DAIDS Regulatory Support Center (RSC)

The DAIDS RSC is a DAIDS contractor responsible for providing day-to-day support to DAIDS and its collaborators for all regulatory activities using the NIAID Clinical Research Management System (NIAID CRMS) at https://ncrms.niaid.nih.gov.

The DAIDS RSC works with Clinical Research Sites (CRSs) regularly to:

- Maintain records of site personnel in the NIAID CRMS Master Contact module
- Register to protocols using the NIAID CRMS Protocol Registration System (DPRS)
- Report adverse events using the NIAID CRMS Adverse Event Reporting System (DAERS)

How does the DAIDS RSC interface with sites?

Activity Type	DAIDS RSC Office	DAIDS RSC Office Role	Site Role	Applicable NIAID CRMS Module
Site Personnel	**Clinical Study Information Office (CSIO)** CSIO@niaid.nih.gov 301-897-7100	Receives and abstracts protocol and/or contact information into the NIAID CRMS for use by DAIDS and its collaborators in support of DAIDS-supported clinical trials	Submits and maintains site personnel information	Site Hub DPRS DAERS
Protocol Registration	**Protocol Registration Office (PRO)** Protocol@tech-res.com 301-897-1707	Receives and processes protocol registration information from sites such as: • Site informed consent forms • IRB/EC approval letters • Form FDA 1572/DAIDS IoR Form • Investigator of Record CVs • Medical license (ML) or equivalent	Submits protocol registration materials via the DPRS in NIAID CRMS	DPRS
Adverse Event Reporting	**Safety Office** DAIDSRSCSafetyOffice@tech-res.com 301-897-1709 or 1-800-537-9979	Receives and processes serious adverse events reported by sites participating in DAIDS-supported studies Processes the events for review by the DAIDS Medical Officer Prepares the reports for transmittal to the appropriate regulatory agency (e.g. the US Food and Drug Administration [FDA]), if required	Submits adverse events via the DAERS in NIAID CRMS	DAERS

CRMS Modules can be accessed at https://ncrms.niaid.nih.gov once individual access has been obtained.

Visit the DAIDS RSC Website (https://rsc.niaid.nih.gov/) for important information about these and other regulatory processes, quick reference guides, web tours, relevant DAIDS procedural manuals, tools, and other useful links to support regulatory activities at your sites.

In addition, please refer to the DAIDS SCORE Manual sections on Introduction to DAIDS Systems, Protocol Registration, and Safety Reporting, for more information on the RSC and regulatory topics. https://www.niaid.nih.gov/research/daids-score-manual

DAIDS Protocol Registration Office (PRO)

This section provides general guidance for clinical research sites (CRSs) regarding protocol registration requirements related to the FY 2021 CTU Grant awards.
Below are instructions for each CRS scenario. Links to the protocol registration policy, manual, and training are located at the end of this section.

Known to DAIDS
After receiving the DAIDS' transition letter, an existing CRS should review their current Form FDA 1572s and/or DAIDS IoR Forms to determine if any changes (i.e., the addition or removal of site staff, the addition or removal of a location where research will be conducted, etc.) are required. **If changes are required, a CRS must submit an updated Form FDA 1572 and/or DAIDS IoR Forms to the DAIDS PRO within 30 days of receipt of the DAIDS' transition letter.**

New to DAIDS
Once the site activation requirements have been met and the site has received the OCSO site activation email, a new CRS can begin making submissions to the DAIDS Protocol Registration Office (PRO) via DPRS. Upon completion of the DPRS training, site personnel will receive a username and password allowing them to make submissions to the DAIDS PRO. A link to the DPRS training is at the end of this section.

Phase-out CRS
CRSs in phase-out status can remain registered to any ongoing studies where participants are being treated or followed. However, CRSs in phase out status will not be able to register to any new studies without the approval of OCSO. Upon completion of a study, a CRS must submit deregistration materials to the DAIDS PRO and complete the DAIDS' deregistration process. Additional information regarding the DAIDS' deregistration process can be found in the DAIDS Protocol Registration manual in the link below.

Useful links for protocol registration materials and trainings:
- DAIDS Protocol Registration Manual
- DAIDS Protocol Registration Policy
- Form FDA 1572 and DAIDS IoR Form
- DAIDS Protocol Registration Training and Resources

Should you have any questions or need more information, please contacts the DAIDS Protocol Registration Team (PRT) at NIAIDOPCROPRTeam@niaid.nih.gov

Click here to visit the OPCRO training page on the DAIDS Learning Portal and see more information and related trainings for the Safety, Protocol Registration, and Protection of Participant groups.