Center for Clinical and Translational Research Standard Operating Procedure

Section: **Clinical Research Center**
Date Effective: **September 12, 2013**
Title: **Monitor Visits & Release of Information**
Version Date: **January 1, 2023**
SOP Number: **SM37**

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
- 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:

- **Adverse Event (AE) – (**adapted from the ICH definition) any undesirable medical occurrence in a clinical trial subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An AE can include any unfavorable and unintended signs, symptoms, or the exacerbation of a pre-existing condition associated with the use of an investigational product, whether or not related to the product. When an AE has been determined to be related to the investigational product, it is considered an Adverse Drug Reaction.
- **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
    - Safety reports and/or Adverse Event documentation
    - Access to study drug storage and accountability documentation
- Review and follow the **Coordinator Guide for Study Monitor Access** located at **https://www.unmc.edu/cctr/resources/crc/studymonitor.html .**
- Provide the monitor with the **Study Monitor Visit Request Form** and the **Study Monitor Access Setup Guide** located at **https://www.unmc.edu/cctr/resources/crc/studymonitor.html .** Each monitor must also complete the **Confidentiality Agreement** linked in the **Study Monitor Visit Request Form** for their first visit of that trial.
- If the monitor plans to conduct any on-site visits, the monitor must register and fully credential with SEC^{3}URE prior to arriving onsite per Nebraska Medicine policy MS40.

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.

- An 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 thee monitor requires, including the pharmacy 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.

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:

Confidentiality Agreement (Attachment B)
https://www.unmc.edu/cctr/_documents/MonitorConfidentialityAgreement.pdf

SEC[3]URE Passport

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
- NM Policy https://now.nebraskamed.com/policies-and-procedures-manual/
    - MS40 – Vendor Interactions Policy

Department Approval

Signed Charles E Miller Clinical Research Center Administrator	Signed: 2/21/2023
Signed Assistant Vice Chancellor for Clinical Research	Signed: 4/3/2023

UNMC Nebraska Medicine

Download this form before entering data.

Study Monitor Visit Request Form

For questions call 402-559-7685

Research Monitor

Last Name: First Name:

Job Title: Sponsor Represented:

Company employed by:

Phone: *(this will be used for DUO 2-Factor Authentication)*

Email:

Is this your first visit monitoring this study? ◉ Yes ○ No

Access Requested

Study Name:

IRB#:

Name of PI:

Visit Start Date: Visit End Date:

Brief description of what you want to review during your visit:

Monitor to Complete	*Columns to be completed by the Study Coordinator*	
Charts Requested (Subject ID)	Medical Record #	Subject Initials

Click here to email form

Confidentiality Agreement

First monitor visit for this study?
← Click to open Confidentiality Agreement
(wet signature required)

For use by Admin Team only

Requester/Authorization

Requester: _____ Phone: _____ E-Mail: _____

Signature of Requester: _____

I authorize the named individual to access One Chart/Vestigo/Advarra systems to review patient and regulatory information. This access is based on our responsibilities to provide access to monitor studies for which we are contracted. I will take responsibility for the individual named. I will also be responsible to be aware of the monitor's activity in One Chart and will ensure no copying or printing of patient information occurs.

To Be Completed Prior to Sending to Access Coordinator

- Confirm Study Monitor Visit Request Form has been signed by Study Coordinator
- Attach Signed Confidentiality Agreement (completed for initial visit)
  - If not attached, is a Signed Confidentiality Agreement already on file? ◉ Yes ○ No
- Provide AD account username: _____
- For on-site visits, confirm monitor has registered in SEC3URE (formally known as REPtrax - policy MS40)

***Wet signature required. Please print, sign and email completed document to study coordinator.

SM37 Attachment B

Requirements for Use of Nebraska Medicine/University of Nebraska Medical Center Electronic Health Record and Forte/Advarra Systems

Your use of One Chart, the electronic health record, and the Forte/Advarra Systems for the University of Nebraska Medical Center, Nebraska Medicine, and Bellevue Medical Center (hence called the "Medical Center") is a privilege and requires that you read and accept the following Requirements for Use. Patient information is sensitive and private and anyone who is given access and who has knowledge of patient information is obligated to keep it confidential.

Terms and Conditions for Use of One Chart and Forte/Advarra Systems

I understand and agree that the Medical Center reserves the right to limit or discontinue my use of One Chart and Forte/Advarra Systems if I do not abide by the following terms and conditions or for any other reason as determined by the Medical Center on a case-by-case basis.

