Research
Standard Operating Procedure**



Section Clinical Research Center

Date Effective: September 12, 2013

Title: Monitor Visits & Release of Information

Date Reviewed: April 5, 2022

SOP Number: SOP-39

Version Number: 7

PURPOSE: The purpose of this standard operating procedure (SOP) is to describe the process to be followed for University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM) and Bellevue Medical Center (BMC) personnel when a study monitor conducts a site visit to:

- Assess adherence to the protocol
- Review regulatory files for completeness
- Ensure appropriate study drug storage, dispensing and accountability
- Verify data in case report forms (CRF's) with source documents

SCOPE: Applies to all study monitoring visits conducted at UNMC, NM, and BMC and is inclusive of research applications:

- One Chart Link,
- Advarra EDC
- Advarra eReg,
- Vestigo

PERSONNEL RESPONSIBLE: Principal Investigator (PI) – and when delegated by the PI -- Sub-investigators, Study/Nurse Coordinator, Regulatory Coordinator and/or other pertinent staff who coordinate research activities.

DEFINITIONS:

- **Case Report Form (CRF or eCRF)**--A printed, optical, or electronic document to record all of the protocol required information to be reported to the sponsor on each study subject.
- **Clinical Trial Coordinator** - is responsible for conducting clinical trials using good clinical practice (GCP) under the auspices of the Principal Investigator (PI).
- **Monitor** – The person hired by a sponsor to give oversight of the clinical and administrative efforts of a clinical trial. The main role of this position is to verify data and to watch for safety issues in a study.
- **Study Protocol** – A document that describes how a clinical trial will be conducted to include the objective(s), design, methodology, statistical considerations and organization. It works to ensure the safety of study participants and integrity of the data collected.
- **Principal Investigator (PI)** – The person who is responsible for the management and integrity of the design, conduct, and reporting of the research project and for managing, monitoring, and ensuring the integrity of any collaborative relationships.

- **Source Data** - All information contained in original records and certified copies of results, observations, or other facets required for the reconstruction and evaluation of the research that is contained in source documents.
- **Source Documentation** - Location where information is first recorded including original documents, data, and records.
- **Sponsor** - An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of the research.

PROCEDURES:

- Prior to the first monitoring visit, a monitoring plan will be developed with the sponsor that defines what will be monitored and at what intervals. Enrollment, protocol complexity, safety issues and/or site performance concerns determine frequency of site monitoring visits.

Prior to the Visit:

- The Research Coordinator (or other designated contact) will work with the study monitor and PI to schedule a mutually convenient date and time to conduct the monitoring visit. This should be at least 14 business days in advance of the visit.
- Request a visit agenda from the monitor, complete with the subjects that will be reviewed at that visit. Make sure the appropriate documentation and files for review are up-to-date, which may include, but are not limited to:
 - Subject source documents and corresponding case report forms (CRFs)
 - Regulatory Binder – hardcopy and/or electronic
 - Safety reports and/or Adverse Event documentation
 - Access to study drug storage and accountability documentation
- Request the monitor complete a **Study Monitor Visit Request Form** (https://www.unmc.edu/cctr/_documents/MonitorVisitRequestForm.pdf). A new form must be completed for each monitor visit scheduled. Separate forms should be completed if multiple studies are being monitored at the same time.
- The monitor must complete and sign the **Confidentiality Agreement** (https://www.unmc.edu/cctr/_documents/MonitorConfidentialityAgreement.pdf) by clicking on the link in the **Study Monitor Visit Request Form**. This is submitted with the initial access request form and only has to be completed once for each monitor per trial.
- Follow the instructions in the **Coordinator Guide for Study Monitor Access** (https://www.unmc.edu/cctr/_documents/MonitorAccessGuideCoordinators.pdf) to Submit an **IT Service Request (All in One) ticket** for either *New User Access* (first time monitor has monitored the clinical trial) or *Update Existing User Access* (for future monitoring visits where the monitor's account was previously created). IT tickets should be submitted at least 14 days in advance of the monitoring visit.
- An AD account will be created for the monitor. Access to the AD account will expire after 45 days from date account was created/activated. Access within each application (ie. Epic Link, Advarra eReg, Advarra EDC &/or Vestigo) will be granted for the specified monitor visit dates. Monitor visit dates should not exceed 5 working days. The study monitor will receive an email with information on how to claim their account. This information is on page 3 of the **Study Monitor Access Setup Guide** which should be shared with the monitor.
(https://www.unmc.edu/cctr/_documents/StudyMonitorAccessSetupGuide.pdf).

