

# Coordinator's Guide for Study Monitor Access

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# Key Notes

## Active Directory Accounts

All Study Monitors are required to have an Active Directory (AD) Account to access any of the systems at UNMC/Nebraska Medicine. In the chance that access needs urgently revoked, this can be done using the AD account, instead of having to revoke access to each individual system.

- AD accounts require a DOB however, Monitors do not use personal identifiers.
  - The study team will communicate a default DOB to the Monitor
    - The DOB is used for identification when calling the Help Desk, Activating AD accounts, and Resetting Passwords

## Study Monitor Visit Request Form

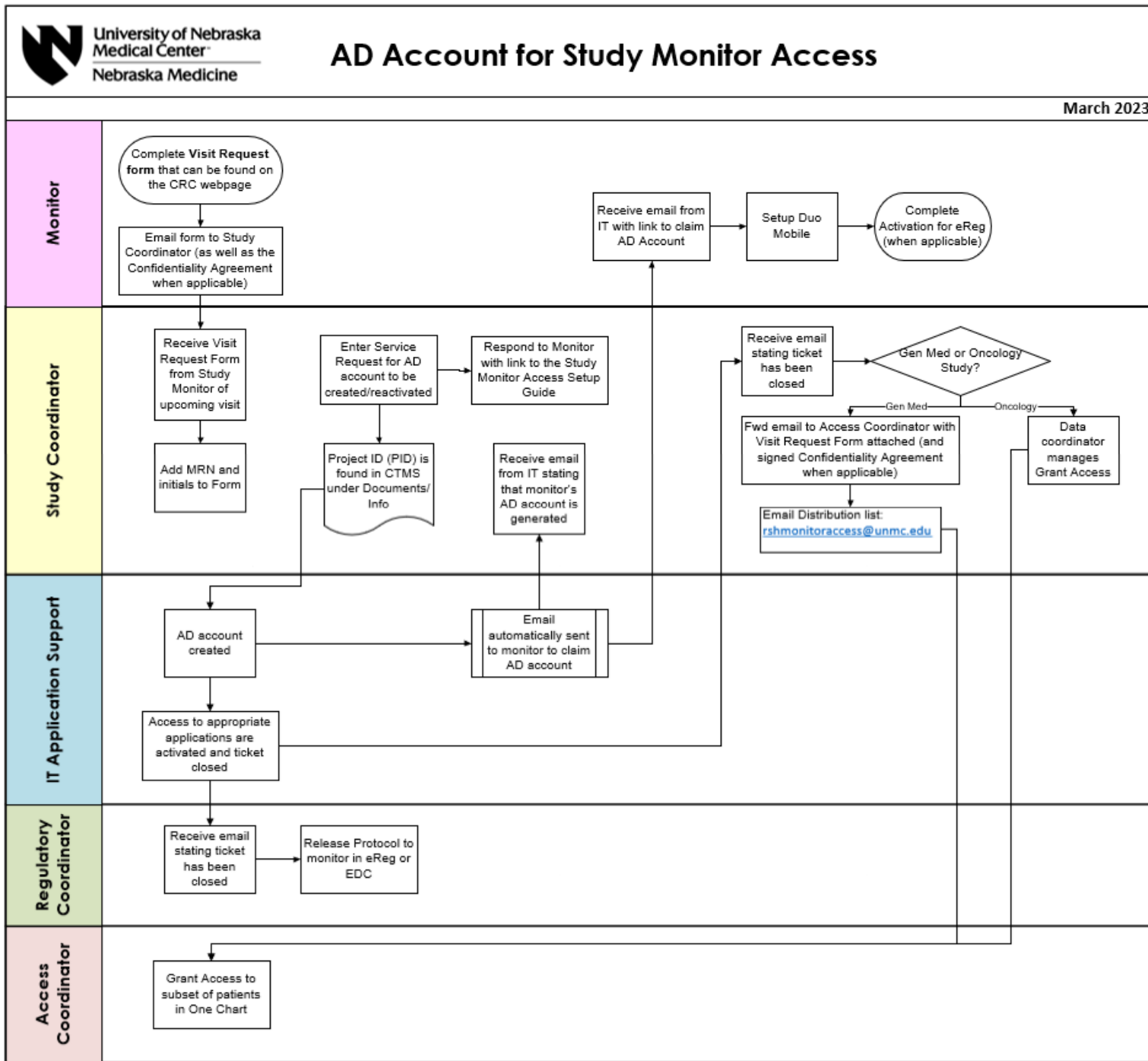
Monitors will be able to access the new Visit Request Form on their own via the [CRC webpage](https://www.unmc.edu/cctr/resources/crc/studyMonitor.html) (<https://www.unmc.edu/cctr/resources/crc/studyMonitor.html>). They will email the completed form to the study coordinator, along with the signed Confidentiality Agreement, when applicable.