1. I am a study monitor who will gain access to research participant records and other study related documents in order to verify the accuracy of data being collected for a contracted research study.
2. I agree to use all reasonable and necessary safeguards to ensure the confidentiality records that I review.
3. I will not use or disclose the confidential information that I have been given access to beyond purposes expressly permitted in the research agreement with UNMC.
4. I will not photocopy, download or print off any health records.
5. I will ask for assistance if I am unsure how to navigate within the electronic health record or Forte/Advarra Systems.
6. I will not share the password assigned to me for the monitoring visit.
7. I will not leave the health records open if I am not personally in attendance at the computer. I will log out if I leave the computer.
8. I will not email or electronically transmit any patient information in any manner that is not secure.
9. I will not "break the glass" in an electronic records without written permission from the investigator.

I understand that my access to the electronic health record and the Forte/Advarra Systems may be audited and any unauthorized entry into patient health records or inappropriate use of data will result in inactivation of the login.

_____ _____ _____

Print Name Signature Date

_____

Research Organization

SEC3URE Passport

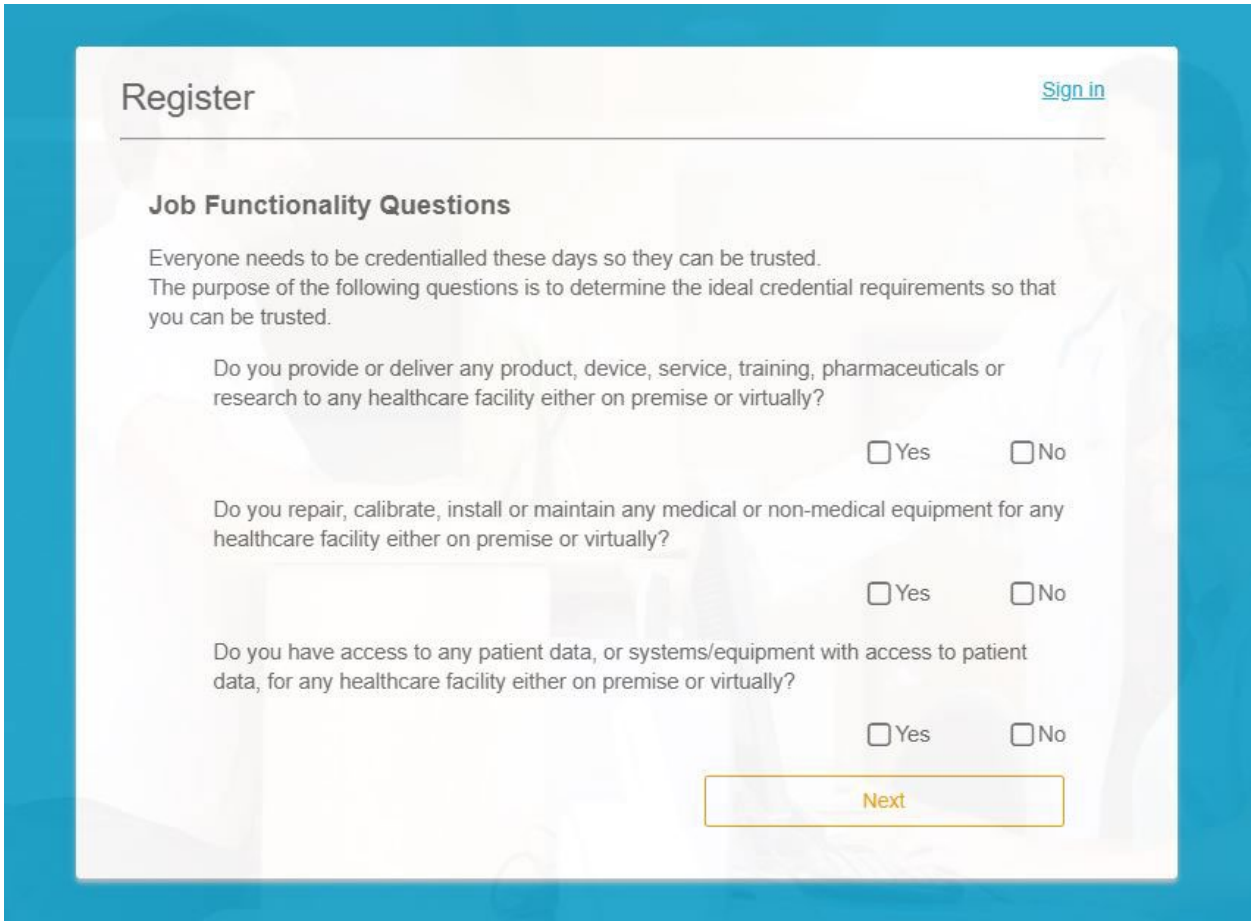
Welcome!