- Monitor must install DUO on their personal device in order to 2-Factor Authenticate their login for each system application. Instructions for installing and using DUO are provided in the **Study Monitor System Access Setup Guide**.
- If the monitor plans to conduct any on-site visits, the monitor must register and fully credential with SEC³URE (formerly REPtrax) prior to arriving onsite [[Nebraska Medicine policy MS40](#)].
- If the monitor does not have access to the electronic medical record, printouts may be provided and certified by the coordinator by stapling them together and initialing and dating the documents. Those documents with patient information should stay on site.

Day of the Visit

On-site Visits

- At the first monitoring visit, the coordinator/designee will meet the monitor upon arrival and escort them to check-in at SEC³URE kiosk. The monitor will need to check-in and check-out of SEC³URE on each day of their visit. After the first visit, the monitor will be able to obtain their SEC³URE ID on their own.
- In the CRC a temporary ID badge allowing access to the monitoring area will be provided to the monitor at the start of the day. These badges must be turned in at the end of each day.
- The coordinator will schedule time to work with the monitor during the visit to review and complete any data clarifications as necessary and to escort the monitor to any other area the monitor requires, including the pharmacy, lab, and clinic areas.
- If onsite, the monitor may use their company/personal computer or a UNMC computer. If using a UNMC computer, the coordinator will turn on the designated computer and the monitor will sign into the computer using their User ID and Password.
- At the end of each day, all paper study materials will be collected and returned to their secure areas.

Following the Visit

- All queries will be resolved, and documentation of the visit will be added to the Regulatory binder.

System Access for both On-site and Remote Visits

- Each application (One Chart Link, Advarra EDC, Advarra eReg, and Vestigo) can be accessed through a web browser using the links provided in the **Study Monitor Access Setup Guide** (Attachment D). Access within each application is dependent on what was selected when the IT ticket was submitted.

ASSOCIATED FORMS:

[SEC³URE – Nebraska Medicine Policy MS40](#)


RESOURCES:

- 21 CFR 312.50 General Responsibilities of sponsors
- 21 CFR 312.56 Review of Ongoing Investigations
- 21 CFR 312.62 Investigator recordkeeping and record retention
- 21 CFR 312.68 Inspection of Investigator’s records and reports
- 21 CFR 54.15 Proposed Obligations of Clinical Investigators
- ICH GCP Consolidated Guidelines—Part 5.18 Monitoring
- CRC-SOP-27 Regulatory Binder
- CRC-SOP-64(.B) Management of Regulatory Documents(-eReg)
- UNMC CCTR website: Study Monitor Visits
<https://www.unmc.edu/cctr/resources/crc/studymonitor.html>

Staff Accountability:

Developed By: Nurse Manager, Clinical Research Center
Associate Vice Chancellor for Clinical Research, Clinical Research Center
Reviewed By: Office Associate, Clinical Research Center

Department Approval

Signed <u><i>LuAnn Larson, RN</i></u> <u>Director of Clinical Research Operations</u>	Date: <u>4/7/2022</u>
Signed <u></u> <u>Assistant Vice Chancellor for Clinical Research</u>	Date: <u>4/7/2022</u>

SEC3URE Passport

Welcome!

To begin your SEC3URE access, utilize the below website:

<https://www.sec3ure.com/login>

1. First time users click Register

(Returning users login with username and password)



2. Job Functionality Questions:

Register [Sign in](#)

Job Functionality Questions

Everyone needs to be credentialed these days so they can be trusted.
The purpose of the following questions is to determine the ideal credential requirements so that you can be trusted.

