

DAIDS Adverse Experience Reporting System (DAERS) Reference Guide for Site Enrollment Users

Under NIAID Order Number HHSN27200001, which is titled "Development and Maintenance of NIAID's Clinical Research Management System (NIAID CRMS)" this document was prepared for:

National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
Department of Health and Human Services (HHS)

DAERS Reference Guide for Site Enrollment Users

Document Version: 1.7
Document Control ID: 201004 005
NIAID CRMS Version: 1.5.1
Date Published: May 4, 2018
Date Last Modified: May 4, 2018

Table of Contents

Introduction to the DAERS Site Enrollment Module	3
What Is DAERS?	3
What Is DAERS Site Enrollment Module?	3
What Can I Do with DAERS Site Enrollment Module?	3
Who Is DAERS Site Enrollment Module Intended for?	3
How Can I Access DAERS Site Enrollment Module?	3
NIAID Clinical Research Management System	3
Obtaining Support	5
Obtaining Support	5
Access to RSC	6
Using Common Functions	7
Using Fields	7
Using List of Values	7
Using Buttons	7
DAERS User Roles Matrix	10
DAERS User Maintenance	11
Adding Users to DAERS	11
Maintenance of DAERS Users	11
Enrolling and Updating Site Staff in DAERS	12
Viewing the Persons at a Site	12
To Access the New Request Screen	12
To View Persons at the Site	12
Adding a New Person for a Site	14
To Enter Name and Contact Information	14
To Select the Person's DAERS Role	15
To Select the Protocols for the Assigned DAERS Role	15
To Review and Submit the Request	15
Editing a Person's Information	16
To Edit a Person's Information	16
Inactivating a Person	17
To Inactivate a Person's DAERS Access	17
Viewing Requests	18
To Access View Requests	18
To Search on a Request	18
To View Details of a Request	18
To Generate the Person Information Report	18
To View All the Changes Submitted by the Site	18

Introduction to the DAERS Site Enrollment Module

What Is DAERS?

The DAIDS Adverse Experience Reporting System (DAERS) enables DAIDS clinical research sites to report Expedited Adverse Events (EAEs) effectively, in accordance with the safety reporting guidelines set forth by DAIDS, FDA, and ICH for the conduct of human subject clinical trials. The DAERS is a Web-based system that enables immediate reporting of and access to EAEs. Built-in data validation checks and lists of values ensure accuracy of data capture. Moreover, data entry is minimized because certain information, such as protocol, participant and site information, is already captured by other DAIDS components.

What Is DAERS Site Enrollment Module?

The DAERS Site Enrollment Module enables DAIDS clinical research sites to enroll and update site staff in DAERS.

What Can I Do with DAERS Site Enrollment Module?

Depending on your role, you can view, add, edit and inactivate a person at a site.

Who Is DAERS Site Enrollment Module Intended for?

DAERS Site Enrollment Module is intended for the easy maintenance of Clinical Research Site Physicians and staff whose role requires that they report EAE information for DAIDS-sponsored clinical trials.

How Can I Access DAERS Site Enrollment Module?

Users with a DAERS Site Enrollment User account can access the system through the following link:

<https://ncrms.niaid.nih.gov>.

NIAID Clinical Research Management System

The NIAID (National Institute of Allergy and Infectious Diseases) Clinical Research Management System (CRMS) supports the managing of clinical research funded by (or otherwise supported by) DAIDS, the Division of Allergy, Immunology and Transplantation (DAIT), Division of Microbiology and Infectious Diseases (DMID), and the Vaccine Research Center (VRC).

Note: All NIAID CRMS applications are accessible only through Internet Explorer (IE) 11 (with Compatibility View turned Off) and Google Chrome.

After logging in, you can navigate to NIAID CRMS applications from the NIAID CRMS home page.



Terms You Should Know

TERM	DEFINITION
Request	<p>A Request is the submission of changes for the site staff regarding access to DAERS for new users, modification of access to protocols for existing users, and/or inactivation of access in the Site Enrollment Module for existing users. Each Request is associated with a four digit Request ID.</p> <p>Note: Requests are also generated upon submission of a Registration Packet in DPRS (DAIDS Protocol Registration System). Specifically, on the DPRS Person Information screen, the users can indicate which site staff requires Reporter and/or Submitter access to DAERS. When the PRO approves the submission, the Request will display on the View Request page of the DAERS Site Enrollment Module.</p>

