



# DAIDS RSC Spotlight



National Institute of  
Allergy and  
Infectious Diseases



Regulatory  
Support  
Center

## Do you know how to obtain access to the DAIDS Adverse Experience Reporting System (DAERS)?

All clinical research sites (CRSs) must have access to DAERS before a study begins to report expedited adverse events (EAEs) to DAIDS. Each CRS must have *at least two (2) staff* who, among themselves, have a combination of DAERS “reporter” and “submitter” roles.

A “reporter” is any CRS staff whom the Investigator of Record (IoR) has authorized to initiate EAE reports using the DAERS system. A “submitter” is any study physician who will submit and electronically sign EAE reports in DAERS and who is listed on the FDA 1572 or the DAIDS IoR Agreement forms.

What are the steps that should be taken by the CRS to obtain access to DAERS?

1. The CRS Leader or CRS Coordinator requests access for CRS staff through the Site Enrollment Module (SEM) in DAERS. The requestor must provide the name, contact information and DAERS role (i.e., “reporter”, “submitter”) for each CRS staff. Visit the [DAIDS RSC Training page](#) for more information.
2. Selected staff complete the on-line DAERS training on the [DAIDS Learning Portal](#). If you do not have an account, visit the following link to request an account: [DAIDS Learning Portal User Registration page](#).
3. Selected staff send the certificate documenting DAERS training completion to NIAIDS CRMS Support at [CRMSSupport@niaid.nih.gov](mailto:CRMSSupport@niaid.nih.gov).
4. Submitters also must mail a **signed, original, hard copy** study physician Attestation and Agreement for Electronic Signatures form to the DAIDS RSC Safety Office. The form may be accessed by using the following link: [Physician Electronic Signature Attestation form](#).

Who should be contacted for assistance?

*For DAERS Access and Training:*

**NIAID CRMS Support**

Phone: +1 (240) 778-2517

Email: [CRMSSupport@niaid.nih.gov](mailto:CRMSSupport@niaid.nih.gov)

*For Attestation Forms and EAE Reporting:*

**DAIDS RSC Safety Office**

Phone: +1 (800) 537-9979 (US toll free) or

+1 (301) 897-1709

Email: [DAIDSRSCSafetyOffice@tech-res.com](mailto:DAIDSRSCSafetyOffice@tech-res.com)

Fax: +1 (800) 275-7619 (US toll free) or

+1 (301) 897-1710

Mail: DAIDS RSC Safety Office

6500 Rock Spring Drive, Suite 650

Bethesda, MD 20817 (USA)