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

- ❑ Form FDA 1572 for IND studies and DAIDS IOR Form for Non-IND studies
- ❑ IOR CV
- ❑ IOR Medical License
- ❑ IRB/EC Submission
- ❑ IRB/EC Approval Letters
- ❑ All correspondence with the IRB/EC relating to the trial approval
- ❑ Documentation of Pediatric risk/benefit category per 45 CFR 46 & 21 CFR 50 – if applicable
- ❑ Regulatory Entity/Regulatory Authority Submission Letters
- ❑ Regulatory Entity/Regulatory Authority Approval Letters
- ❑ All correspondence with the Regulatory Entity relating to the trial approval
- ❑ IBC Submission Letter
- ❑ IBC Approval Letter
- ❑ All correspondence with the IBC relating to the trial approval
- ❑ Protocol Signature Page
- ❑ Site Specific ICFs(s) - all applicable languages. All ICFs required by the protocol must be submitted or justification provided for their omission must be provided.
- ❑ Site Specific Informed Assent(s) - all applicable languages. All ICFs required by the protocol must be submitted or justification provided for their omission must be provided.
- ❑ Translation Certificate (if applicable).
- ❑ Translation Confirmation Documentation (If applicable)
- ❑ Regulatory Entity/Regulatory Authority Clinical Trial Application

2. FULL VERSION PROTOCOL AMENDMENT

- ❑ IRB/EC Submission
- ❑ IRB/EC Approval Letters
- ❑ All correspondence with the IRB/EC relating to the trial approval
- ❑ Documentation of Pediatric risk/benefit category per 45 CFR 46 & 21 CFR 50 – if applicable
- ❑ Regulatory Entity/Regulatory Authority Submission Letters
- ❑ Regulatory Entity/Regulatory Authority Approval/ Acknowledgment Letters
- ❑ All correspondence with the Regulatory Entity/Regulatory Authority relating to the trial approval
- ❑ Submission Letter to Regulatory Entity/Regulatory Authority
- ❑ Protocol Signature Page
- ❑ Site Specific ICFs - all applicable languages. All previously approved ICFs must be submitted or justification provided for their omission must be provided. Any new ICFs added within the protocol ICFs must be submitted as an Additional ICF submission or justification provided for their omission must be provided.
- ❑ Site Specific Informed Assent(s) - all applicable languages. All previously approved Assents must be submitted or justification provided for their omission must be provided. Any new Assents required must be submitted as an Additional ICF submission must be submitted or justification provided for their omission must be provided.
- ❑ Translation Certificate (if applicable).
- ❑ Translation Confirmation Documentation (if applicable)

3. LETTER OF AMENDMENT (LOA)

- ❑ IRB/EC Submission
- ❑ IRB/EC Approval Letters
- ❑ All correspondence with the IRB/EC relating to the trial approval
- ❑ Documentation of Pediatric risk/benefit category per 45 CFR 46 & 21 CFR 50 – if applicable
- ❑ Regulatory Entity/Regulatory Authority Submission Letters
- ❑ Regulatory Entity/Regulatory Authority Approval/ Acknowledgment Letters
- ❑ All correspondence with the Regulatory Entity relating to the trial approval
- ❑ Protocol Signature Page

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- ❑ Translation Certificate (if applicable).
- ❑ Translation Confirmation Documentation (if applicable)

4. ADMINISTRATIVE REGISTRATION

- ❑ Form FDA 1572 for IND studies and Form FDA 1572 or DAIDS IOR Form for Non-IND studies
- ❑ IOR CV
- ❑ IOR Medical License
- ❑ IRB/EC Submission
- ❑ IRB/EC Approval Letters
- ❑ All correspondence with the IRB/EC relating to the trial approval
- ❑ Documentation of Pediatric risk/benefit category per 45 CFR 46 & 21 CFR 50 – if applicable
- ❑ Regulatory Entity/Regulatory Authority Submission Letters
- ❑ Regulatory Entity/Regulatory Authority Approval Letters
- ❑ All correspondence with the Regulatory Entity/Regulatory Authority relating to the trial approval
- ❑ Regulatory Entity Clinical Trial Application (See Clinical Trial Application below)
- ❑ IBC Submission Letter (if applicable)
- ❑ IBC Approval Letter (if applicable)
- ❑ All correspondence with the IBC relating to the trial approval
- ❑ Protocol Signature Page
- ❑ Translation Certificate (if applicable).
- ❑ Translation Confirmation Documentation (if applicable)

5. CHANGE OF INVESTIGATOR

- ❑ Form FDA 1572 for IND studies and Form FDA 1572 or DAIDS IOR Form for Non-IND studies
- ❑ IOR CV
- ❑ IOR Medical License
- ❑ Protocol Signature Page

6. CONTINUING REVIEW

- ❑ IRB/EC Approval Letters and applicable correspondence

7. SITE INITIATED REVISED ICFS

- ❑ IRB/EC Submission
- ❑ IRB/EC Approval Letters
- ❑ All correspondence with the IRB/EC relating to the trial approval
- ❑ Regulatory Entity/Regulatory Authority Submission Letters
- ❑ Regulatory Entity/Regulatory Authority Approval Letters
- ❑ All correspondence with the Regulatory Entity/Regulatory Authority relating to the trial approval
- ❑ Site Specific ICFs - all applicable languages
- ❑ Site Specific Informed Assent(s) - all applicable languages
- ❑ Translation Certificate (if applicable).
- ❑ Translation Confirmation Documentation (if applicable)

8. UPDATED FORM FDA 1572 OR DAIDS IOR FORM

- ❑ Form FDA 1572 for IND studies and Form FDA 1572 or DAIDS IOR Form for Non-IND studies

9. DEREGISTRATION

- ❑ Memo stating that the CRS no longer intends to participate in the protocol(s) and/or A Copy of the IRB/EC closure/termination letter for the protocol if the protocol has been closed with the IRB/EC at the time of deregistration

10. SUSPENSION OR TERMINATION OF IRB EC APPROVAL

- ❑ Documentation from the IRB/EC that identifies the reason for suspension or termination

11. CLINICAL TRIAL APPLICATIONS

- ❑ Submit Clinical Trials Application (CTA) Form/Documentation to the DAIDS RSC prior to the submission of an initial protocol registration by submitting the CTA checklist and Clinical Trials application/submission Form/document to the DAIDS RSC at ClinicalTrialApplication@tech-res.com.

National Institute of Allergy and Infectious Diseases
DAIDS RSC Regulatory Support Center

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