The image shows a screenshot of the UNMC Clinical Research Center (CRC) webpage. The navigation bar includes links for 'About Us', 'Resources & Services', 'For the Public', 'Clinical Trials', 'Community Engagement', and 'Education'. The breadcrumb trail reads 'UNMC > CCTR > Resources & Services > Clinical Research Center (CRC)'. The main heading is 'Clinical Research Center (CRC)'. A sidebar menu on the left lists various resources, with 'Clinical Research Center (CRC)' expanded to show 'Resources', 'Study Intake Form', 'Study Monitor Visits' (highlighted with a red star and a red box), and 'Site Information Sheet'. A red dashed arrow points from the 'Study Monitor Visits' link to a callout box on the right. The callout box, titled 'For Study Monitors:', contains the text: 'The below request form should be completed for each visit'. It lists two items: 'Study Monitor Visit Request Form' and 'Study Monitor Access Setup Guide', both enclosed in red boxes.

## Two-Factor Authentication

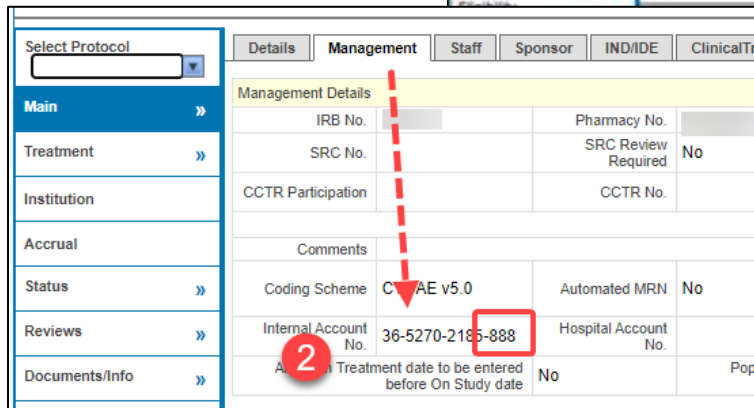
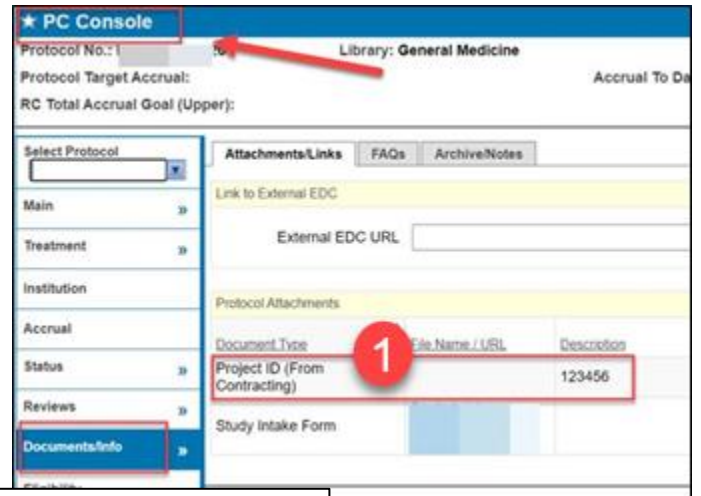
Monitors will have to complete Two-Factor Authentication (2FA) to be able to access One Chart Link, Advarra EDC, and Advarra eREG. 2FA reduces the likelihood that hackers can successfully impersonate a Monitor and gain access to the systems. Monitors will need to set up this on their own, and can reference the [Monitor Access Setup Guide](#) that is also on the CRC webpage.

