

SUMMARY OF CHANGES TO THE DAIDS PROTOCOL REGISTRATION MANUAL DATED MARCH 2010

1. The Introduction has been updated.
2. Definitions have been updated to be consistent with DAIDS/NIAID definitions.
3. The DAIDS Protocol Registration Office (DAIDS PRO) contact information has been updated to reflect new information on how and where to submit registration documents.
4. The Form FDA 1572/DAIDS Investigator of Record (IoR) Form sections have been updated to reflect:
 - The IoR Agreement has been renamed the DAIDS IoR Form and all sections have been renumbered for consistency with the Form FDA 1572.
 - Original forms should not be submitted to the DAIDS PRO.
 - An updated Form FDA 1572/DAIDS IoR Form must be submitted when there is any major change in information.
 - Updated guidance has been included for when a CRS has more than one IoR sharing responsibilities for a clinical trial.
 - Updated guidance has been provided regarding clinical laboratories that should be listed on the Form FDA 1572/DAIDS IoR Form.
 - Updated guidance has been provided regarding what Institutional Review Boards (IRBs)/Ethics Committees (ECs)/ other Regulatory Entities (REs) should be listed on the Form FDA 1572/DAIDS IoR Form.
 - Updated guidance has been provided regarding who should be listed as a sub-IoR on the Form FDA 1572/DAIDS IoR Form. This includes updated requirements for submission of SAEs/EAEs to DAIDS and financial disclosure forms.
5. The Curriculum Vitae (CV) section has been update to reflect:
 - The new requirement that IoRs must sign and date their CV.
6. The new requirement that IoRs must submit an updated, signed and dated CV when there is any major change in information OR at a minimum of every 2 years.
7. The IRB/EC and Other RE section has been updated to reflect:
 - The addition of a new section on RE approvals.
 - The requirement to submit all appropriate IRB/EC/RE documentation in addition to the final approval letter.
8. The Site-Specific Informed Consent Forms (ICFs) section has been updated to reflect:
 - The change in acceptable documentation explaining deletions/changes to site-specific ICFs.
 - Updated guidance on types of ICFs and protocol registration requirements.
9. The Translation requirements have been updated. This includes a new Translation Confirmation document.
10. The Amendment Registration section has been updated to reflect:
 - Removal of the ninety (90) calendar day requirement to submit IRB/EC approved amendment registration materials to the DAIDS PRO.
 - The new requirement that sites must submit full version protocol amendments and letters of amendment (LoAs) to the local IRB/EC within 45 calendar days for U.S. sites/75 calendar days for non-U.S. sites of the date the amendment/LoA was approved by DAIDS and distributed to sites.

- The new requirement that once a site receives final approval from their IRB/EC/RE for a full version protocol amendment or LoA it must be implemented immediately. A final Registration Notification is no longer required from the DAIDS PRO prior to implementing a full version protocol amendment.
 - The new requirement that sites must protocol register to all LoAs.
 - The new requirement that sites must submit full version protocol amendment and LoA registration documents to the DAIDS PRO within 14 calendar days after receiving the final written IRB/EC approval for the full version protocol amendment or LoA.
 - The new requirement that sites must submit documentation to the DAIDS PRO regarding the date that the full version protocol amendment or LoA was submitted to the local IRB/EC.
11. A section was added on Requested Materials, Disapprovals, and Registrations with Required Corrections.
 12. A new section was added regarding Administrative Registrations.
 13. The Change of IoR section was updated to reflect the new requirement that sites must officially change the IoR for a protocol(s) within 30 calendar days of the date the CRS became aware that the current IoR will no longer serve as the IoR for the protocol.
 14. The Continuing/Annual Review, Site Initiated Revisions to Site ICFs and the Deregistration sections were updated to provide additional guidance on submission requirements.
 15. Instructions on how to submit protocol registration submissions through the DAIDS Protocol Registration System (DPRS) was included in Appendix A.