Terms You Should Know	
TERM	DEFINITION
Request Status	<p>Draft — Request for changes for the site is yet to be submitted to NIAID CRMS Support.</p> <p>Submitted — Request for changes for the site is submitted to NIAID CRMS Support</p> <p>In Progress — NIAID CRMS Support is processing the Request submitted by the site.</p> <p>Completed — NIAID CRMS Support has completed processing of the Request submitted by the site.</p> <p>*Completed — NIAID CRMS Support has completed processing of the Request submitted by the site with some outstanding issues.</p>
User Information Report:	The DAERS User Information Report displays a list of users associated with the selected Site, the user's contact information, and the protocols to which they have access in DAERS in a Microsoft® Excel sheet.
Electronic Signature Attestation Form (for compliance with 21CFR Part 11)	<p>During the process of submitting an EAE Report to RSC, the Study Physician reviews and signs with an electronic signature (username and password) to indicate that the EAE Report is accurate and complete. Before a Study Physician can electronically sign or have access to DAERS, the following requirements must be met:</p> <p>Each Study Physician must mail to the RSC the original completed and signed 21 CFR Part 11 – Attestation and Agreement for Electronic Signatures form for each site which designates the Physician as a submitter within the DAERS system and each Study Physician must be listed on the FDA 1572 or IoR Agreement form for their study and site.</p> <p>Note: To expedite access, an electronic version of the document will be accepted with the understanding that the hard copy is mailed. Access to DAERS will be revoked if the hard copy is not received within 2 weeks.</p> <p>You may access the form by clicking https://rsc.niaid.nih.gov/sites/default/files/physician-electronic-signature-attestation-form.pdf</p> <p>MAIL THE ORIGINAL SIGNED ATTESTATION FORM(S) TO: DAIDS Safety Office 6500 Rock Spring Drive, Suite 650 Bethesda, MD 20817</p>

Obtaining Support

Obtaining Support

To report a problem, make a suggestion, or request regarding DAERS, contact NIAID CRMS Support directly by telephone or e-mail. Live assistance is available 8:30 A.M. to 5:30 P.M. U.S. Eastern Time, Monday through Friday (excluding holidays). You may also submit a ticket request from within DAERS through the NIAID CRMS Support web page. Once you contact NIAID CRMS Support, you will receive a confirmation e-mail with a unique ticket number.

Note: When in doubt, please copy both NIAID CRMS Support and RSC Safety Office.

①

Contact Information for NIAID CRMS Support

Phone: (1) (240) 778 - 2517

E-mail: CRMSSupport@niaid.nih.gov

②

Submit a Problem or Suggestion/Request or View My Ticket Status

You can report a problem or make a suggestion/request from within DAERS.

To Submit from DAERS

1. From within the application, go to the top right navigation bar and then point to **Help**.
2. Click **NIAID CRMS Support** from the drop-down list.
The links to contact NIAID CRMS Support display on a web page.

3. Click one of the following links:

- **Report a problem**
- **Make a suggestion or request**

The NIAID CRMS Support Submission form displays.

4. Enter the required information into the submission form.
5. Click **Submit**.

An e-mail is sent that confirms your submission and gives you a ticket number to reference the submission in the future.

To View My Ticket Status

1. From within the application, go to the top right navigation bar and then point to **Help**.
2. Click **NIAID CRMS Support** from the drop-down list.
The links to contact NIAID CRMS Support display on a Web page.
3. Click **Search my tickets**.
4. Locate the ticket from the list of your submitted tickets currently in the database.

Tip: Use the Quick Search option to locate the ticket.

5. View the current status of the selected ticket, ask for further assistance, or submit comments and requests.

③

Contact Information for RSC

For questions on the DAIDS EAE manual or EAE reporting requirements, contact DAIDS RSC Safety Office.

Phone: 1-800-537-9979 (U.S. only) or 301-897-1709

E-mail: DAIDSRSCSafetyOffice@tech-res.com

Fax: 1-800-275-7619 (U.S. only) or 301-897-1710

Mail: DAIDS Safety Office, 6500 Rock Spring Drive, Suite 650, Bethesda, MD 20817

Access to RSC

Instructions for DAERS and necessary documents can be found on the RSC website

<https://rsc.niaid.nih.gov/clinical-research-sites/daids-adverse-experience-reporting-system>. You can access the RSC website by clicking on **RSC** from the horizontal menu bar.

Using Common Functions

There are standard features used throughout DAERS Site Enrollment Module. The following sections provide descriptions of these features and their use.

Using Fields

The following are the field types used within DAERS Site Enrollment Module and a description of each, along with the attributes associated with a field and instructions on how to use the field.

- **Smart Search** — As you type in a field marked with the Smart Search icon, the system searches through the database for the best match. You can select a match from the drop-down list and edit the text. If there is no match, the text turns red. When you leave the field, the text turns black.

