Protocol Registration at a Glance

Prior to implementing any new or amended protocol at a clinical research site, all sites must receive approval from DAIDS through the Protocol Registration Office. For further explanation of procedures, please review the DAIDS Protocol Registration Policy and Procedures Manual dated August 2004.

A clinical research site is required to submit the following documents to the Protocol Registration Office by fax at (301) 897-1701 or 800-418-3544, e-mail at EPR@tech-res.com or standard mail. Required documents are the same regardless of submission method. If submitting electronically, please review the guidelines for electronic protocol registration submission, which can be found at http://rcc.tech-res-intl.com/forms.htm.

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

I. Initial and Amendment Registrations

	Initial	**Amendment**
DAIDS Protocol Registration Checklist	×	×
Form FDA 1572/ Investigator of Record (IoR) Agreement *	×	
Investigator of Record (IoR) CV	×	
IRB/EC approval letter(s)	×	×
IRB/EC approved Site Informed Consent(s)	×	×
Materials Transfer Agreement – if applicable	×	
IBC approval – if applicable	×	
Local Language Informed Consent Verification Document – if applicable	×	×
IRB documentation of 45 CFR 46 pediatric risk category – if applicable	×	×

*A Form FDA 1572 is required for all studies being conducted under an IND. An IoR Agreement is required for all non-IND studies.

NOTE: Failure to include any of these required documents at the time of submission may result in processing delays until all required protocol registration materials are received at the Protocol Registration Office.

II. Change of Investigator of Record

DAIDS Protocol Registration Checklist	×
Letter Requesting Change of IoR	×
New Investigator of Record CV	×
Updated Form FDA 1572 or IoR Agreement	×

NOTE: To avoid potential delays in registration, all change of IoR requests should be submitted immediately to the Protocol Registration Office for processing.

III. Continuing Review/ Annual Review

DAIDS Protocol Registration Checklist	×
IRB/EC approval letter(s)	×
IRB/EC approved Site Informed Consent(s)	×

Initial Protocol Registration

A complete "initial" protocol registration submission must include:

- Completed DAIDS Protocol Registration Checklist (checking **Initial Protocol Registration-Section 2 of the DAIDS Checklist**)
- Original Form FDA 1572 completed, dated and signed by the Investigator of Record (IoR) (for studies conducted under an IND)
- Original Investigator of Record Agreement, completed, dated and signed by the Investigator of Record (for non-IND studies)
- Investigator of Record Curriculum Vitae
- Copy of IRB/EC Approval Letter with all of the following DAIDS-required identifiers in place:
  - Complete protocol title, DAIDS protocol number and DAIDS protocol version number
  - Date of IRB/EC approval
  - IRB/EC Chairperson or member designee signature
  - IRB/EC Representative's title
- IRB Documentation of 45 CRF 46 Pediatric risk category – if applicable
- Materials Transfer Agreement (MTA)—if applicable
- IBC approval – if applicable
- Local language Informed Consent Verification Statement – if applicable
- Copy of IRB/EC approved site-specific Informed Consent(s) with the following DAIDS-required identifiers in place:
  - Complete protocol title (or DAIDS approved short-title)
  - DAIDS protocol number and DAIDS protocol version number
  - No strike-outs

AMENDMENTS

A complete "amendment" protocol registration submission must include:

- Completed DAIDS Protocol Registration Checklist (checking **Amendment Protocol Registration - Section 2 of the DAIDS Checklist)**
- Copy of IRB/EC Approval Letter with all of the DAIDS-required identifiers listed above
- IRB Documentation of 45 CRF 46 Pediatric risk category – if applicable
- IRB/EC approved site-specific Informed Consent(s) with all of the DAIDS-required identifiers

ANNUAL REVIEW / CONTINUING REVIEW

The materials Required for Annual Review include

- Completed DAIDS Protocol Registration Checklist (checking **"Other Materials" in section 2 and "Continuing Review" in section 4)**
- Copy of IRB/EC Continuing Review Approval Letter with the DAIDS-required identifiers listed above
- IRB Documentation of 45 CRF 46 Pediatric risk category – if applicable
- Copy of IRB/EC approved site-specific Informed Consent(s) with all of the DAIDS-required identifiers listed above

CHANGE OF INVESTIGATOR OF RECORD (IoR)

To request a change of Investigator of Record, the submission must include:

- Completed DAIDS Protocol Registration Checklist (checking **"Other Materials" in section 2 and "Change of Investigator of Record" in section 4 of the DAIDS Checklist**.)
- Memo from the site to the Protocol Registration Office requesting a change of Investigator of Record (IRB/EC Letter is acceptable)
- New Investigator of Record CV
- Original, completed Form FDA 1572 signed and dated by the new Investigator of Record (for studies conducted under an IND)
- Original, completed Investigator of Record Agreement signed and dated by the new Investigator of Record (for non IND studies)