# Overall Workflow Process



# Prep Steps Prior to Entering Request

1. Obtain the PID# that is located in CTMS under PC Console>Documents/Info Tab.
2. If there is no PID listed, you will need to identify if the study is through SPA or UNeHealth by reviewing the Internal Account No. (WBS), under PC Console>Main>Management tab.
  - a. If the last 3 numbers are 888, this is UNeHealth, please contact [amanda.leingang@unmc.edu](mailto:amanda.leingang@unmc.edu) for the PID#
  - b. If the last 3 numbers are 001, 002, 003, etc. please contact [SPAdmin@unmc.edu](mailto:SPAdmin@unmc.edu) for the PID#.



3. Add MRNs and Subjects initials to the Monitor Visit Request Form.
  - a. Open the Monitor's PDF request form that they emailed, and add the One Chart MRNs and initials.
  - b. If there are more than 10 subject charts to be reviewed, those IDs/MRNs can be provided as an attachment via a Word doc, Excel, etc. and are not required to be on the request form.

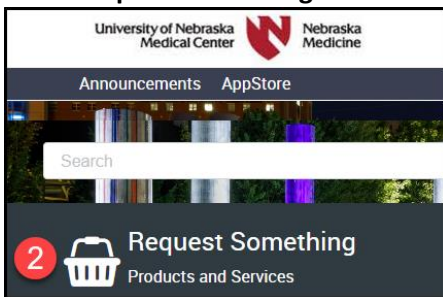
Access Requested																																		
<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <p><i>Monitor to Complete</i></p> <p>Charts Requested (Subject ID)</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>AB1245-12</td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> <tr><td> </td></tr> </table> </div> <div style="text-align: center; border: 2px solid red; padding: 5px;"> <p><i>Columns to be completed by the Study Coordinator</i></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Medical Record #</th> <th>Subject Initials</th> </tr> </thead> <tbody> <tr> <td>0989995</td> <td>F.Z.</td> </tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> <tr><td> </td><td> </td></tr> </tbody> </table> </div> </div>			AB1245-12										Medical Record #	Subject Initials	0989995	F.Z.																		
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# Creating a Service Request for Research Monitors

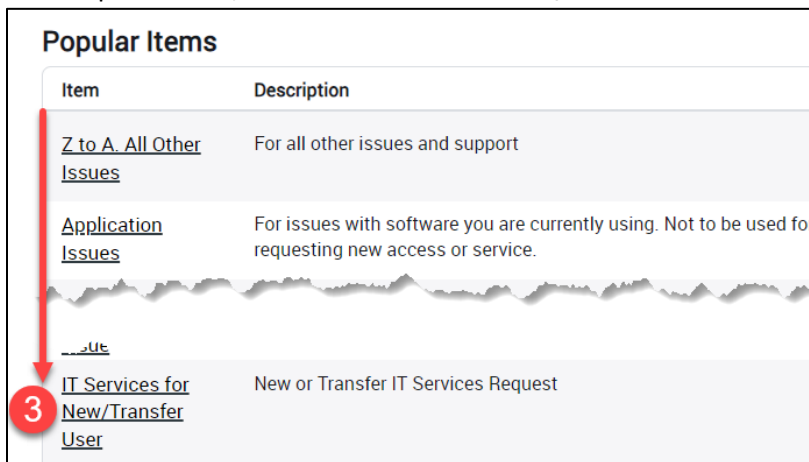
! It may take up to **3 weeks** for access setup to be complete after a request has been entered. Be sure there is enough lead time from the date you enter the request, to the date the Monitor has requested.

The Study Coordinator will enter the Service Request from self-service portal, ServiceNow. Follow the steps below to submit a request for Research Monitors.


1. Go [ServiceNow](#)
2. Select **Request Something**.



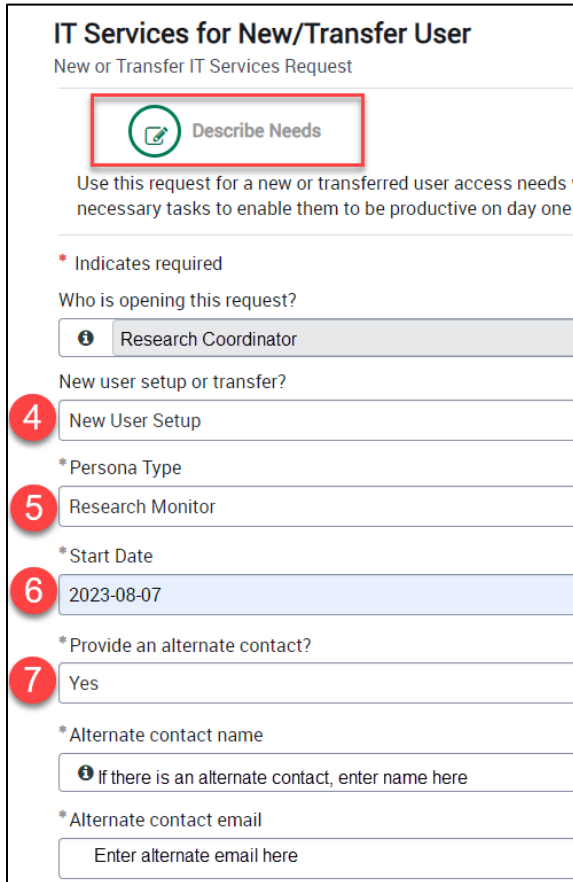
3. From Popular Items, select **IT Services for New/Transfer User**



