

Guidance regarding DAIDS Deregistration Process

The purpose of this document is to provide clarification regarding the DAIDS deregistration process and to inform sites of responsibilities that exist if the protocol remains open with their Institutional Review Board (IRB)/Ethics Committee (EC).

Completion of the DAIDS deregistration process indicates that a site's participation in a study is completed but does not reflect the completion of a multi-center study at all clinical research sites. Data clean-up activities and queries may be ongoing even after a site deregisters from a protocol. Deregistration is required once a study is completed, meaning that all participants at all sites are off study and the primary analysis has been completed, for any study for which a site was registered.

Study closure/termination with a site's IRB/EC is not required for a CRS to deregister with DAIDS. If a site plans to complete the DAIDS deregistration process for a study but will not be closing/terminating the study at their IRB/EC, the site should consult their IRB/EC to confirm any requirements and/or standard operating procedures that must be met prior to deregistering with DAIDS. A site's IRB/EC may require the continued submission of safety information and/or other data (e.g., from data queries) for the study. In this case, deregistration with DAIDS cannot be done until the study has been completed and closed out with the IRB/EC.

Upon completion of the DAIDS deregistration process, a site will not receive safety information (e.g. safety reports, safety memos, investigator's brochures, etc.) from the Regulatory Support Center (RSC) Safety Information Center. Although deregistered sites will not receive safety information as it is distributed from the RSC, all active sites will continue receiving the monthly comprehensive report (MCR) that lists all safety information distributed. Sites can utilize the MCR to identify and request any safety information that was distributed pertinent to their protocols still open with the IRB/EC.

**Summary of site responsibilities once deregistration with the
DAIDS Protocol Registration Office (PRO) has occurred**

Scenario	Study Closed with the IRB/EC	Study Still Open with the IRB/EC
If there are any updates to Forms FDA Form 1572 or DAIDS IoR Forms must the updated forms be submitted to the DAIDS PRO?	No	No
If there is a protocol amendment/LoA, must the site submit the amendment/LoA to the IRB/EC?	No	<i>Yes – Sites must continue to follow their IRB/EC requirements for submission of protocol changes even if all participants have completed the study. If sites will be implementing any new procedures outlined in the protocol amendment the site must re-register with the DAIDS PRO.</i>
If there is a protocol amendment/LoA that is approved by the IRB/EC must the site submit an amendment/LoA registration packet to the DAIDS PRO after IRB/EC approval?	No	No
Are sites still responsible for submitting new safety information (e.g., DAIDS safety reports related to that particular protocol, updated IBs and package inserts) to the IRB/EC?	<i>No- however, if new safety information emerges (e.g., a safety alert) sites should follow their IRB/EC procedures for submitting the new safety information to the IRB/EC. In addition, the IRB/EC can provide guidance to the site regarding how former participants are to be informed about the new safety information.</i>	<i>Yes – Since sites are removed from the automatic DAIDS safety distribution after deregistration, sites will be responsible for verifying and requesting any new safety information that was distributed by the RSC Safety Information Center to be able to submit to the IRB/EC.</i>
Is continuing review required?	No	<i>Yes – the documentation of IRB/EC continuing review approval must be kept in the regulatory files at the site. Documentation of IRB/EC previous continuing review approval, study close out with the IRB/EC, and other essential documents must be stored in accordance with Policy DWD-POL-CL-006.01, DAIDS Policy on Storage and Retention of Clinical Research Records.</i>

Scenario	Study Closed with the IRB/EC	Study Still Open with the IRB/EC
Must documentation of continuing review be submitted to the DAIDS PRO?	No	No- <i>the documentation of IRB/EC continuing review approval must be kept in the regulatory files at the site. Documentation of IRB/EC previous continuing review approval, study close out with the IRB/EC, and other essential documents must be stored in accordance with Policy DWD-POL-CL-006.01, DAIDS Policy on Storage and Retention of Clinical Research Records.</i>
Can sites respond to and address data queries even though they have deregistered from the protocol with DAIDS?	Yes	Yes