Tip: Press the space bar to display the first 100 values in the drop-down list.
- **Text Box** — A single line rectangular box in which you can type text or select from smart search.
- **Text Area** — A multiline rectangular box in which you can type text, such as comments or description. In the large text areas, as you type information, DAERS gives you a running count of remaining characters just below the text area.
- ***** (Asterisk) — Displays next to a required field.
- **!** (Exclamation point) — An indicator that the value you entered or selected is incorrect. Correct the entry or click **Save** to view the error message.
- **ToolTip** — A pop-up appears for three seconds when you hover the cursor over a field, providing the definition or other pertinent information for the field or column label. Can also display for links and pop-ups.

Using List of Values

A List of Values (LOV) displays items that form a long list from which you select a value for a field. Usually, an LOV is used when the list is too long to display in a drop-down list. Although there are LOV fields where you can select multiple values at a time (check boxes), most require only one value (option button). Also, some LOVs provide search functions to help you find the value you need faster than scrolling through the list.

Within an LOV dialog box, you can:

Search for a Value

1. Click  next to the field. The List of Values displays in a dialog box.
2. Click the **Filter by**  and select an option to filter by. The value selected further refines the LOV (*List of Values*) results. Example: Organization Name.

3. Type the specific values you are searching for in the text box next to the **Filter by** field.
4. *Optional:* Click **Add more search criteria**. An additional drop-down list and text box displays in the LOV dialog box for you to filter your search. Refer to the section below "Add Additional Search Criteria" for more details in using this feature.
5. Click . The search results display only those LOV results within the postal code 21771.

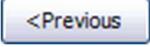
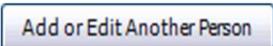
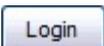
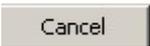
Select an Item

1. Whether you use the search function, do one of the following to select an item in an LOV:
 - Select an option of the value needed.
 - Select a check box of the value(s) needed.
2. Click **Close**.
The selected items display in the page field.

Using Buttons

Buttons and navigation features used within DAERS Site Enrollment Module.

Section 3

	Horizontal menu bar.
	Runs a query based on your selections.
	Removes contents from fields on a page.
	Modify an individual record.
	Inactivates a person or deletes a report.
	Creates a new person record.
	Download list of all DAERS users for a site in an excel sheet.
	Go to previous screen.
	Returns the information in the fields to the previously saved value. If no values have been saved, the fields will be reset to their default values.
	Save and go to next page.
	Displays the current request details.
	Submit all changes to the database
	Close without saving to the database.
	Add/Edit another person
	Export all details to an excel sheet.
	Saves the record to the database.
	Submits user ID and password to access DAERS.
	Proceed with the current action.
	Cancel the current action.
	Move back or forward one page.
	Goes to the first or last page.

Section 3



Drop-down lists the number of pages within the table. Select a page number to display a specific page (sometimes faster than using the forward button).



Sort table column contents in alphanumeric order. Hover over the column heading to activate the arrow icon.



Closes the page or box from the upper right corner of the page.



Use check box to make selections.

DAERS User Roles Matrix

The DAERS recognizes your Role and associated site studies when you first log on to the system and organizes the information accordingly. The following Roles are available in the application:

DAERS User Roles	
USER ROLE	FUNCTIONS/TASKS
Reporter	Site study staff responsible for creating EAE reports. Have the ability to create and check a report for completion, search, and view reports.
Submitter	Study Physicians have the ability to create, sign, submit EAEs to RSC, search and view reports. Note: In order to use the DAERS, each study physician at your site must: <ul style="list-style-type: none">• Provide a signed copy of the “21 CFR Part 11 – Attestation and Agreement for Electronic Signatures.”• Be listed on the appropriate FDA Form 1572 or Investigator of Record Agreement. Updates to any of these forms must be forwarded to the RSC.

DAERS User Maintenance

Adding Users to DAERS

1. The CRS Leader or CRS Coordinator must request access for site staff using the Site Enrollment Module in DAERS for all protocols with EAE reportability to NIAID CRMS. They must provide the User's name, contact information (e-mail, phone, fax) and the DAERS role by protocol.

Note: While submitting a registration packet in the DAIDS Protocol Registration System (DPRS), you can use the Person Information screen to specify the list of personnel (e.g., sub investigators, IoRs) associated with a study, and to indicate who requires Reporter and/or Submitter access to DAERS. This screen is only accessible when completing the following submission types: Initial, Change in IoR, Updated 1572, and Updated IoR Form. Upon approval of the submission by the PRO, the Person Information screen is locked and cannot be modified.

