Dear All,

Since the implementation of the DAIDS protocol registration manual and policy in November 2010, several questions have been raised regarding registration requirements and procedures for sub-studies. With the implementation of the electronic DAIDS Protocol Registration System (DPRS), and the requirement for sites to submit all registration materials through the DPRS, the DAIDS checklist is no longer a required document. Thus, it is extremely important for sites to inform the Protocol Registration Office (PRO) when submitting materials through the DPRS, regarding what and why materials are being submitted. At this time, the way sites inform the PRO that they will be participating in a sub-study and need to register to the sub-study in addition to the main study is by creating a new submission record for the sub-study in the DPRS. Thus, it is VERY important for sites to register to all sub-studies that have a protocol number and/or DAIDS protocol id number regardless of whether the sub-study is considered embedded or stand alone.

An example that illustrates the need for separate sub-study registration is for protocol A5001 (ALLRT). As part of the Version 4.0 amendment, sub-study A5276s, Version 1.0 was added to the A5001 protocol. Although the sub-study (A5276s) is embedded in the main protocol, the sub-study has its own protocol number. Thus, a separate registration record needs to be created in DPRS for the amendment registration to A5001, Version 4.0 and the initial registration to sub-study A5276s, Version 1.0. A registration record in the DPRS triggers several things: 1. Informs the Data Management Centers (DMCs) regarding the registration status for main and any sub-studies at each site, 2. Enables accrual information to be exchanged between the DMCs and DAIDS, 3. Allows for safety reporting for the main and sub-study (if ever applicable) in DAERS, and 4. Informs monitors regarding all main and sub-studies that a site is participating in.

IMPORTANT NOTE - The requirement to submit a separate registration record for main and sub-studies through the DPRS is ONLY related to protocol registration records and does NOT impact or mandate how sites submit protocols (main and sub-studies) to the IRB/EC. If a site prepares one packet for IRB/EC review that includes the main and sub-study, this one packet can be uploaded (or copied) under each registration record (main and sub-study) in the DPRS.

In the next update to the DAIDS ES, planned for November 2011, DPRS will be enhanced to accommodate easier sub-studies registrations. Also, the next version of the protocol registration policy and manual will provide appropriate instructions for sub-study registrations.

If you need additional information, please contact the DAIDS Protocol Registration Team (PRT) at NIAIDOPCROPRTEAM@niaid.nih.gov.

Thank you,
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