Do you provide or deliver any product, device, service, training, pharmaceuticals or research to any healthcare facility either on premise or virtually?

Yes No

Do you repair, calibrate, install or maintain any medical or non-medical equipment for any healthcare facility either on premise or virtually?

Yes No

Do you have access to any patient data, or systems/equipment with access to patient data, for any healthcare facility either on premise or virtually?

Yes No

[Next](#)



3. Next Page. Important Note: If you are monitoring, Primary Job Function, please select “Research Personnel – no patient access”, which is currently free and requires only a profile photo. Choosing “patient access” requires a yearly subscription.



Answer the scope of service questions carefully and complete registration when finished. Please see the example below.

THE MOST TRUSTED NAME IN VENDOR CREDENTIALING.

Fifteen minutes. You've spent more time waiting for a parking space, a hamburger, or a latte. That's how long it takes to create a SEC³URE Passport supplier profile, and eliminate the repetitive paperwork required to access more than 11,000 locations of care worldwide.

Wouldn't you rather be selling, than waiting for permission to do it?

Register

[Sign In](#)

Company Name

My company

Job Title

Monitor

Primary Job Function

Research Personnel - no patient

Do you provide support or visit an area in the facility where ionizing radiation equipment or radiation producing material is used?

Yes

No

By checking this box I agree to the Terms and Conditions details in the [Terms of Use](#), [Privacy Policy](#) and [Cookie Policy](#).

Complete Registration



4. Add Facilities: Choose Nebraska State, then Nebraska Medicine. (You may add more facilities later, if needed.)

<input type="checkbox"/>	Methodist Physicians Clinic - Women's Center	707 N 192nd St.	Omaha	NE	68022
<input type="checkbox"/>	Methodist Physicians Clinic 8601 Dodge Dermatology	8601 West Dodge Rd.	Omaha	NE	68114
<input type="checkbox"/>	Methodist Women's Hospital	707 N. 192nd St.	Omaha	NE	68022
<input type="checkbox"/>	Midwest Surgical Hospital	7915 Farnam Drive	Omaha	NE	68114
<input type="checkbox"/>	Miracle Hills Surgery Center	11819 Miracle Hills Dr. STE 201	Omaha	NE	68154-4428
<input type="checkbox"/>	Morrill County Community Hospital	1313 S Street	Bridgeport	NE	69336
<input type="checkbox"/>	Nebraska Heart Institute	7440 S. 91st Street	Lincoln	NE	68526
<input checked="" type="checkbox"/>	Nebraska Medicine	987400 Nebraska Medical Ctr	Omaha	NE	68198
<input type="checkbox"/>	Nebraska Medicine - 110 N 175th Street (MOB1)	110 N 175th Street	Omaha	NE	68118
<input type="checkbox"/>	Nebraska Medicine - Brentwood Clinic (Shared With IM GEN & RHEUM)	8021 S 84th Street	La Vista	NE	68128
<input type="checkbox"/>	Nebraska Medicine - ECCP	3333 Farnam St. 3rd Floor	Omaha	NE	68131
<input type="checkbox"/>	Nebraska Medicine - Poynter Hall Psychiatry Clinic	510 South 42nd Street Poynter Hall	Omaha	NE	68105



There are likely Outstanding Policies and/or Attachments to complete. Notice the example below. Please access your phone for the remaining registration.

