

Section Clinical Research Center

Date Created: January 16, 2012

Title: Monitoring Visits

Date Reviewed/Modified: April 1, 2019

SOP Number: SOP-18

Version Number: 4

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

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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.

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- 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 Reprax
Add or change prof

REPTrax add or delete hospital instructions

SOP-18 RepTrax
Add or delete hospi

REPTrax Login Logout procedures

SOP-18 Reprax
Login logout proces

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

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Department Approval

Signed 
Director of Clinical Research Operations

Signed 
Medical Director of 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 smart phone.

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](http://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

Instruction guide



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.



REPTrax Rep Area

Home Profile REPScore Credentialing Marketing Help & Instructions

Profile Photo

! no photo on record

Click to Update

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



Current Photo


! no photo on record

*New Photo Browse...

Upload Photo >>

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.

Current Photo	
*New Photo	C:\Documents and Settings\Amy\Desktop\R <input type="button" value="Browse..."/>

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.

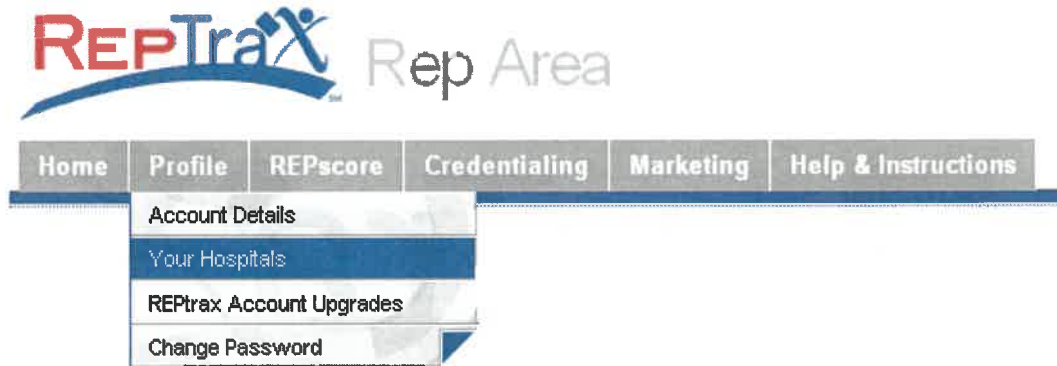
Current Photo	
*New Photo	<input type="text"/> <input type="button" value="Browse..."/>

Instruction guide

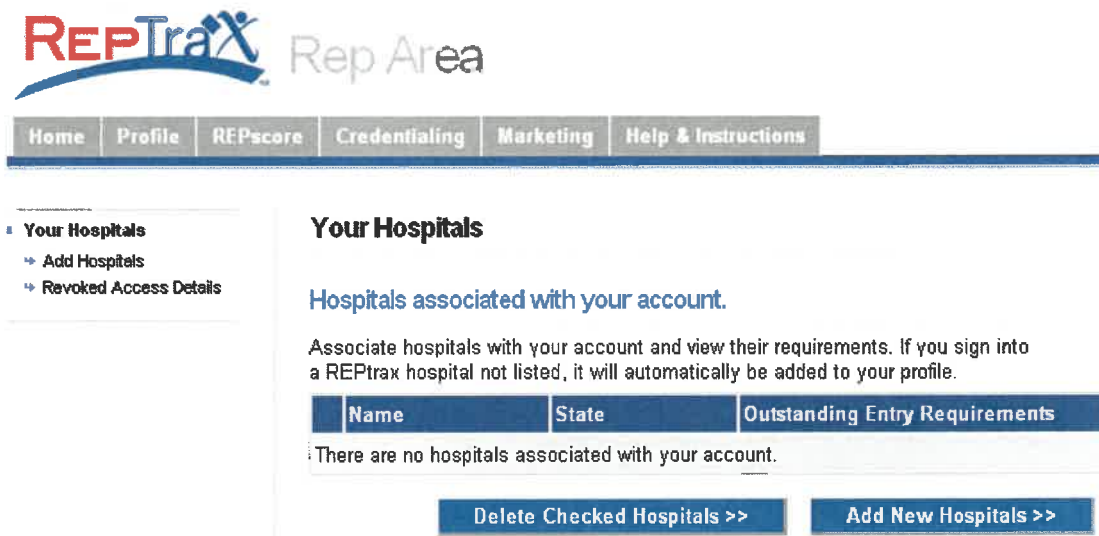


How to add /delete hospitals to your account

Log into REPtrax and select Your Hospitals under the Profile tab.



Choose Add New Hospitals, this will allow you to associate hospitals with you 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 your hospitals from the list and press the Add button, this will move the selected hospital(s) to the right hand column.

REPtraX Rep Area

Home Profile REPScore Credentialing Marketing Help & Instructions

Your Hospitals

- Add Hospitals
- Revoked Access Details

Add Hospitals

Associate new hospitals with your account.

Select hospitals in your territory to associate with your profile. You to be alerted to the entry requirements for any REPtraX facilities selected. There is a profile limit of 500 hospitals. Your current hospital count is 0.

Show Hospitals in State: -

State Hospitals:

Selected Hospitals:

Add >>

<< Rem

Once you have all your hospitals selected press the Add Selected Hospitals button.

Show Hospitals in State: Massachusetts

State Hospitals:

- Addison Gilbert Hospital
- Baystate Medical Center
- Berkshire Medical Center
- Beth Israel Deaconess Hospital Needf
- Beth Israel Deaconess Medical Center
- Beverly Hospital Corporation
- Boston Shriners Hospital
- Brigham & Womens Hospital
- Brockton Hospital
- Cape Cod Hospital
- Caritas - Carney Hospital
- Caritas - Good Samaritan Medical Cen
- Caritas - Holy Family Hospital & Medic
- Caritas - Norwood Hospital
- Caritas - St. Annes Hospital

Selected Hospitals:

- Anna Jaques Hospital
- Boston Medical Center

Add >>

<< Rem

Add Selected Hospitals >>

You will now see the hospitals were added successfully, you will also be able to view any outstanding requirements for any hospital selected.