2. All new users must complete DAERS training.
3. In addition, the following requirements apply per role:
 - a. Reporters: Will only have access to report EAE's on protocols that have at least one Physician who also has access to submit EAEs on those protocols.
 - b. Submitters
 - i. Must mail an Electronic Signature attestation form to RSC. To expedite access, an electronic version of the document will be accepted with the understanding that the hard copy is mailed. Access will be revoked if the hard copy is not received within 2 weeks.
 - ii. Must appear on the 1572 or IoR Agreement forms that is currently on file with the RSC. RSC will verify the site's request for submitters against the documents the site has filed with RSC. If updates to the 1572 are required, the form must be provided to the RSC in accordance with the current Protocol Registration standard operating procedures.

following submission types: Initial, Change in IoR, Updated 1572, and Updated IoR Form. Upon approval of the submission by the PRO, the Person Information screen is locked and cannot be modified.

CRS Leaders and CRS Coordinators are responsible for maintaining their DAERS User's Information through the Site Enrollment Module. This includes the following scenarios:

- a. If additional people join the organization, sites must follow the process to add users to DAERS.
- b. When a site registers to a new EAE reporting DAIDS protocol, the CRS Leader or CRS Coordinator must request access for the users who have been identified for the role of Submitter or Reporter for that particular protocol, and submit the associated documentation to the RSC. (Physician Electronic Signature Attestation Form - If the submitter is not a current user of the DAERS system)
- c. When a user leaves the site's organization or no longer requires access to DAERS, the CRS Leader or CRS Coordinator is responsible for notifying NIAID CRMS Support to remove the user's rights by using the DAERS Site Enrollment Module.
- d. When a site deregisters from a protocol, contact NIAID CRMS Support. All communication should include site ID and site name.

Maintenance of DAERS Users

Note: CRS Leaders and CRS Coordinators will not be able to request access to a new protocol until the protocol registration for that site is approved. Such approval is granted in the Protocol Registration module.

Also, note that while submitting a registration packet in DPRS, you can use the Person Information screen to indicate who requires Reporter and/or Submitter access to DAERS. This screen is only accessible when completing the

Enrolling and Updating Site Staff in DAERS

Note: Entering information into the Site Enrollment Module constitutes a request submission to the NIAID CRMS Support.

1. The CRS Leader/CRS Coordinator can submit a request to NIAID CRMS Support for addition of authorized staff requiring access to DAERS. They will provide the Names, Contact Information, Roles (Submitter or Reporter) and applicable Protocols for each user of the DAERS application.
2. The CRS Leader/CRS Coordinator can also submit a request to NIAID CRMS Support for modification to Names, Contact Information, Roles (Submitter or Reporter) and/or applicable Protocols for a person associated with their CRS/Organization.
3. The CRS Leader/CRS Coordinator can also submit a request to NIAID CRMS Support to deactivate a person's account in NIAID CRMS.
4. NIAID CRMS Support and DAIDS RSC Safety Office will review and process the submitted request. Once the processing is complete, NIAID CRMS will be updated with the requested changes and an e-mail notification will be sent to the site.

Viewing the Persons at a Site

Before making changes to a Site's enrollment, it is usually necessary to review the persons who are already present in DAIDS for the selected Site. The New Request screen lists all Sites available so that you can view a list of the persons at the Site who are currently present in DAIDS. You have the option to export the list to Microsoft® Excel or you can view the User Information Report for a site which contains detailed site personnel information for DAERS.

To Access the New Request Screen

1. From the DAERS menu bar, click **Person > New Requests**. This will display the New Request screen.



Figure 1: New Request (Select Site) Screen.

To View Persons at the Site

1. If user is associated with more than one site, select a Site ID from the drop-down list else the default site is selected.
2. For users associated with more than one site, click **Search** to narrow results.

The New Request screen lists the persons enrolled at the Site. The red exclamation mark (!) next to a record indicates that changes have been created for that person in draft.

Note: Click on **Clear** to clear selection, return to previous screen and start all over again.

3. *Optional:* To export the list to Microsoft® Excel, click **Export to Excel**. The View Associated Persons report displays.
4. *Optional:* To view a list of all DAERS users associated with the selected site, click **User Information Report**.

The DAERS User Information Report displays in Microsoft Excel. The report displays a list of users associated with the selected Site, the users' contact information, and the protocols to which they have access in DAERS.

Note: You can submit a request to NIAID CRMS Support for multiple changes in your Site personnel. The submitted request will be reviewed and processed by NIAID CRMS Support.

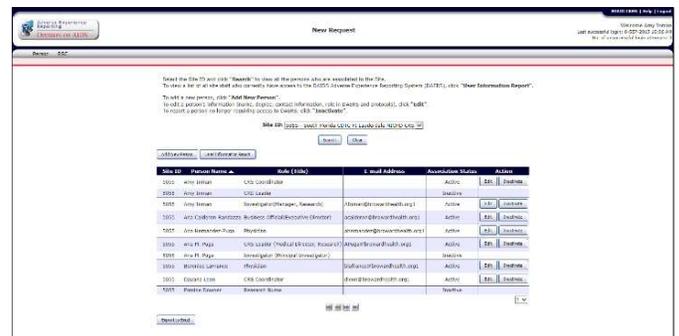


Figure 2: New Request (View Persons at Site) Screen.

