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 andto 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 SEC^{3}URE (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 SEC^{3}URE kiosk. The monitor will need to check-in and check-out of SEC^{3}URE on each day of their visit. After the first visit, the monitor will be able to obtain their SEC^{3}URE 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:

SEC^{3}URE – 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 LuAnn Larson, RN Date: 4/7/2022
Director of Clinical Research Operations

Signed Date: 4/7/2022
Assistant Vice Chancellor for Clinical Research

SEC3URE Passport

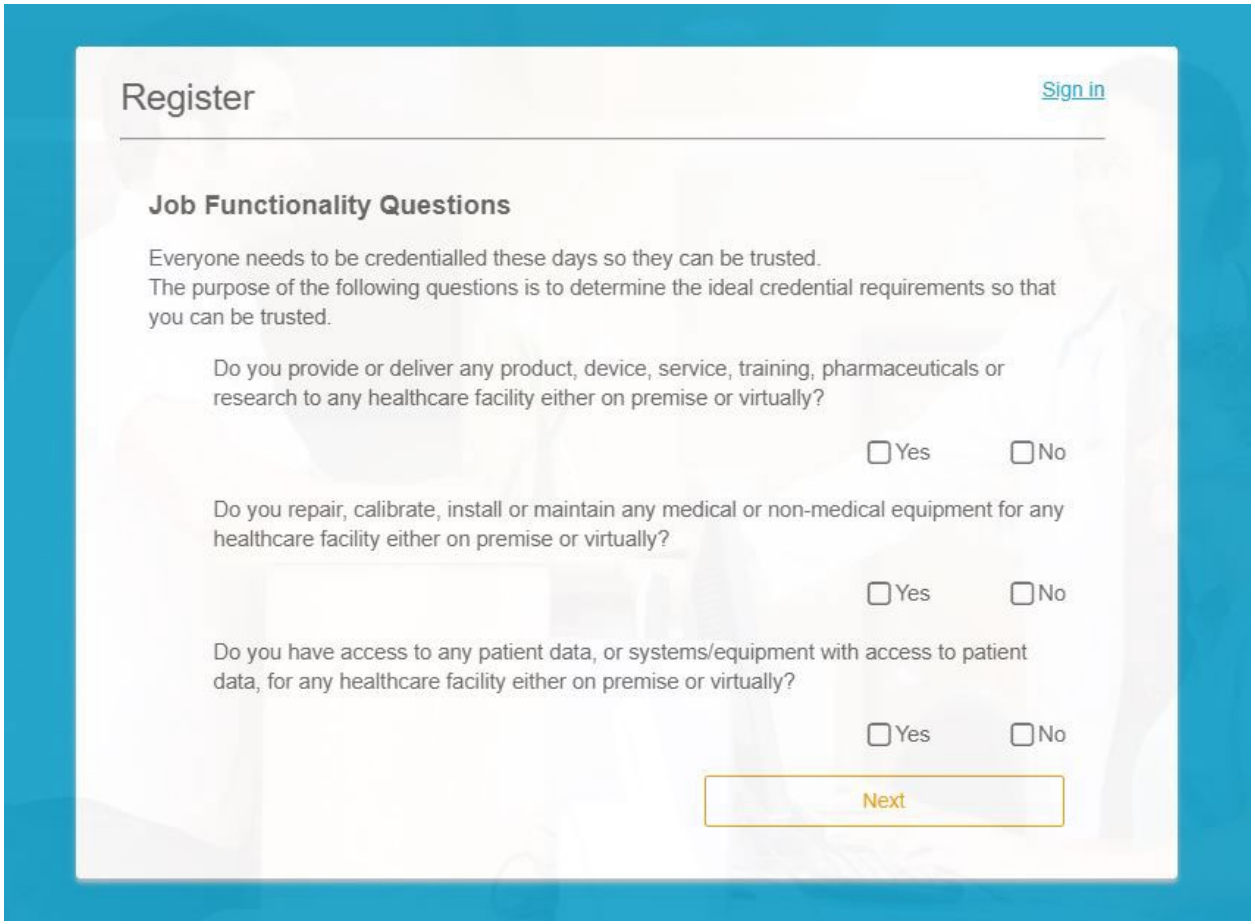
Welcome!

