

Dear Site Leaders, Site Coordinators and Investigators of Record,

On September 28, 2009, the new DAIDS Protocol Registration System (DPRS) will be launched. This is the newest module of the DAIDS Enterprise System that will allow your site to easily submit documents to the DAIDS Protocol Registration Office and view the status of the submission directly in the system. The DPRS will replace the current processes for submission of all Protocol Registration documents.

To facilitate this process, DAIDS is asking that all active and approved DAIDS sites begin the enrollment process to the DPRS system by December 2009. The DPRS enrollment website is available to begin the enrollment process now (<http://rcc.tech-res.com/prs/default.html>). Training will be done on a first come first serve basis and will continue over the next several months. After May 1, 2010, the DPRS will be the only means of submitting materials to the DAIDS PRO.

There are 3 simple steps for enrollment into the DPRS:

1. Enroll in the DPRS by providing contact information via the DPRS enrollment website: <http://rcc.tech-res.com/prs/default.html>
Contact information is required so that access to the DPRS can be given.
2. Complete the DPRS training by either:
Attending a web-teleconference (sign-up on the DPRS enrollment website),
or
Training with a colleague who has completed the DPRS web-teleconference training (documentation must be provided to DAIDS)
3. Receive a user name and password from DAIDS ES Support within approximately 2 weeks of completing training.

A short description of the DPRS and roll out process are attached.

DAIDS is very excited about the new DPRS believes that this will be a useful tool not only for DAIDS but for sites, networks and collaborators.

UPDATE:

We would like to make you aware of a few changes that will be apparent beginning September 28, 2009 and to notify you of some benefits of using the system.

Changes:

1. Receipts will be generated from the DPRS system.
2. Receipt recipients will include the Investigator of Record, the CRS leader and the CRS coordinator. In addition, for submissions received via the DPRS, any contact listed in the additional contact section will also be included.
3. If the appropriate Network Operations center has not designated your site in the system as eligible for restricted protocols, submissions will not be accepted. Once the Network Operations center has designated your site as eligible, you can then submit a registration package for the specified protocol.

Advantages:

4. Ability to see real time updates to the submission status of any submitted material.

5. Report ability: While the ability to generate reports will not be immediately available, you will be able to generate site status reports for sites and studies for which you are associated. Additional information will be provided when available.

If you have any questions about the DPRS please feel free to contact Melissa Kin at mkin@niaid.nih.gov and John Hojnowski at jhojnowski@tech-res.com .

Thank you for your support of this important endeavor.

What is the DAIDS Protocol Registration System (DPRS)?

The DAIDS Protocol Registration System (DPRS) is an internet-based system for DAIDS Clinical Research Sites (CRS) to submit protocol registration documents to the DAIDS Protocol Registration Office (PRO). The DPRS will ensure a more efficient and timely registration process as well as create a centralized location for accessing protocol registration information.

The DPRS is the official source of information for all protocol registrations performed by the DAIDS PRO.

Features of the DPRS

- Electronic Submission and tracking of registration materials
- Real-time access to data and documents
- Supports submission of all types of registration materials
 - Initial & Amendment registrations, Letter of Amendment (LOA) submissions & IRB/EC Continuing review, Revised site ICs and De-registrations
 - New/Change of Investigator of Record (IoR), FDA 1572/IoR Agreements, New / Updated CVs
 - Required Corrections, Disapproval reversals, Requested documents/information
- Supports all types of sites and studies
 - Network / Non-Network studies, Sub-studies
 - Domestic and Foreign sites
- Tracks findings, review outcomes and follow-up action required by sites to address noted deficiencies
- View registration reports

ROLL OUT PLAN FOR THE DAIDS PROTOCOL REGISTRATION SYSTEM

- Sign-ups for training will be done on a first come first serve basis. All sites must be trained on and using the DPRS system by May 1, 2010. It is expected that the majority of the sites will be using in the system by January 2010.
- Sites will be able to enroll as a user in the DPRS and sign-up for training using a web site, similar to what is done for DAERS and DAIDS Regional Training Events.
<http://rcc.tech-res.com/prs/default.html>
- Training sessions will start in October 2009, with 1 training session a week during this month. Starting in November 2009, the number of sessions will be increased with various times to account for the different schedules, time zones and locations of all the sites.
- Training will be given via web-teleconference (presentation via the web with call in information). As a part of the training, sites will be given a Power Point Presentation and a Quick Reference Guide. In addition, User Names and Passwords will be distributed to training participants within 2 weeks of completing the training.
- At least one person from each site must attend training to be given access to the DPRS. If additional people who did not attend the DAIDS web-teleconference training request access to submit registration documents, the individual that attended the DAIDS web-teleconference training will have to verify that person(s) requesting access have been trained on the DPRS by sending an email to the DPRS Training Team (DPRS_Team@tech-res.com). Internal training at sites is highly encouraged.
- As soon as one person at a site has been trained on the DPRS and has received a user name and password, DAIDS requires that the site make all protocol registration submissions via the DPRS.
- To facilitate site staff training in the future, an eLearning module will be available to use in May 2010.

ENROLLMENT INSTRUCTIONS

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