DAIDS RSC Regulatory Support Center

Quick Reference Card

Protocol Registration At A Glance

Below is a list of the required documents for each specified registration submission.

1. INITIAL PROTOCOL REGISTRATION

A complete initial protocol registration submission must include:

- ❑ Copy of the Form FDA 1572 signed and dated by the Investigator of Record (IoR) (for studies conducted under an IND) or Copy of the DAIDS IoR Form, signed and dated by the IoR (for non-IND studies)
- ❑ IoR Curriculum Vitae (CV), signed and dated and other required documentation
- ❑ Copy of all IRB/EC and other applicable Regulatory Entity (RE) approval letter(s) and any other appropriate documentation from the IRB/EC and other applicable REs with information linking the approval to the current DAIDS approved version of a protocol
- ❑ Documentation of Pediatric risk/benefit category per 45 CFR 46 & 21 CFR 50 – if applicable
- ❑ Institutional Biosafety Committee (IBC) approval – if applicable
- ❑ Copy of all IRB/EC other applicable RE approved site-specific Informed Consent Forms (ICFs) - all languages including English translations, if applicable
- ❑ Translation Confirmation Document – if applicable

2. FULL VERSION PROTOCOL AMENDMENT REGISTRATION

A complete full version protocol amendment registration submission must include:

- ❑ Copy of all IRB/EC and other applicable RE approval letter(s) and any other appropriate documentation from the IRB/EC and other applicable REs with information linking the approval to the current DAIDS approved version of a protocol
- ❑ Documentation of the date the amended protocol and any revised site-specific ICF(s) were submitted to the local IRB/EC
- ❑ Documentation of Pediatric risk/benefit category per 45 CFR 46 & 21 CFR 50 – if applicable
- ❑ Institutional Biosafety Committee (IBC) approval – if applicable
- ❑ Copy of all IRB/EC other applicable RE approved revised site-specific ICFs - all languages including English translations, if applicable
- ❑ Translation Confirmation Document – if applicable

3. LETTER OF AMENDMENT (LoA) REGISTRATION

A complete LoA registration submission must include:

- ❑ Copy of all IRB/EC and other applicable RE approval letter(s) and any other appropriate documentation from the IRB/EC and other applicable REs with information linking the approval to the current DAIDS approved version of the LoA
- ❑ Documentation of the date the LoA and any revised site-specific ICF(s) were submitted to the local IRB/EC
- ❑ Institutional Biosafety Committee (IBC) approval – if applicable
- ❑ Copy of all IRB/EC other applicable RE approved revised site-specific ICFs - all languages including English translations, if applicable
- ❑ Translation Confirmation Document – if applicable

4. ADMINISTRATIVE REGISTRATION

A complete administrative registration submission must include:

- ❑ Copy of all IRB/EC and other applicable RE approval letter(s) and any other appropriate documentation from the IRB/EC and other applicable REs with information linking the approval to the current DAIDS approved version of the protocol including the IRB/EC decision regarding protocol review and approval
- ❑ Copy of the Form FDA 1572, signed and dated by the Protocol/Grant PI/Protocol Chair/Co-Chair (for studies conducted under an IND) ***OR*** Copy of the DAIDS IoR Form, signed and dated by the Protocol/Grant PI/ Protocol Chair/Co-Chair (for non-IND studies)
- ❑ Protocol/Grant PI/Protocol Chair/Co-Chair IoR CV, signed and dated and other required documentation

DAIDS RSC Regulatory Support Center

Quick Reference Card

Protocol Registration At A Glance

Below is a list of the required documents for each specified registration submission.

5. CHANGE OF INVESTIGATOR OF RECORD (IoR)

A Change of IoR submission must include:

- ❑ Memo requesting the change of IoR (IRB/EC Letter is acceptable)
- ❑ Copy of the new Form FDA 1572, signed and dated by the new IoR (for studies conducted under an IND) ***OR*** Copy of the new DAIDS IoR Form, signed and dated by the new IoR (for non IND studies)
- ❑ New IoR CV, signed and dated and other required documentation

6. REQUESTED MATERIALS – Response to a Registration with Required Corrections notification OR to a Disapproval notification

A Requested/Corrected Materials submission must include:

- ❑ Copy of all IRB/EC and other applicable RE approval letter(s) and any other appropriate documentation from the IRB/EC and other applicable REs with information linking the approval to the current DAIDS approved version of a protocol and any other revised documents
- ❑ Copy of IRB/EC other applicable RE approved revised site-specific ICFs - all languages including English translations, if applicable

7. REGISTRATION WITH REQUIRED CORRECTIONS REVERSAL OR DISAPPROVAL REVERSAL REQUEST

A Registration with Required Corrections notification reversal or disapproval reversal submission must include:

- ❑ Written justification ***and/or*** a copy of any documentation supporting the CRS's request for the reversal

8. CONTINUING/ANNUAL REVIEW

A continuing/annual review submission must include:

- ❑ Copy of the IRB/EC continuing/annual review approval letter(s) and any other appropriate documentation from the IRB/EC with information linking the continuing/annual review approval to the current DAIDS approved version of a protocol
- ❑ Copy of all IRB/EC approved site-specific ICFs if revised at the time of continuing/annual review - all languages including English translations, if applicable
- ❑ Translation Confirmation Document – if applicable

9. SITE INITIATED REVISIONS TO SITE INFORMED CONSENT FORMS (ICFs)

A complete site initiated revised site ICF submission must include:

- ❑ Copy of all IRB/EC and other applicable RE approval letter(s) and any other appropriate documentation from the IRB/EC and other applicable REs with information linking the approval to the current DAIDS approved version of a protocol
- ❑ Copy of all IRB/EC other applicable RE approved revised site-specific ICFs - all languages including English translations, if applicable
- ❑ Translation Confirmation Document – if applicable

10. UPDATED FORM FDA 1572 / DAIDS IOR FORM – For all updates EXCEPT to change the IoR

A complete submission must include:

- ❑ Copy of the Form FDA 1572, signed and dated by the IoR (for studies conducted under an IND) ***OR*** Copy of the DAIDS IoR Form, signed and dated by the IoR (for non-IND studies)
- ❑ Translation Confirmation Document – if applicable

11. DEREGISTRATION

A complete deregistration submission must include:

- ❑ Memo requesting deregistration as the CRS no longer intends to participate in the protocol(s) ***AND/OR*** Copy of the IRB/EC closure/termination letter for the protocol(s)

NIH National Institute of Allergy and Infectious Diseases

DAIDS RSC Regulatory Support Center

This project has been funded in whole or in part with Federal funds from the Division of AIDS (DAIDS), NIAID, NIH, DHHS, under contract No. HHSN272201000013C, for the NIAID DAIDS Regulatory Support Center (RSC).