To begin your SEC3URE access, utilize the below website:
https://www.sec3ure.com/login

1. First time users click Register

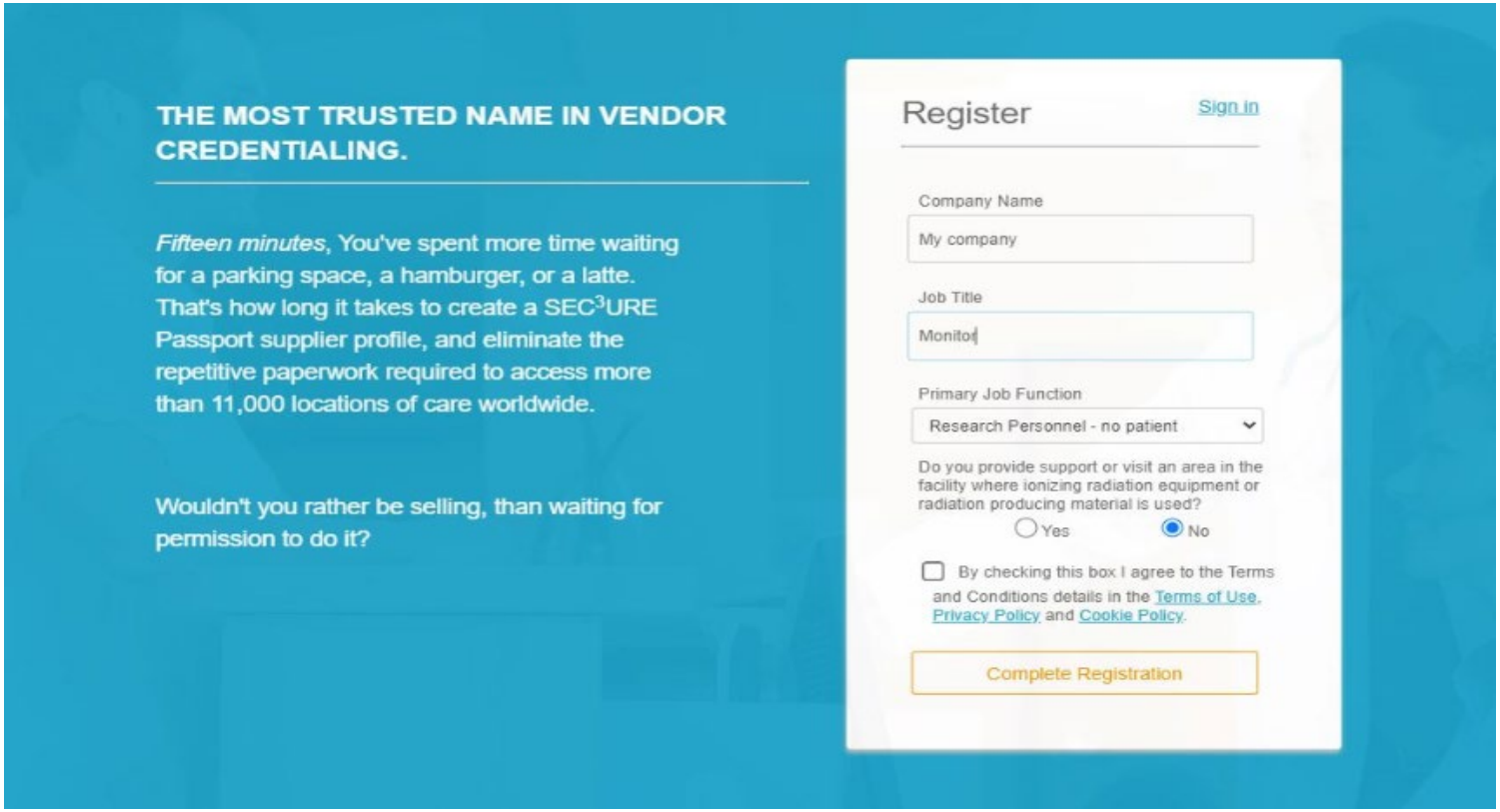
(Returning users login with username and password)