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

1. First time users click Register

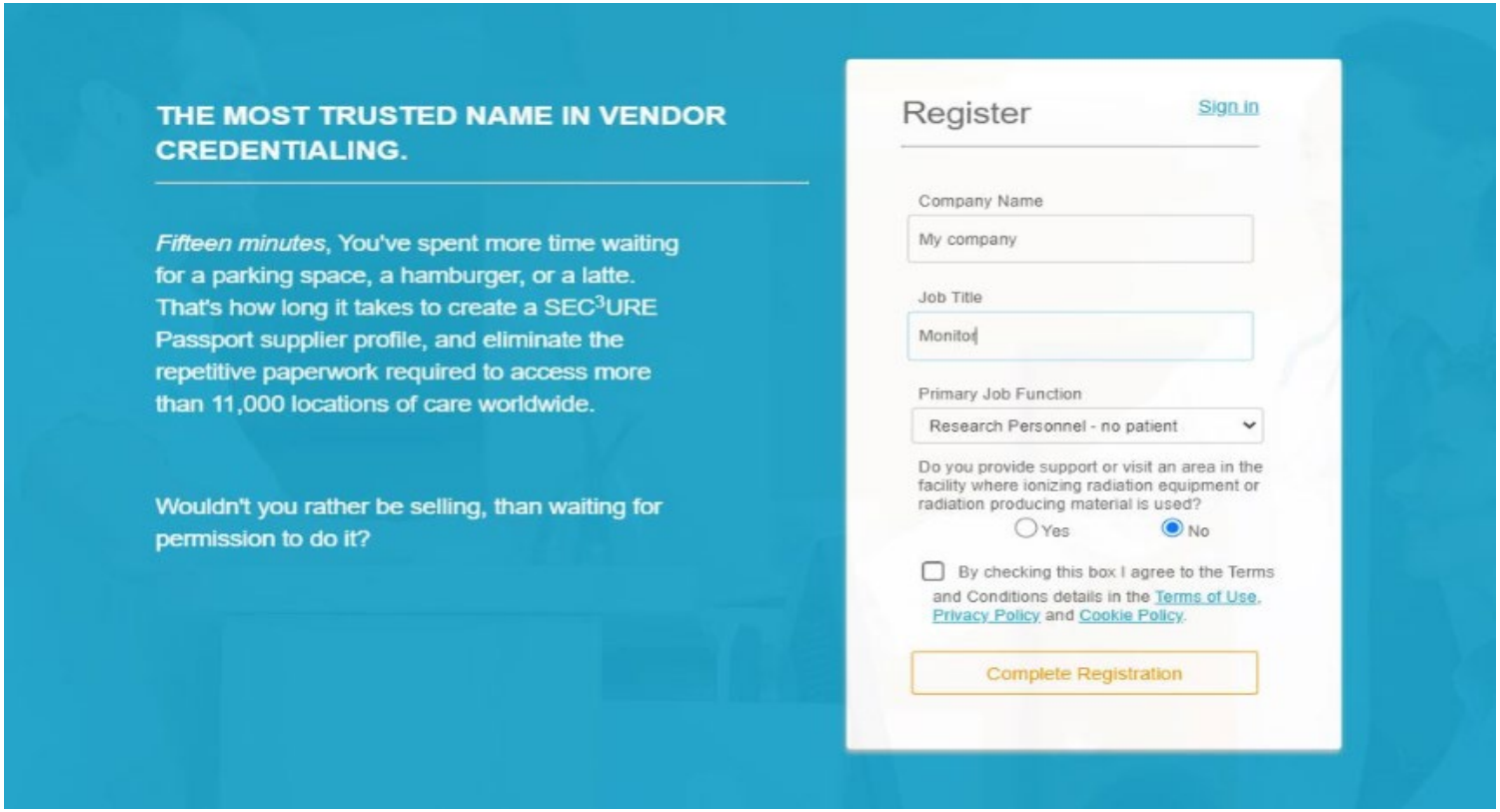
(Returning users login with username and password)