Section 6

Site ID	Person Name	Role (Title)	E-mail Address	Association Status
31447	Koleka P. Mlisana	CRS Leader	mlisanak@ukzn.ac.za1	Active
31447	Thola Bennie	CRS Coordinator	bennie@ukzn.ac.za1	Active

Figure 3: View Associated Persons Report.

Site Personnel Information For DAERS					
Site Name: [Site County Health and Human Services CRS]				Site ID: 31447	
Network/Non Network: [H/T]				Site Status: [C/S]	
Person Name	Association Role (Title)	Email	Phone	DAERS Roles - Reporter	DAERS Roles - Submitter
Carl Cole	Investigator	cm@med.unc.edu1	1-919-859-8948	None	None
Cheryl J. Marcus B.S.N., R.N.	Research Clinician	chm@med.unc.edu1	1-919-843-8761	None	None
Clara Zekasly	Research Clinician	clara_zekas@med.unc.edu1	1-919-843-8739	PAVE 100, H7N1/072	None
David Cunn	Research Clinician	dcun@med.unc.edu1	1-919-856-2634	PAVE 100, H7N1/072	None
David Ragan	Research Clinician	drag@med.unc.edu1	1-919-856-2633	PAVE 100, H7N1/072	None
David M. Margolis M.D.	Investigator	dmarg@med.unc.edu1	1-919-856-4388	Enter and review EAE reports for all protocols at a site	H7N1/072, PAVE 100
Deena Pfister	Research Clinician	deena_pfister@med.unc.edu1	1-919-843-8712	PAVE 100, H7N1/072	None
Kelley Carpenter	Research Clinician	kelley_carpenter@med.unc.edu1	1-919-856-8829	PAVE 100, H7N1/072	None
Kristine Pedersen M.D.	CRS Leader	kp@med.unc.edu1	1-919-843-2444	Enter and review EAE reports for all protocols at a site	H7N1/072, PAVE 100, H7N1/072, PAVE 100
Rosalee Brown	Research Clinician	rosalee_brown@med.unc.edu1	1-919-843-8763	PAVE 100, H7N1/072	None
Susan Pedersen	CRS Coordinator	sped@med.unc.edu1	1-919-856-8713	Enter and review EAE reports for all protocols at a site	None
Susan Richter	Research Clinician	susan_richter@med.unc.edu1	1-919-843-8764	PAVE 100, H7N1/072	None

Figure 4: DAERS User Information Report

Section 6

Adding a New Person for a Site

Adding a new person to a site in DAERS is a four-step process:

- Enter the new person’s name and contact information.
- Select the role the person will have in DAERS.
- Select the protocols for the assigned DAERS role.
- Review and submit the request.

To Enter Name and Contact Information

1. From the DAERS menu bar, click **Person > New Requests**.
The New Request screen displays by default.
2. If user is associated with more than one site, select a Site ID from the drop-down list else the default site is selected.
3. For users associated with more than one site, click **Search** to narrow results.
The New Request screen lists the persons enrolled at the Site. The red exclamation mark (!) next to a record indicates that changes have been created for that person in draft.
Note: Click on **Clear** to clear selection, return to previous screen and start all over again.
4. Click **Add New Person**.
The Person Information screen displays.
5. Enter the name, contact information, and role of the person associated with your Site in the fields provided.
6. Click **Save & Next>** to save the information that you have entered and proceed to the Assign DAERS Roles screen or **<Previous** to return to the New Request screen without saving.

Fields prefaced with a red asterisk (*) indicate a required field.

Person Information Fields	
FIELD	DESCRIPTION
Prefix	Select an option from the drop down list in this field.
*First (Given)	Type in the first name of the person in this field.
Middle Name	Type in the middle name of the person in this field.
*Last (Family)	Type in the last (family) name of the person in this field.

Person Information Fields

FIELD	DESCRIPTION
Degree	Click on the list of values icon to select a Degree obtained by the person being added.
Title (position)	Type in the job title or position currently held by the person being added in this field.
*Association Role	Select an Association role with site from the drop down list.
*Phone 1	Type in primary phone number of the person in this field. Enter extension number if any, in the Ext.: field.
Phone 2	Type in secondary phone number of the person in this field. Enter extension number if any, in the Ext.: field.
*E-mail 1	Type in primary E-mail address of the person in this field.
E-mail 2	Type in secondary E-mail address of the person in this field.
Comments	Type in comments in this field.