2. Job Functionality Questions:



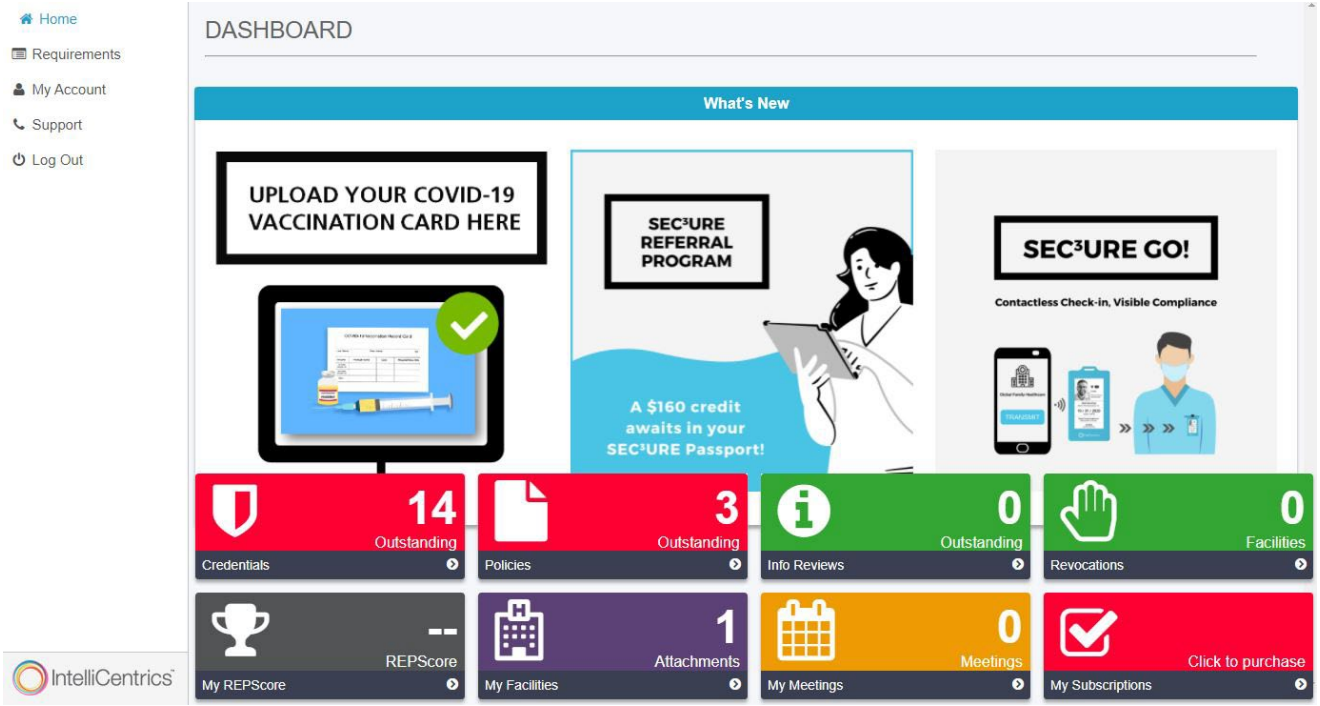
3. Next Page. Important Note: If you are monitoring, Primary Job Function, please select “Research Personnel – no patient access”, which is currently free and requires only a profile photo. Choosing “patient access” requires a yearly subscription.