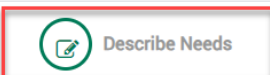
4. For New user set up or transfer? - select **New User Setup**.

 All Monitor requests will be **New User Setup** regardless of whether the Monitor is new or returning.

5. For Persona Type – select **Research Monitor**
6. For Start Date – enter the date the visit starts.
7. If entering an Alternate Contact, type the coordinator’s first and last name and contact info.



**IT Services for New/Transfer User**  
New or Transfer IT Services Request

 Describe Needs

Use this request for a new or transferred user access needs with necessary tasks to enable them to be productive on day one.

\* Indicates required

Who is opening this request?

New user setup or transfer?  
**4**

\*Persona Type  
**5**

\*Start Date  
**6**

\*Provide an alternate contact?  
**7**

\*Alternate contact name

\*Alternate contact email

8. Next, enter the Monitor's information.
9. The Date of Birth will default. As a reminder, the study team must communicate the default DOB to the Monitor.

**\*First Name**  
monitor 1st name

Middle Initial  
 

**\*Last Name**  
monitor last name

**\*Email Address**  
monitor@sponsor.com

**\*Phone Number**  
312-111-1111

**\*Date of Birth (YYYY-MM-DD)**

10. Fill in the following information:

- **Sponsor Name**
  - i. If the sponsor's name cannot be found, select the checkbox next to **Sponsor not found** and free text the sponsor's name.

**\*Sponsor Name**  
 

Sponsor not found

Sponsor not found

**\*Enter sponsor name**  
Avid Bio

- **IRB#**
- **PID#** (Project ID which is found in CTMS under Documents/Info)
- **Visit Start and End Date**
  - i. Contracted end date is 45 days and will auto calculate.

**\*IRB#**  
123-45

**\*PID#**  
32168153

**\*Visit Start Date**  
2023-08-07

**\*Visit End Date**  
2023-08-09

**\*Contracted End Date**  
2023-09-21



If the Monitor is Monitoring more than one study during the same visit, rather than submitting separate requests for each study, you may enter multiple IRB#s and PID#s on each line. This is only allowed if the Visit Start Date and Visit End Date are the same for all studies being Monitored.

11. Under **IT Service Options**, select **Network Access**.

12. Select **Next**

13. From the **Choose Options** page, select the drop-down carrot **∨**.

- Review the information to ensure accuracy.

14. Select the boxes for the applications the Monitor will need access to:

- One Chart- access to patient medical records
- Advarra EDC - eCRFs for UNMC Investigator-initiated studies
- Advarra eREG - electronic regulatory binders
- Vestigo - investigational pharmacy for drug studies)

If there is an unblinded team and blinded team, then the blinded Monitor **should not** have access to Vestigo. Questions regarding this should be directed to Investigational Pharmacy prior to submitting the request.

15. One Chart Access Options – select **One Chart Link**

Check with your regulatory coordinator to confirm your study is in eREG if you are not sure

16. Select **Next**

17. Select **Submit**



18. An email will be sent with the Service Request ID. This is a reference to keep when there are questions related to status.