2. Job Functionality Questions:



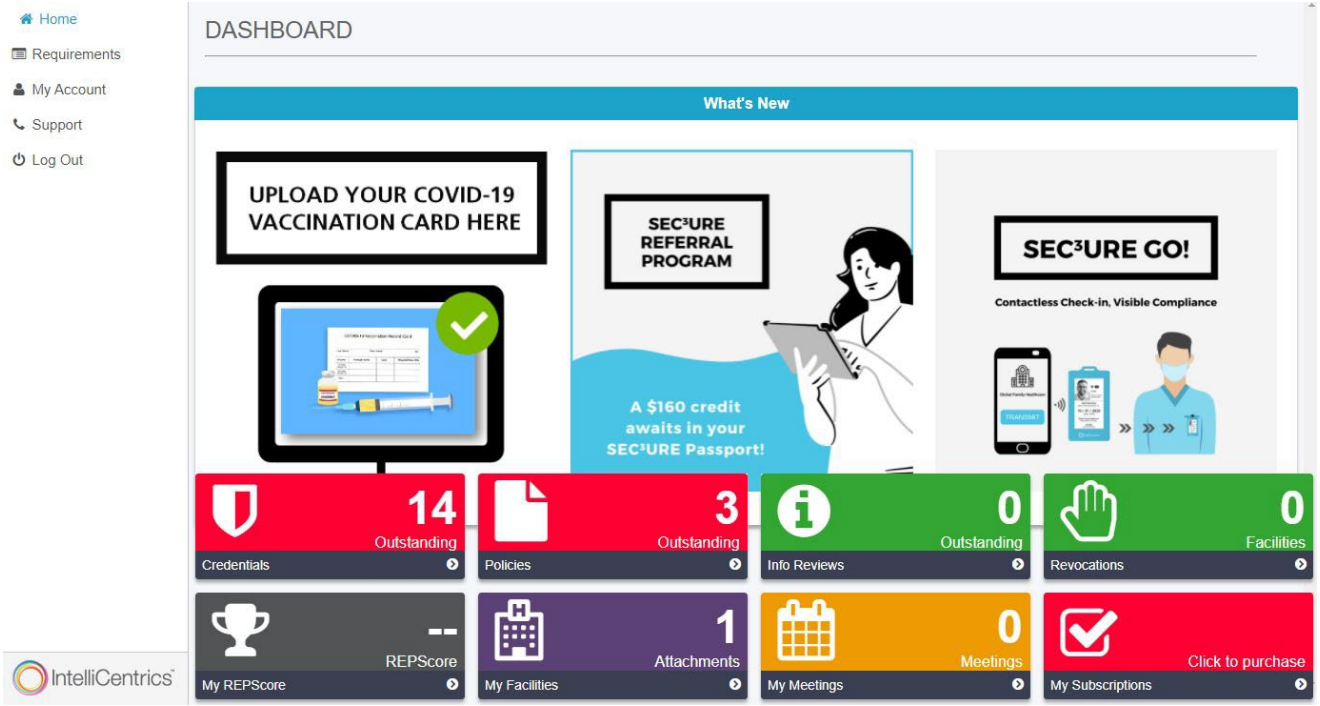
3. Next Page. Important Note: If you are monitoring, Primary Job Function, please select "Research Personnel – no patient access", which is currently free and requires only a profile photo. Choosing "patient access" requires a yearly subscription.