Figure 5: New Request (View Persons at Site) Screen.

Section 6

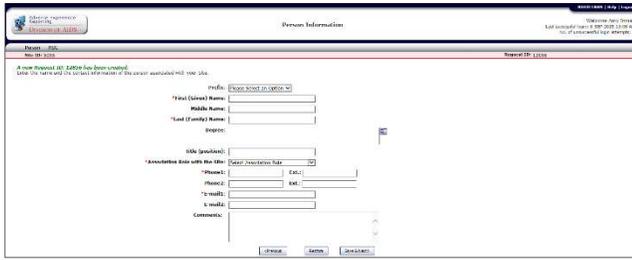


Figure 6: Person Information Screen.

To Select the Person’s DAERS Role

1. From the Assign DAERS Roles screen, select the role the person will have in DAERS.
2. Click **Save & Next>** to save the information that you have entered and proceed to the Assign Protocols screen or **<Previous** to return to the Person Information screen without saving.

Notes:

- If no selection was made for DAERS roles, then review the current request screen will display on click of **Save & Next>**.
- If no roles are selected, the system provides a confirmation pop-up.
- Ensure the selection of Submitter role is based on the site staff listed on the 1572/loR form.
- For the requested role of Submitter, the site is required to submit a complete electronic attestation form to DAIDS RSC safety office.
- CRS Leader/CRS Coordinator have reporter access to all EAE reporting protocols the site is registered to.



Figure 7: Assign DAERS Roles Screen.

To Select the Protocols for the Assigned DAERS Role

1. From the Assign Protocols screen, select the protocols for the assigned DAERS role by clicking > or click the >> button to add all protocols at once. To unselect protocols, click < or click << to remove all protocols at once.
2. Click **Save & Next>** to save the information that you have entered and proceed to the Review Current Request screen or **<Previous** to return to the Assign DAERS Roles screen without saving.



Figure 8: Assign Protocols Screen.

Note: If you cannot find the protocol for the assigned role, this may be due to the following reasons:

- Your site is not registered to the protocol yet.
- The protocol is not EAE reporting.
- DAIDS is not the sponsor of the protocol.

If your site is not registered on the EAE reporting protocol you wish to select, you can go to the Protocol Registration module to submit your site registration packet. While completing the registration packet, you will be able to use the Person Information screen to specify which staff at your site require Reporter and/or Submitter access in DAERS for that protocol. However, this screen is only accessible on certain submission types: Initial, Change in loR, Updated 1572, and Updated loR Form. In these cases, the screen will be a mandatory step.

To Review and Submit the Request

The Review Current Request screen displays all changes requested for the Site that are not yet submitted to NIAID CRMS Support. The user can make further updates to these changes.

1. Choose from the following options:
 - To edit the changes associated with a person in this list, click the name of the person under the **Person Name** column.
 - To remove the changes associated with a person in this list, click **Discard**.
 - To add more changes to this request, click **Add or Edit Another Person**.
 - To view all the changes being requested by the site, click **View Current Request**. The Changes to Site Personnel for DAERS Report displays in PDF.
 - To submit the request to NIAID CRMS Support for processing, click **Submit All**.



Figure 9: Review Current Request Screen.

Section 6

Editing a Person’s Information

The steps for editing the information for a person associated with your Site in DAERS are similar to adding a new person:

- Edit (if necessary) the new person’s name and contact information.
- Edit (if necessary) the role the person will have in DAERS.
- Edit (if necessary) the protocols for the assigned DAERS role.
- Review and submit the request.

To Edit a Person’s Information

1. From the DAERS menu bar, click **Person > New Requests**.
The New Request screen displays by default.
2. If user is associated with more than one site, select a Site ID from the drop-down list else the default site is selected.
3. For users associated with more than one site, click **Search** to narrow results.

The New Request screen lists the persons enrolled at the Site. The red exclamation mark (!) next to a record indicates that changes have been created for that person in draft.

Note: Click on **Clear** to clear selection, return to previous screen and start all over again.

4. Click the **Edit** button next to the person whose information you want to update.
The Person Information screen displays.
5. Update the name, contact information and role of the person associated with your Site in the fields provided.
6. Click **Save & Next>** to save the information that you have updated and proceed to the Assign DAERS Roles screen or **<Previous** to return to the New Request screen without saving.
7. Continue with the procedures described within the “Adding a New Person to a Site” section on page 12 for selecting the person’s DAERS role, selecting the protocols for the assigned DAERS role, and reviewing and submitting the request.

Note: Unselecting a role will revoke the corresponding role in DAERS. Also, unselecting a protocol will revoke the corresponding access for a protocol to which the person currently has access in DAERS.