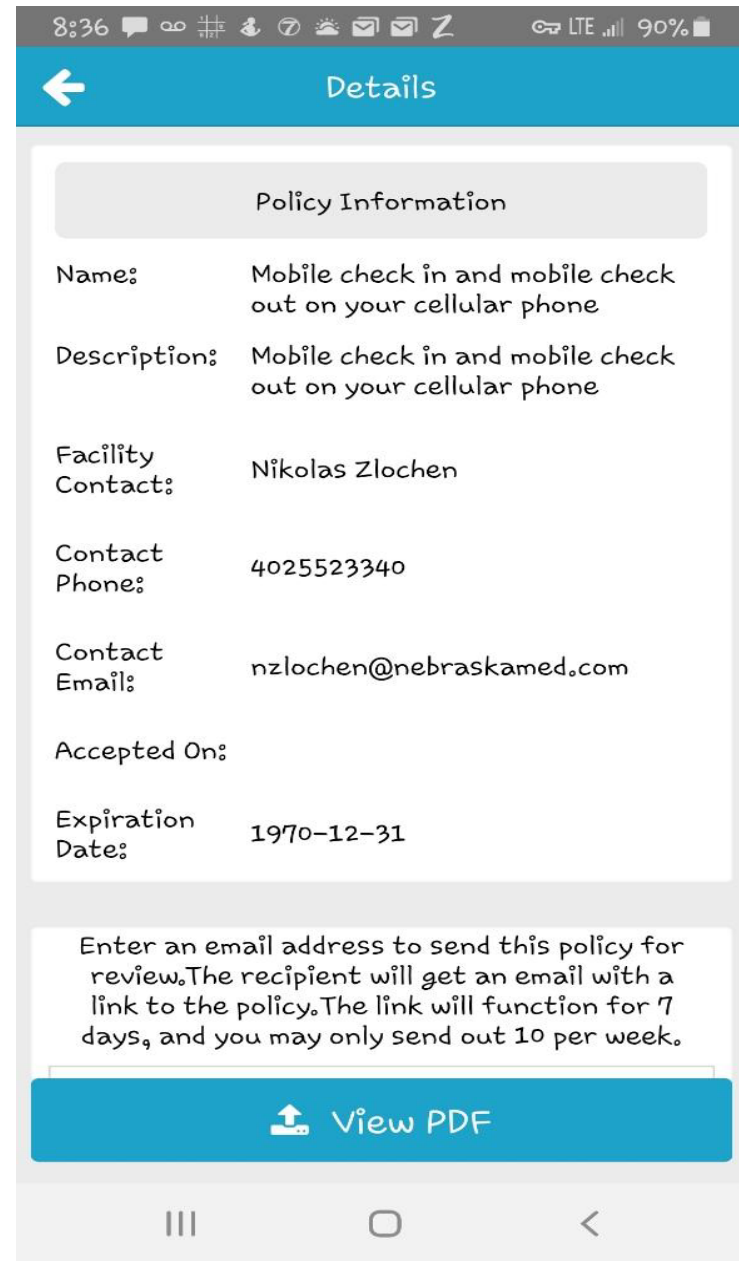
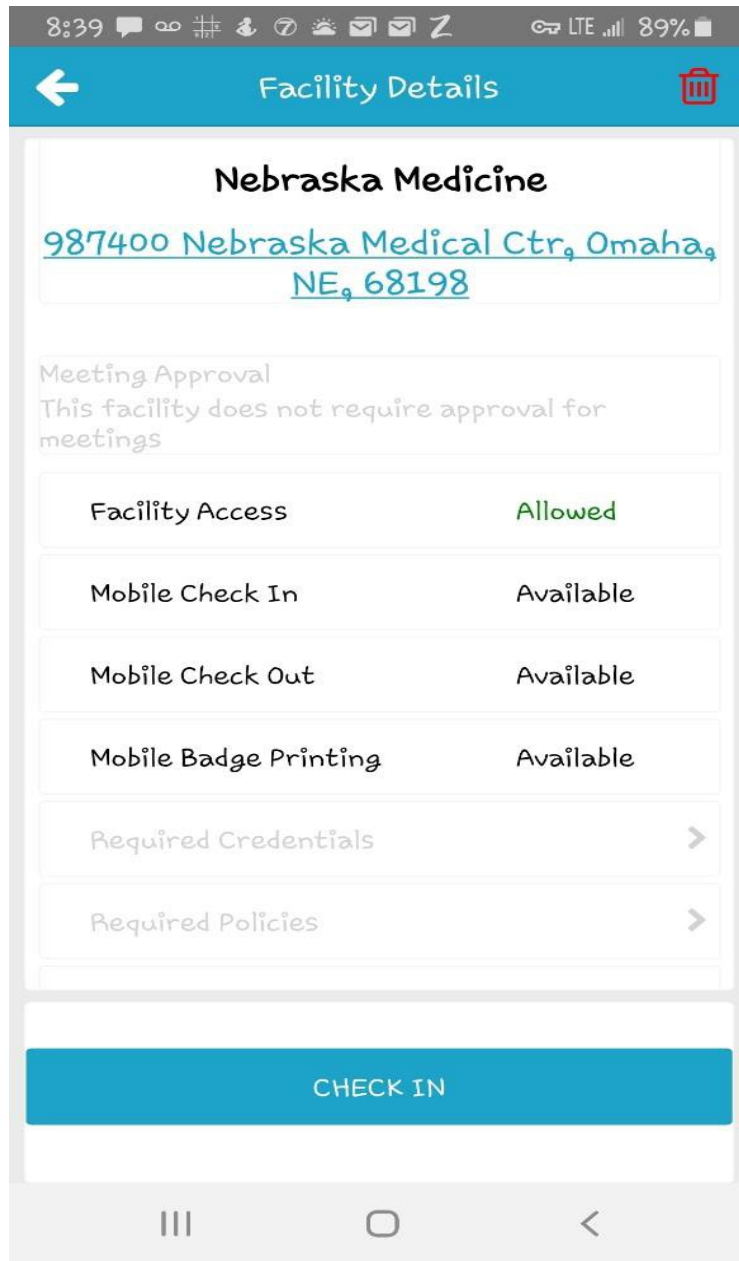
The screenshot displays the IntelliCentrics dashboard. On the left is a navigation menu with links for Home, Requirements, My Account, Support, and Log Out. The main dashboard area is titled 'DASHBOARD' and features a 'What's New' section with three announcements: 'UPLOAD YOUR COVID-19 VACCINATION CARD HERE', 'SEC³URE REFERRAL PROGRAM' (offering a \$160 credit), and 'SEC³URE GO!' (contactless check-in). Below these are eight metric tiles: Credentials (14 Outstanding), Policies (3 Outstanding), Info Reviews (0 Outstanding), Revocations (0 Facilities), My REPScore (REPScore), My Facilities (1 Attachments), My Meetings (0 Meetings), and My Subscriptions (Click to purchase). The IntelliCentrics logo is in the bottom left corner.