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

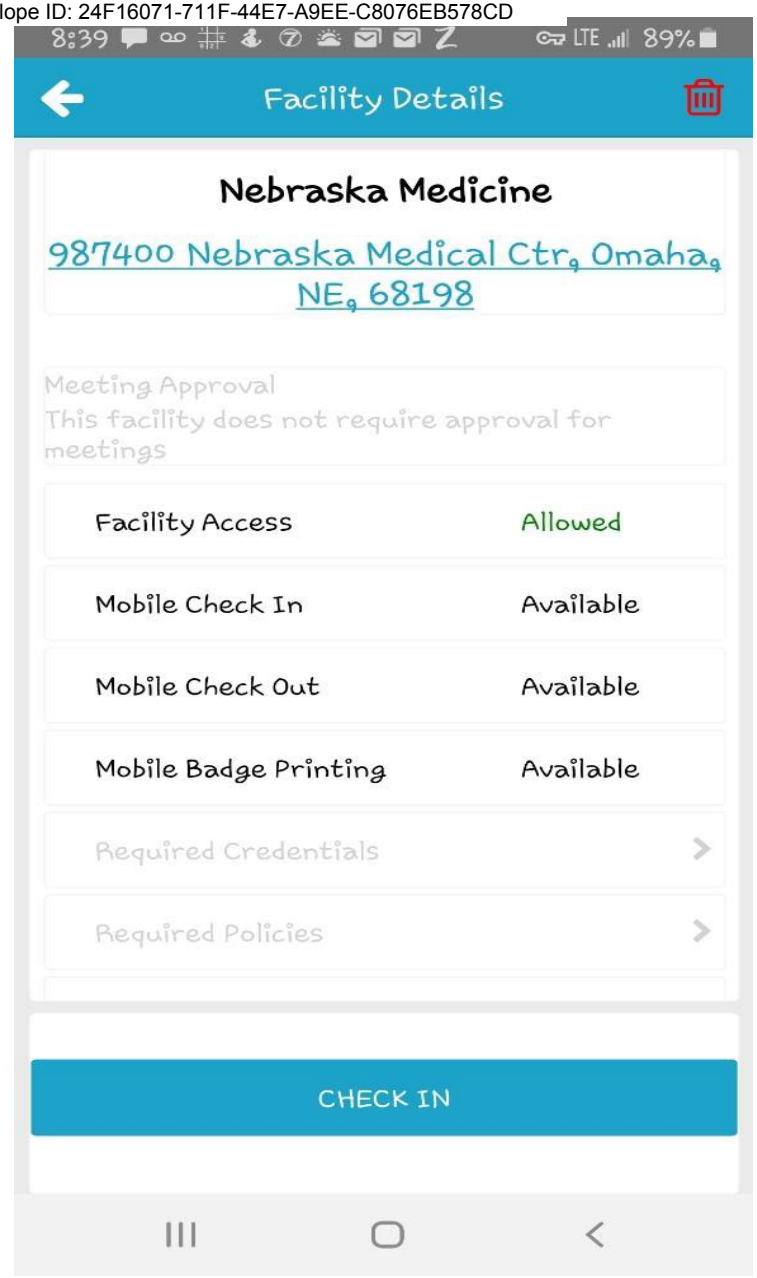


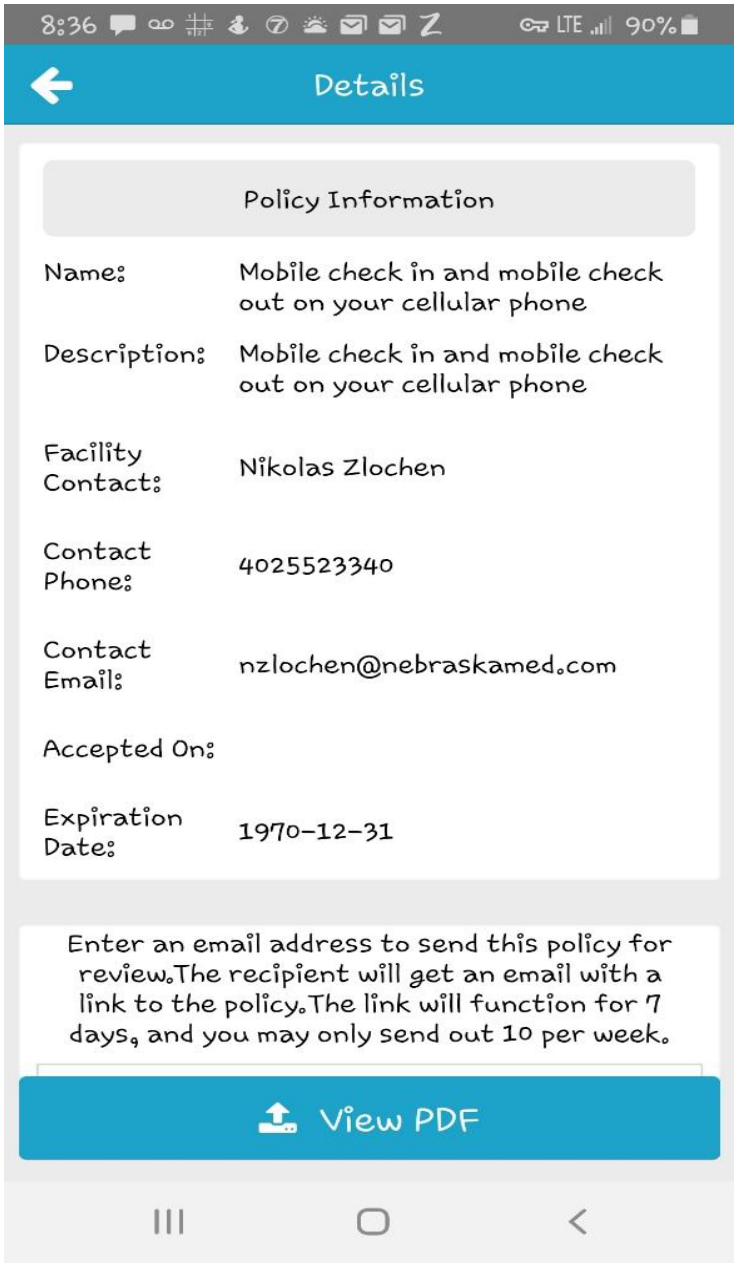
4. Add Facilities: Choose Nebraska State, then Nebraska Medicine. (You may add more facilities later, if needed.)

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.





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