Figure 10: New Request (View Persons at Site) Screen.

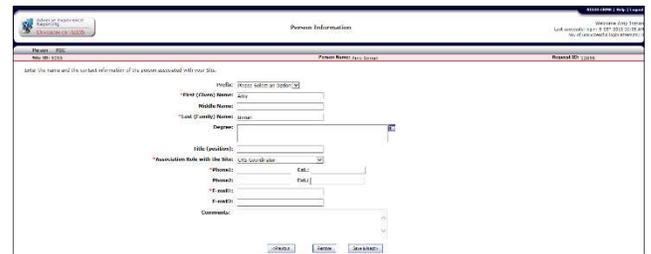


Figure 11: Person Information Screen.



Figure 12: Assign DAERS Roles Screen.



Figure 13: Assign Protocols Screen.



Figure 14: Review Current Request Screen.

Section 6

Inactivating a Person

Inactivating a person will revoke their access from DAERS.

To Inactivate a Person’s DAERS Access

1. From the DAERS menu bar, click **Person > New Requests**.
The New Request screen displays by default.
2. If user is associated with more than one site, select a Site ID from the drop-down list else the default site is selected.
3. For users associated with more than one site, click **Search** to narrow results.

The New Request screen lists the persons enrolled at the Site. The red exclamation mark (!) next to a record indicates that changes have been created for that person in draft.

Note: Click on **Clear** to clear selection, return to previous screen and start all over again.

4. Click the **Inactivate** button next to the person for whom you want to request removal of access to DAERS or removal of access to an organization/site.
The Inactivate Person screen displays.
5. Provide a reason for inactivation in the field provided.
6. Click **Save**.

The Review Current Request Screen displays.

7. Choose from the following options:
 - To edit the reason for inactivation, click the name of the person under the **“Person Name”** column.
 - To remove the line item, click **Discard**.
 - To add more changes to this request, click **Add or Edit Another Person**.
 - To view all the changes being requested by the site, click **View Current Request**. The **Changes to Site Personnel for DAERS** is displayed in PDF.
 - To submit the request to NIAID CRMS Support for processing, click **Submit All**.



Figure 16: Inactivate a Person Screen.



Figure 17: Review Current Request Screen.



Figure 15: New Request (View Persons at Site) Screen.

Section 6

Viewing Requests

The View Requests screen lists all the requests created by your sites. This screen will also display any requests submitted through the DAIDS Protocol Registration System (DPRS).

To Access View Requests

1. From the DAERS menu bar, click **Person > View Requests** to display the View Requests screen.

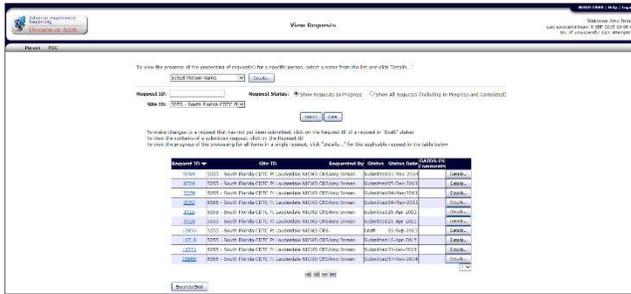


Figure 18: View Requests Screen.

Each request has a unique ID, along with a Site ID, name of requestor, status, status date, and comments. Possible values in the Status column include the following:

- **Draft** — Request for changes for the site is yet to be submitted to NIAID CRMS Support.
- **Submitted** — Request for changes for the site is submitted to NIAID CRMS Support
- **In Progress** — NIAID CRMS Support is processing the request submitted by the site.
- **Completed** — NIAID CRMS Support has completed processing of the Request submitted by the site.
- ***Completed** — NIAID CRMS Support has completed processing of the Request submitted by the site with some outstanding issues.

Furthermore, the DAIDS-ES Comments field displays comments entered by the NIAID CRMS Support team for that Request ID.

2. *Optional:* Click **Export to Excel** to view the details in an Excel spreadsheet.

To Search on a Request

Users can filter requests based on any known information. Search options include:

- **Request ID** — Type in the Request number and click Search.
- **Site ID** — Click on the drop-down menu, select the desired Site, and click Search.
- **Request Status** — Choose between the available radio buttons and click Search.

To View Details of a Request

1. Click the Request ID of the desired request. (If you click on a request that is in the Draft status, you can make changes to it.
2. Review the request details.
3. An e-mail notification will be sent to the CRS Coordinator/ CRS Leader when a request is in the Submitted, Completed, or *Completed status.

