PURPOSE: The purpose of this standard operating procedure (SOP) is to outline the activities required when a study monitor conducts a site visit. Monitoring visits are usually performed by a sponsor representative or Contract Research Organization (CRO) working for a sponsor. The visit is conducted to help ensure that the investigator and site are compliant with the clinical protocol and Good Clinical Practices (GCPs), that data are of high quality, and that the facilities and staffing are adequate to continue participation.

SCOPE: This SOP applies to all sponsored clinical trials which the Clinical Research Center (CRC) has been contracted to provide study coordination at University of Nebraska Medical Center (UNMC)/Nebraska Medicine (NM).

PERSONNEL RESPONSIBLE: Principal Investigator (PI) --and when delegated by the principal investigator--Sub-investigators, Study/Nurse Coordinator, Data, Regulatory and/or other pertinent staff.

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 of 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.
- **Contract Research Organization (CRO)** - A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's research-related duties and functions.
- **Good Clinical Practice (GCP)**-- A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

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. Frequency of site monitoring
visits is determined by enrollment, protocol complexity, safety issues or site performance concerns.

- The Study Coordinator (or other designated contact) will work with the Monitor and PI to schedule a mutually convenient date and time to conduct the monitoring visit. This should be at least 2 weeks in advance of the visit. Every attempt will be made to accommodate monitoring deadlines. However, the designated monitoring spaces are limited. If all available monitoring spaces are already full, then a different day will need to be selected.

- Once a date is selected and the space is confirmed, an entry must be made in the Monitoring Calendar to reserve the monitoring space.

- Prior to each visit, the sponsor representative will confirm with the PI or designee what will be reviewed so that appropriate documentation and files will be available. These materials include, but may not be limited to:
  - Subject source documents and corresponding case report forms (CRFs)
  - Regulatory binders – hardcopy and/or electronic
  - Safety reports and/or Adverse event documentation
  - Access to study drug storage and accountability documentation

- An agenda will be made and any staff that are required for the visit will confirm their availability at the scheduled time.

- Prior to the visit, the monitor will provide a list of the subjects that will be reviewed.

- Each monitor will need to complete a Confidentiality Agreement once for each new study.

- Prior to the monitoring visit the coordinator/designee needs to request access to the electronic Medical Record (EMR) following the guidelines outlined in CRC SOP #39. 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.

- At the first monitoring visit, the coordinator/designee will meet the monitor and escort them to sign up for REPtrax (see associated form for details). The monitor will need to sign in and out of REPtrax on each day of their visit. After the first visit the monitor will be able to obtain their REPtrax 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 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 that monitor requires, including the pharmacy and clinic areas.

- At the end of each day, all 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.

ASSOCIATED FORMS:
REPtrax NM specifics_2019

SOP-18 REPtrax NM specifics_2019+.doc
REPTrax add or change profile photo instructions

SOP-18 Reptrax
Add or change prof
REPTrax add or delete hospital instructions

SOP-18 RepTrax
Add or delete hospi
REPTrax Login Logout procedures

RESOURCES:
- Title 21 CFR 54.15 Proposed Obligations of Clinical Investigators
- ICH GCP Consolidated Guidelines—Part 5.18 Monitoring
- CRC SOP #40 Release of Information

Staff Accountability:
Developed By: Director of Clinical Research Operations, Clinical Research Center
Associate Vice Chancellor for Clinical Research, Clinical Research Center
Reviewed By: Regulatory Coordinator, Clinical Research Center
REPtrax for Clinical trials

Any Healthcare vendor representative (HCVR) conducting a clinical trial-related visit will obtain a free basic membership in REPtrax.

Representatives’ must sign-in to REPtrax for each visit. If on campus, the rep must sign-in at a REPtrax kiosk. If at an off-site clinic, the representative must login using the REPtrax mobile app. At the conclusion of the visit, the representative must log out via REPtrax.

If on campus, the representative must wear the orange badge generated by the printer at the kiosk as well as a company identification badge. If at an off-site clinic, the representative must wear their company badge and show proof of login to REPtrax on their smartphone.

For each visit, each HCVR must register at one of the following locations:

REPtrax Kiosks: (laptop computers designated for REPtrax on the ledge of the information desks or other designated area at the locations listed.

- Information/Access Services Clarkson Tower (24/7)
- Information/Access Services Durham Outpatient Center (DOC) 24/7
- Facilities Management and Planning (Clarkson basement Rm B8111; 0700-1700 M-F

Other Registration Sites: All off-site clinics: Register with off-site clinic manager

TO REGISTER: for a free basic membership in REPtrax, go to www.REPtrax.com.

- Click on “Register.”
- Complete registration of rep and his/her manager’s name, phone & email.
- Select a password.
- Under “Your Job Responsibilities,” select “Research capacity only-non sterile environment.” This is needed in order to be “free.” Only pharmaceutical sales would be charged a fee.
- Under “Facilities you do business with,” select Nebraska Medicine, NE (ID: 2518) or if off campus, select specific clinic.
- Check the box “Agree to Terms.” If this is not checked, the badge will not be printed.
- Rep will also need a photo ID to upload to the system and will need an ID at checkin.