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

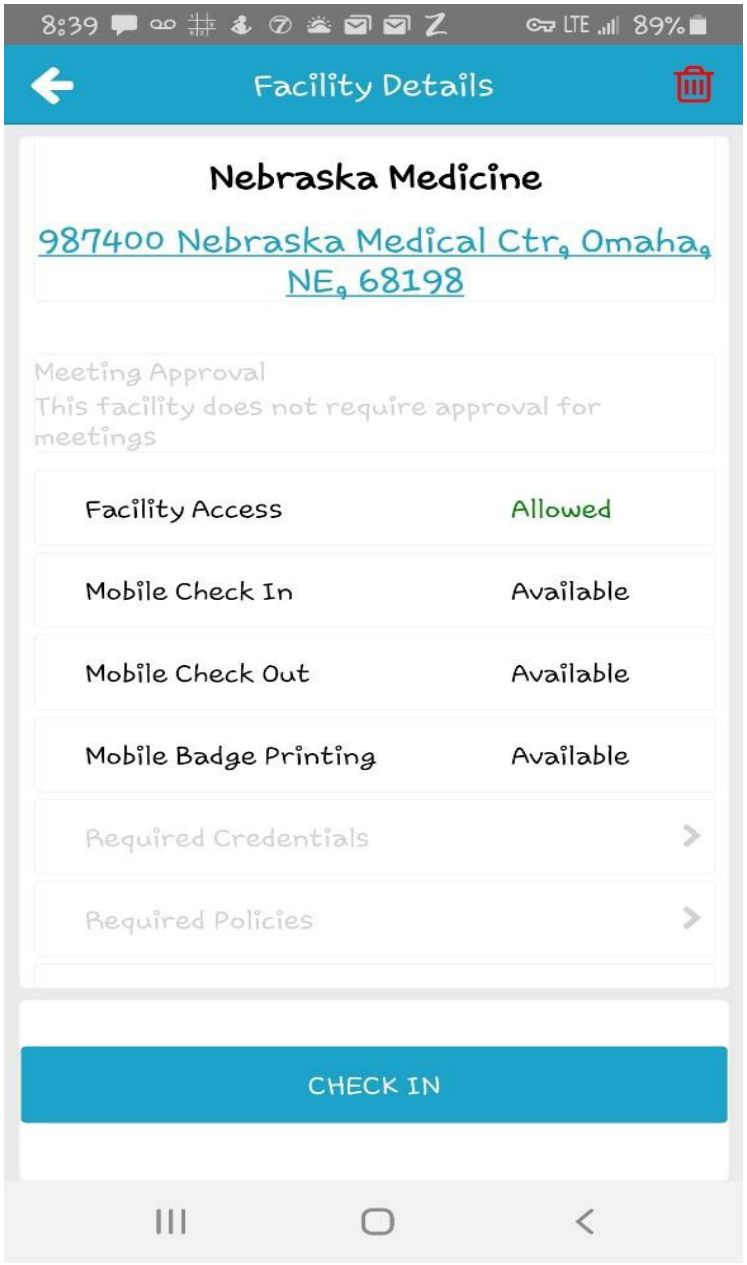


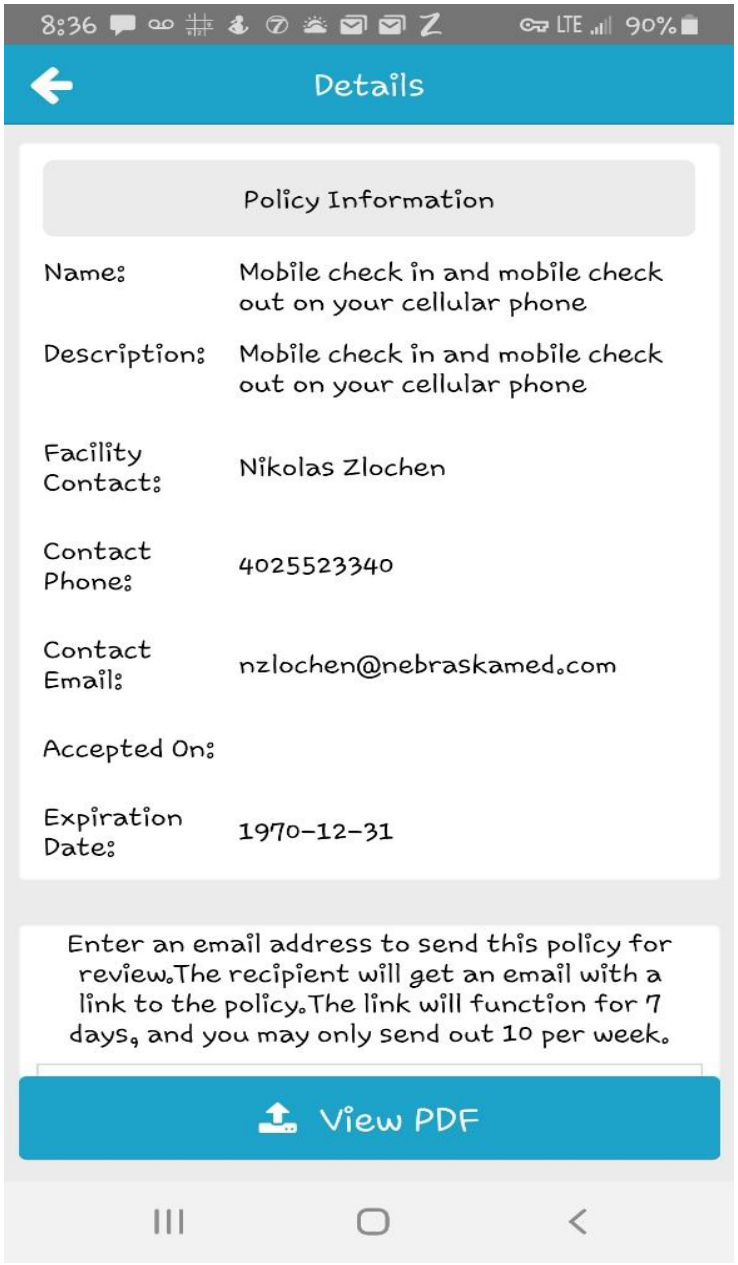
4. Add Facilities: Choose Nebraska State, then Nebraska Medicine. (You may add more facilities later, if needed.)

