



DAERS INSTRUCTIONS FOR SITES



DEFINITIONS

DAERS: An internet-based system for DAIDS Clinical Research Sites (CRSs) to report Expedited Adverse Experiences (EAEs) to DAIDS/RSC. DAERS will ensure that reports are submitted in a timely fashion as well as create a centralized location for accessing EAE information for reporting purposes.

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

Reporter: Any CRS staff member who will initiate EAE reports via the DAERS system. This would include any personnel, such as a nurse or data manager, whom the Investigator of Record (IoR) has authorized to initiate an EAE report. The Reporter is not required to provide an attestation form.

Submitter: Any study physician who will ultimately submit and electronically sign EAE reports via the DAERS system. Per DAIDS policy, all submitters must be study physicians listed on either the Form FDA 1572 or the DAIDS Investigator of Record Agreement (IoRA) which have been submitted to the DAIDS Protocol Registration Office at the Regulatory Support Center (RSC).

INFORMATION TO BE PROVIDED BY SITES

DAERS Site Enrollment Module:

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 DAIDS. They must provide the User's name, contact information (e-mail, phone, fax) and the DAERS role by protocol. Below are brief instructions on how to use the Site Enrollment Module. You may access more detailed instructions in the DAERS Reference Guide by clicking on the following link:

<http://RSC.tech-res.com/safetyandpharmacovigilance/>

1. CRS Leader or CRS Coordinator must contact DAIDS-ES support at DAIDS-ESSupport@niaid.nih.gov for access to the DAERS Site Enrollment Module.
2. Log in to DAERS Site Enrollment Module using the username and password you have been provided. The login page can be accessed by clicking on the link <https://daidses.niaid.nih.gov/Phoenix> or copying and pasting the link into your browser.
3. Click the **Person** menu on the horizontal navigation bar and select "**New Request**".
4. From the table listing all site staff, click on the "**Edit**" button for the selected site staff that would require access to the application to report or submit EAEs.
5. On the **Review Current Request** screen, you may click on the "**Add/Edit Another Person**" button to continue adding site staff for access to this protocol.
6. On the **Review Current Request** screen, click on the "**Submit All**" button to submit the request to DAIDS-ES Support.

Electronic Signature Attestation Form (for compliance with 21CFR Part 11):

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. You may access the form by clicking on <http://RSC.tech-res.com/safetyandpharmacovigilance/>

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.

PLEASE PROVIDE BOTH THE REQUEST FOR ACCESS AND THE ATTESTATION FORM(S) (ONE FOR EACH SUBMITTER) AT THE SAME TIME.

WHAT TO DO WITH THE DOCUMENTS

- MAIL THE ORIGINAL SIGNED ATTESTATION FORM(S) TO:
DAIDS Safety Office
6500 Rock Spring Drive, Suite 650
Bethesda, MD 20817
- E-mail the scan of the signed attestation form(s) to: RSCSafetyOffice@tech-res.com



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CONTACT INFORMATION

DAIDS-ES Support:

- **Phone:** (1) (866) 337-1605 (toll free USA), or (1) (240) 499-2239 (Outside USA)
- **Email:** DAIDS-ESSupport@niaid.nih.gov
- **Fax:** (1) (866) 337-1606 (toll free USA), or (1) (301) 948-2242 (Outside USA)

RSC SAFETY OFFICE:

- **Phone:** 1 (800) 537-9979 (US only) or +1 (301) 897-1709
- **Email:** RSCSafetyOffice@tech-res.com
- **Fax:** 1 (800) 275-7619 (US only) or +1 (301) 897-1710
- **Mail:** DAIDS Safety Office, 6500 Rock Spring Drive, Suite 650, Bethesda, MD 20817