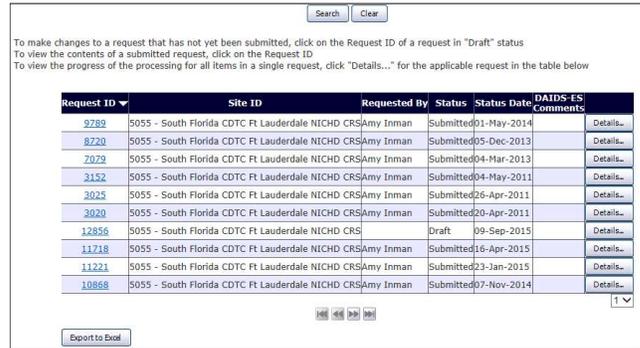


Figure 19: Request ID Numbers.

To Generate the Person Information Report

An alternative to clicking through various request is to use the Person Information Report. This functionality allows for the user to generate a report that presents each line item for the desired user and their associated role requested, associated protocol, and associated site.

1. From the View Requests screen, click on the **Person Name** drop-down and select the desired user.
2. Select **Details** and save the Person Information Report.
3. Open the Excel file to view the report. Columns include Request ID, Request Date, Request Item Completed, and Requested Role.

A	B	C	D	E	F	G	H	I	J	K	L	M	N
Site ID	Request ID	Request Date	Request Status	Request Item Completed	Person Name	Request Type	Change Type	Requested Role	Protocol ID	Amendment Form?	On 1/2/3?	Trained?	DAIDS-ES Support Comments
5055	9985	8-Apr-14	Submitted	Yes	Michael Rekins	AAI	User Contact Info	N/A	N/A	No	No	No	
5055	9985	8-Apr-14	Submitted	No	Michael Rekins	AAI	DAERS Access	Submitter	P1133	Invalid	No	No	
5055	10146	14-Aug-14	Submitted	No	Michael Rekins	AAI	DAERS Access	Submitter	P1056	No	Yes	No	Incomplete attestation

Figure 20: Person Information Report Output.

To View All the Changes Submitted by the Site

1. From the View Requests screen, click the Request ID for an entered request. This will open a PDF report titled “Changes to Site Personnel for DAERS.” The middle columns of the report display the current value in DAIDS (“Currently in DAIDS-ES”) and the changed value requested by the Site (“Requested Information”).

Section 6

Changes to Site Personnel for DAERS			
Request ID: 2007		Request Status: Draft	
Request Date: 8/24/2009 8:29:07 PM (GMT-05:00) Eastern Time (US & Canada)		Requested By: Stacy Carroll	
Site Name: Wake County Health and Human Services CRS		Site ID: 30076	
Site Address: 10 Sunnybrook Road,Raleigh, NC, 27630-4049,United States			
Update Person: Cheryl J. Marcus			
Currently in DAIDS ES		Requested Information	Request Type
Prefix:			
First Name: Cheryl	Cheryl		No Change
Middle Name: J.	J.		No Change
Last Name: Marcus	Marcus		No Change
Role: Research Clinician	Research Clinician		No Change
Title:			
Degree: Bachelor of Science in Nursing Registered Nurse	Bachelor of Science in Nursing Registered Nurse		No Change No Change
Phone 1: 1-919-843-8761	1-919-843-8761		No Change
Phone 2:			
E-mail 1: cjm@med.unc.edu	cjm@med.unc.edu		No Change
E-mail 2:			
List of Protocol(s) on which EAEs can be Reported:	A5001		Add
List of Protocol(s) on which EAEs can be Submitted:			
Overall Comments:			
Report Date: 8/24/2009 9:00:25 PM (GMT-05:00) Eastern Time (US & Canada) Page 1 of 1			

Figure 21: Example of a “Changes to Site Personnel for DAERS” PDF.

The PDF also includes a column for displaying the following request types:

- Add: Request to add a new value
- No Change: Keep the existing value
- Update: Request to change to an existing value
- Delete: Request to remove an existing value

Figure 22 below displays an example of how the PDF will look when a request is to “Inactivate” a site staff.

Changes to Site Personnel for DAERS			
Request ID: 2004		Request Status: Draft	
Request Date: 3/31/2010 4:40:59 PM (GMT-05:00) Eastern Time (US & Canada)		Requested By: Stacy Carroll	
Site Name: Massachusetts General Hospital ACTG CRS		Site ID: 101	
Site Address: 55 Fruit Street,ACTG, Cox 626 Boston, MA, 02114,United States			
Inactivate Person(s) - Name		Reason for Inactivation	
Eric S. Rosenberg		No longer at the site	
Report Date: 31-Mar-2010 2:49:58 PM (GMT-05:00) Eastern Time (US & Canada) Page 1 of 1			

Figure 22: Example of a “Changes to Site Personnel for DAERS” PDF showing a deletion.