The Authorizing Manager has **3 days** from request creation to approve, otherwise the request will get auto-closed and the access request will be cancelled

# Initial Training and Access Setup

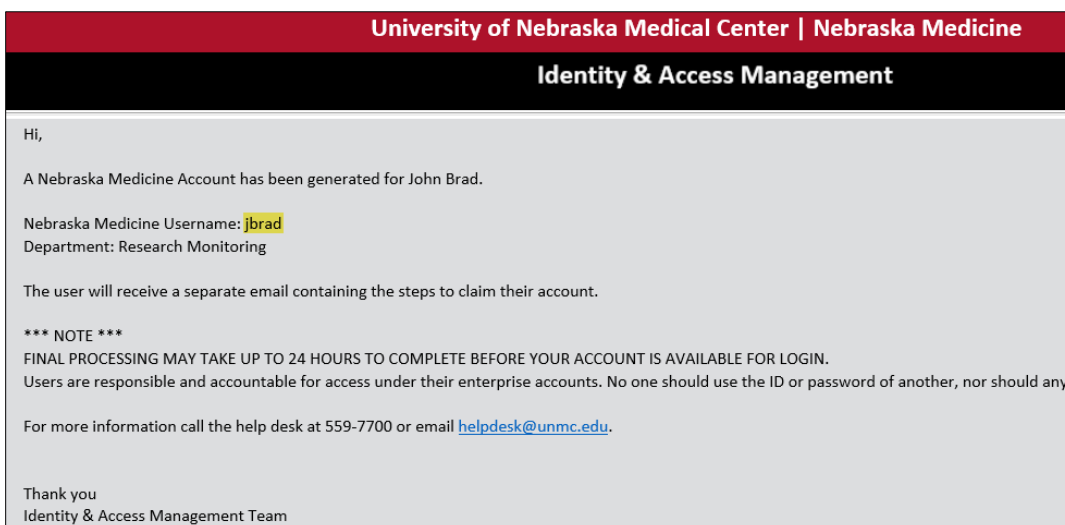
Once the AD account has been generated, the Identity and Access Management Team will send two separate emails directly to the Monitors. The first email provides instructions to claim their account. Once the Monitor has successfully claimed their account, the Identity and Access Management Team will send a confirmation email to the Monitor with login information.

If this is the Monitor's first visit with our organization, they will be **required** to complete the following:

1. Setup DUO Mobile- instructions can be found in the [Monitor Access Setup Guide](#)
2. The Monitor's account is activated in Advarra eREG and an activation email is sent to the Monitor.
  - The Monitor has 24 hours to click on the link within the email to activate their account. If link has expired before the Monitor activates their account, they will need to contact the Help Desk at 402-559-7700 option 2 to have the activation link resent.

The Study Coordinator (or person that entered the request) will receive three emails:

- Initial email that notifies you of the request number to use a reference if needed
- A second email that notifies you that the Monitor's AD account has been generated. See example below.
- A third email that notifies you when the request has been closed



When the request is closed, that indicates that access to the appropriate applications has been activated. If the Monitor will be reviewing subject medical records, Monitors must be granted access to patient.

- For general medicine studies, the Study Coordinator emails the completed Monitor Visit Request form (includes the MRNs, subject initials, and Monitor's username) to [rshMonitoraccess@unmc.edu](mailto:rshMonitoraccess@unmc.edu), "Research Monitor Access."
- For oncology studies, the data coordinator will grant access.

# Subsequent Visits: Catalog Item Request Creation

A Catalog Item Request needs to be entered each time a Monitor comes for a site visit. See steps 1 to 18.

## Monitor Password Information

If a Monitor's subsequent visit is *within* 45 days of their last visit date, no additional setup is needed from the Identity and Access Management Team.

If the Monitor's subsequent visit is *more than* 45 days from their last visit date, the Identity and Access Management Team will need to reactivate the account. The Monitor will receive an [email notification](#) as previously mentioned.

They will not need to setup DUO Mobile again.

# Technical Support

## Internal Resources

- DUO Mobile- Call the Help Desk 402-559-7700, option 2
- One Chart- [OneChartResearch@nebraskamed.com](mailto:OneChartResearch@nebraskamed.com)
- eREG/EDC- [CTMS@nebraskamed.com](mailto:CTMS@nebraskamed.com)
- Vestigo- [investigationalpharmacy@nebraskamed.com](mailto:investigationalpharmacy@nebraskamed.com)
- FAQ document can be found on the [Study Monitor Visit](#) webpage

## Applications for Monitors

- [One Chart Link](#) (Subject's Medical Records)
- [eREG](#) (Electronic Regulatory Binder)
- [Vestigo](#) (Investigational Pharmacy)
- [EDC](#) (Electronic Data Capture)