PROTOCOL REGISTRATION TIMELINES

The DAIDS Protocol Registration Office (DAIDS PRO) follows specific timelines when processing materials submitted to the DAIDS PRO. Below are the timelines for protocol registration. These timelines reflect the maximum number of days the DAIDS PRO has to process, review, and issue a decision (e.g. Registration Notification, Disapproval Notification, Deregistration Notification, Change of IoR Approval Notification, etc.) to a clinical research site (CRS) regarding protocol registration materials submitted.

1) Initial Protocol Registration   10 business days

2) Full Version Amendment Protocol Registration   7 business days*

3) LoA Registration   7 business days*

4) Administrative Registration   10 business days

5) Deregistration   10 business days

6) Change of Investigator of Record   10 business days

7) Disapproval Reversal Request   4 business days

* This timeline may increase to 10 business days if DAIDS PRO review and approval is required for a full version protocol amendment or LoA as determined by DAIDS. This change in procedure will be noted in the protocol document.

U.S. government holidays and weekends are not counted business days and are therefore not reflected in the timelines. Materials received on these days will be considered received on the following business day.

The following types of submissions will be processed by the DAIDS PRO within 15 business days.

1) Continuing/Annual Review

2) Site Initiated Revisions to Site-Specific Informed Consent Forms

3) Updated Form FDA 1572

4) Updated DAIDS IoR Form

CRSs will *ONLY* receive a Confirmation of Submission notice that indicates materials have been successfully submitted to the DAIDS PRO. CRSs will *NOT* receive any additional notifications from the DAIDS PRO unless there is a problem with the documentation submitted. If problems are noted, the DAIDS PRO will follow-up via e-mail to inform the CRS about the deficiencies and to request corrected materials.

For real time information on the status of a registration submission(s), CRSs can check the DAIDS Protocol Registration System (DPRS).