Metric	Value	Status
Credentials	14	Outstanding
Policies	3	Outstanding
Info Reviews	0	Outstanding
Revocations	0	Facilities
My REPScore	REPScore	
My Facilities	1	Attachments
My Meetings	0	Meetings
My Subscriptions	Click to purchase	



- ✓ Use your mobile phone and download the SEC3URE application.
- ✓ Upload a professional photo.
- ✓ Review all the facility policies.
- ✓ Green light. You may now check-in.
- ✓ You may send your badge info to one of the facility kiosks for printing, if needed.





6. Additional **Support** may be accessed on the left-hand side under the Home Icon on the DASHBOARD. Response time has been slow.

- 🏠 Home
- 📄 Requirements
- 👤 My Account
- 📞 Support
- Help
- 🔌 Log Out

Contact Us

Phone and Email Support

Please be aware that we do not accept credential submissions through email. To submit your credentials please go to Credentials under My Account on the left navigation menu and click the Submit Credentials button at the top of the page.

SEC³URE, a service offered by IntelliCentrics, Inc.
777 International Parkway, Suite 400
Flower Mound, Texas 75028

Office Hours: 6:00 a.m. - 6:00 p.m. Central, Monday-Friday

Phone: [817-SEC3URE \(732-3873\)](tel:817-SEC3URE(732-3873)), Select Option 1

Email: CustomerService.US@IntelliCentrics.com

Chat Hours: 6:00 a.m. - 6:00 p.m. Central, Monday-Friday

Chat: [Click Here to Open Chat Window](#)



Back-up Contact: LuAnn Larson

llarson@unmc.edu

Director of Clinical Research Operations

We look forward to working with you.