- Home
- Profile
- REPScore
- Credentialing
- Marketing
- Help & Instructions

- Your Hospitals
 - ➔ Add Hospitals
 - ➔ Revoked Access Details

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 added successfully.

	Name	State	Outstanding Entry Requirements
<input type="checkbox"/>	Anna Jaques Hospital	MA	
<input type="checkbox"/>	Boston Medical Center	MA	Credential: Tuberculosis Credential: MMR - Measles, Mumps and Rubella Credential: Hepatitis B Credential: Chicken Pox Credential: Consent of Use Form

To remove any hospital from you profile put a checkmark in the box before the name of the hospital and press Delete Checked Hospitals.



- Home
- Profile
- REPScore
- Credentialing
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- Help & Instructions

- Your Hospitals
 - ➔ Add Hospitals
 - ➔ Revoked Access Details

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.

	Name	State	Outstanding Entry Requirements
<input checked="" type="checkbox"/>	Anna Jaques Hospital	MA	
<input type="checkbox"/>	Boston Medical Center	MA	Credential: Tuberculosis Credential: MMR - Measles, Mumps and Rubella Credential: Hepatitis B Credential: Chicken Pox Credential: Consent of Use Form

- Delete Checked Hospitals >>
- Add New Hospitals >>

You have successfully deleted hospitals from your account.



- Home
- Profile
- REPScore
- Credentialing
- Marketing
- Help & Instructions

- **Your Hospitals**
 - ➔ Add Hospitals
 - ➔ Revoked Access Details

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.

	Name	State	Outstanding Entry Requirements
<input type="checkbox"/>	Boston Medical Center	MA	Credential: Tuberculosis Credential: MMR - Measles, Mumps and Rubella Credential: Hepatitis B Credential: Chicken Pox Credential: Consent of Use Form



Login / Logout Procedures
For



Existing Members
And
New Users

REPtrax Existing Members

If you are an existing REPtrax member, sign in to the REPtrax Kiosk by entering your e-mail address and either your password or REPtrax ID#. It is also 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.



Sacred Alaska Regional (REPtrax Demo) | A Kiosk

Existing User Login & Logout

Email	<input type="text"/>
Password or REPtrax ID #	<input type="text"/>
<input type="button" value="Login / Logout >>"/>	

New User Signup

Create a new REPtrax account that can used at all REPtrax facilities

[Kiosk Home](#)

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



Visit Details

Welcome Terry Louthan, 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	<input type="text"/>
*Location in Facility	<input type="text"/>
*Meeting Topic	<input type="text"/>
*Expected Visit Duration	<input type="text"/> hours

[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.



Welcome

Thank-you. You are now checked in.

This kiosk will now attempt to print your badge. You are required to wear it while you are inside this facility.

Be sure to return to this kiosk and check out when your visit is complete.

This page will redirect to the kiosk home in 27 seconds.

[Main Kiosk Page >>](#)

[Kiosk Home](#)

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.



Facility Access Denied

You are missing requirements for entry into this facility.

Please proceed to Purchasing to receive permission to enter. Hospital personnel have been sent notification and are expecting your arrival.

Outstanding Requirements

Credential: American Association of Tissue Banks Certification

[Main Kiosk Page >>](#)

[Kiosk Home](#)

REPtrax New Users

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



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 used at all REPtrax facilities.



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 User Signup

Enter your details below to signup as a new REPtrax user.
If you have signed up at another REPtrax facility, you don't need to sign up again

All fields are required. Your account details will be emailed to you.

User Details

*First Name

*Last Name

*Company

*Email

*Confirm Email

*Phone

*Password Must be at least 6 characters

*Confirm Password

*User Type Select this carefully as it will determine what areas you can access

*Agree to Terms I agree to the REPtrax Terms & Conditions

Signup >>

Kiosk Home

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	--
*Agree to Terms	<input type="checkbox"/>

Sales Rep with access to OR/Invasive Labs
Sales Rep with access to Patient Care Areas
Sales Rep with access to Administration Offices/IT
Sales Rep with access to Laboratories
Tissue/Bone Representative with access to OR/Invasive Labs
Pharmaceutical Rep/Manager with access to Hospital
Distributor Rep with access to OR/Invasive Labs/Patient Care Areas
Distributor Rep/Consultant/GPO with access to Administration Offices/IT
Service Technician with access to OR/Invasive Labs/Patient Care Areas
Service Technician with access to General Hospital Grounds
Delivery Person with access to General Hospital Grounds
Facilities Management with access to General Hospital Grounds

[Signup >>](#)

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



Welcome to REPTRAX

Your account has been created, and the details have just been sent to your email address.

Your Account ID # is: 8674

The badge printer should print out your ID # for your reference. You will need it to log in on the next page.

[Go to Login Page >>](#)

[Kiosk Home](#)

- 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 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.}



Sacred Alaska Regional (REPtrax Demo) | A Kiosk

Existing User Login & Logout

Email	<input type="text"/>
Password or REPtrax ID #	<input type="password"/>
Login / Logout >>	

New User Signup

Create a new REPtrax account that can used at all REPtrax facilities

[Signup to REPtrax >>](#)

[Kiosk Home](#)

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	<input type="text"/>
Password or REPTrax ID #	<input type="text"/>
Login / Logout >>	

New User Signup

Create a new REPTrax account that can 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](#)