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

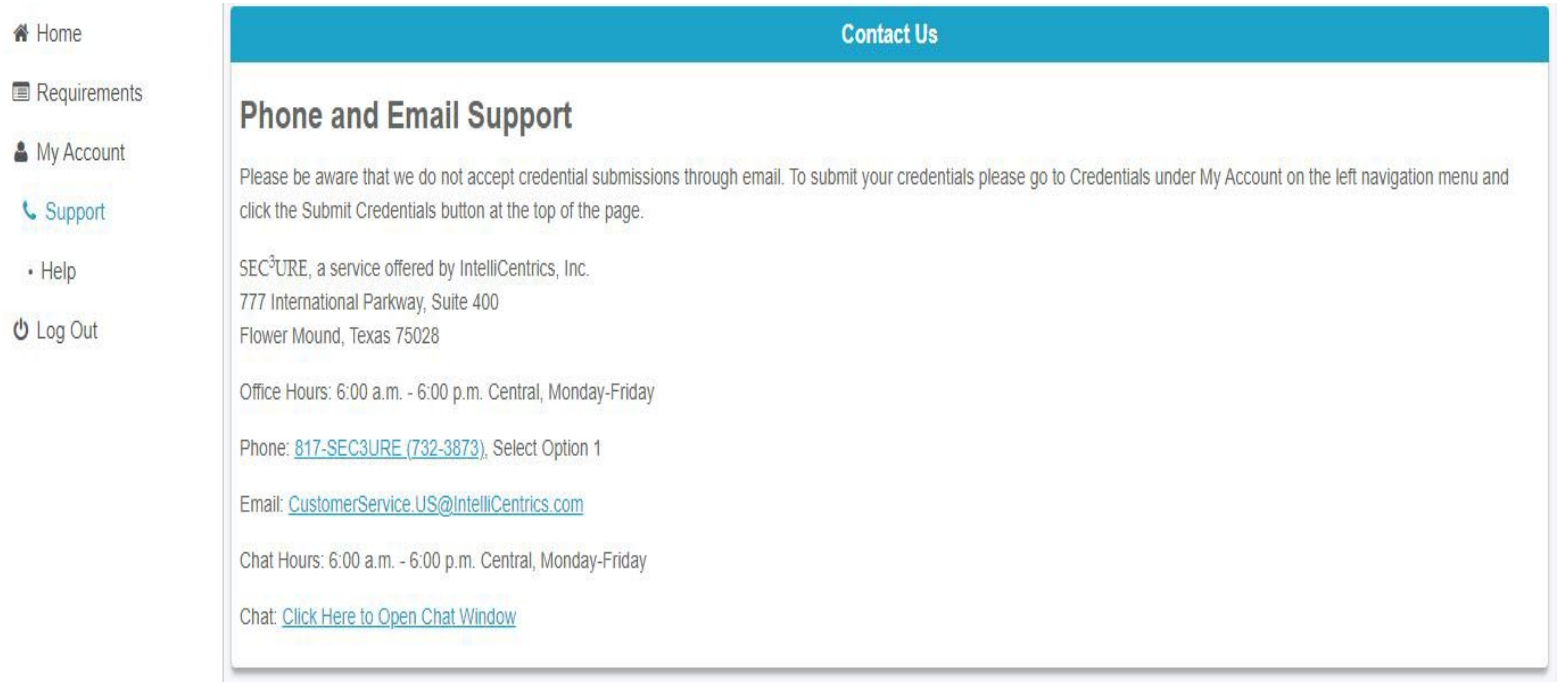


- ✓ Use your mobile phone and download the SEC3URE application.
- ✓ Upload a professional photo.
- ✓ Review all the facility policies.
- ✓ Green light. You may now check-in.
- ✓ You may send your badge info to one of the facility kiosks for printing, if needed.


8:39
89%
Facility Details
Nebraska Medicine
987400 Nebraska Medical Ctr, Omaha, NE, 68198
Meeting Approval
This facility does not require approval for meetings
Facility Access
Allowed
Mobile Check In
Available
Mobile Check Out
Available
Mobile Badge Printing
Available
Required Credentials
Required Policies
CHECK IN


8:36
90%
Details
Policy Information
Name:
Mobile check in and mobile check out on your cellular phone
Description:
Mobile check in and mobile check out on your cellular phone
Facility Contact:
Nikolas Zlochen
Contact Phone:
4025523340
Contact Email:
nzlochen@nebraskamed.com
Accepted On:
Expiration Date:
1970-12-31
Enter an email address to send this policy for review.The recipient will get an email with a link to the policy.The link will function for 7 days, and you may only send out 10 per week.
View PDF

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



Back-up Contact: LuAnn Larson

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Director of Clinical Research Operations

We look forward to working with you.

UNMC

BREAKTHROUGHS FOR LIFE