For problems with the REPtrax kiosk call 2-3340
For problems with REPtrax Software contact REPtrax directly
How to add / change your profile photo
Log into REPTrax and on your home page you will see your profile photo or a blank box if you have not previously uploaded a photo.

Left click in the photo area to bring up the next screen.

**Change Photo**

**Upload a New REPtrax Photo**

Select a photo from your computer to use for your profile. Your photo should be of a professional nature, as it will be displayed on your online REPtrax profile.

**Photo Guidelines:**

- Photo should be "passport style," showing the face and shoulders.
- Must be JPG format (.jpg file extension)
- Must be under 2MB in file size
Browse to the location of the photo and select Upload Photo.
*Note: The image must be in a JPEG format and must be under 2MB in size.*

You have successfully updated your photo. The updated or new image will now appear on your home page.

**Change Photo**

**Upload a New REPtrax Photo**

**Photo Guidelines:**

- Photo should be "passport style", showing the face and shoulders.
- Must be JPG format (.jpg file extension)
- Must be under 2MB in file size

*Your photo was updated successfully.*
How to add /delete hospitals to your account
Log into REPTTrax and select Your Hospitals under the Profile tab.

Choose Add New Hospitals, this will allow you to associate hospitals with your account and view their requirements.
First select a State from the first dropdown list then the available hospitals will be listed under State Hospitals. Select you hospitals from the list and press the Add button, this will move the selected hospital(s) to the right hand column.

Once you have all your hospitals selected press the Add Selected Hospitals button.
You will now see the hospitals were added successfully, you will also be able to view any outstanding requirements for any hospital selected.

To remove any hospital from you profile put a checkmark in the box before the name of the hospital and press Delete Checked Hospitals.
You have successfully deleted hospitals from your account.

## Your Hospitals

**Hospitals associated with your account.**

Associate hospitals with your account and view their requirements. If you sign into a REPtrax hospital not listed, it will automatically be added to your profile. The hospitals were deleted successfully.

<table>
<thead>
<tr>
<th>Name</th>
<th>State</th>
<th>Outstanding Entry Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boston Medical Center</td>
<td>MA</td>
<td>Credential: Tuberculosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Credential: MMR - Measles, Mumps and Rubella</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Credential: Hepatitis B</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Credential: Chicken Pox</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Credential: Consent of Use Form</td>
</tr>
</tbody>
</table>
Login / Logout Procedures
For
Existing Members
And
New Users
REPTTrax Existing Members

If you are an existing REPTTrax member, sign in to the REPTTrax Kiosk by entering your e-mail address and either your password or REPTTrax ID#. It is also hospital policy to sign out at the REPTTrax kiosk upon the completion of your visit. Failure to do so will create an automated negative REPscore.

Sacred Alaska Regional (REPTTrax Demo) | A Kiosk

Existing User Login & Logout

Email
Password or REPTTrax ID #

Login / Logout >>

New User Signup
Create a new REPTTrax account that can used at all REPTTrax facilities

Signup to REPTTrax >>

Kiosk Home

It will be necessary to fill out the meeting details page as seen below.

Visit Details
Welcome Terry Lothen, please complete the following meeting information.

Visit Info
Please provide accurate, descriptive details about your meeting. Hospital Administrators will be monitoring your entry.

*Employee Hosting Meeting
*Location in Facility
*Meeting Topic
*Expected Visit Duration

Enter Visit Details >>

Kiosk Home
After completing the visit details, the system will print out a temporary visitor’s badge for you to wear while in the facility providing all your credentials are in good standing.

If your credentials are not in good standing, a message will be displayed on the Kiosk similar to the one below with directions on how to proceed.
REPTrax New Users

When a new user (a non-REPTTrax member) needs to gain entry, the user would press the Signup to REPTrax button.

The new user page is displayed with basic information that will need to be filled out in order to go to the next step. NOTE: Please add company name exactly as it appears on your business card.
New members will have to select the correct user type as this defines what credentials will be needed for access. If you have any questions about the user type please verify with hospital personnel.

![User Type Selection](image)

Upon selecting **Signup** you will see the following message:

![REPTraX Welcome Message](image)

- The printer should print the ID # so you will have it for future reference.
- It is hospital policy that you are to **sign out** at the REPTraX Kiosk at the conclusion of your visit.
- You will be sent an email with your username and password to the REPTrax system and will be notified of any outstanding items. Please log into your account at [www.reptrax.com](http://www.reptrax.com) to update your account details and to submit your outstanding credentials.
From this point on, you will need to log into the system as an existing user. The kiosk at this point has returned to the login page.

{Please review these procedures above starting at page 2.}
Logout Procedure

The process of signing out is the same as signing in. Enter your e-mail address and either your password or your REPTraX ID#.

Select Login/Logout

Sacred Alaska Regional (REPTraX Demo) | A Kiosk

Existing User Login & Logout

Email
Password or REPTraX ID #
Login / Logout >>

New User Signup
Create a new REPTraX account that can be used at all REPTraX facilities
Signup to REPTraX >>

Kiosk Home

You have been successfully logged out of the system for the current visit. Remember, it is hospital policy to sign out at the REPTraX kiosk upon the completion of your visit. Failure to do so will create an automated negative REPscore.

Logout

You logged out successfully.

This page will redirect to the kiosk home in 9 seconds.

Main Kiosk Page >>

Kiosk Home