1. PURPOSE

1.1 This document describes the process for collection of Essential Documents for the conduct of a clinical trial on behalf of the National Institute of Allergy and Infectious Diseases (NIAID), Division of Microbiology and Infectious Diseases (DMID).

2. SCOPE

2.1 This document applies to all clinical trials for which DMID will maintain the sponsor files as described in International Council for Harmonization Good Clinical Practice (ICH GCP) guidelines.

3. DEFINITIONS

3.1 Essential Documents: Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. This includes both site and sponsor documents.

3.2 Essential Document Collection Organization (EDCO): The organization responsible for the collection, review, acceptance of essential documents from the trial site.

For other definitions, see DMID glossary.

4. RESPONSIBILITIES

4.1 Contracting Officer's Representative (COR)/Program Officer (PO) is responsible for communicating with DMID staff which entity has been identified as the Essential Document Collection Organization (EDCO) for a study supported by DMID.

4.2 The DMID Clinical Project Manager is responsible ensuring that the required electronic systems (e.g. NIAID Clinical Research Management System (NCRMS)) capture the appropriate EDCO information and ensuring that any specific requirements for essential documents have been communicated to DMID staff and the EDCO as necessary.

4.3 Office of Clinical Research Affairs Nurse Consultant or designee is responsible for oversight of the essential document collection under the Clinical Research and Operations Management Support contract. In addition, if a protocol has been identified as requiring a Trial Master File (DMID-TD-POL-00001), the OCRA NC or designee is responsible for communicating the need for additional essential documents specifically needed for the TMF.

4.4 The designated EDCO is responsible for the collection, review, and maintenance of the protocol and site-specific essential regulatory documents. The EDCO is also responsible for the distribution of the Site Activation memo authorizing a site to begin study related activities.

5. PROCEDURE

5.1 Selection of an EDCO

5.1.1 During the development of the protocol, the DMID COR/PO and CPM will discuss with the protocol team which group will be responsible for the collection, review, and approval of the essential documents for a protocol on behalf of DMID.

5.1.2 Once the EDCO has been identified, the EDCO name and contact information will be entered in to the NCRMS and the appropriate EDCO will be notified.

5.2 Prior to Study Initiation/ Activation

5.2.1 Once the activation requirements have been decided upon with the DMID CPM, the EDCO will provide the site(s) with the list of all required documents for the protocol, the site essential regulatory documents file.

5.2.2 Upon receipt of the requested essential documents, it is expected that the EDCO performs a quality review for completeness, accuracy, and compliance to all applicable regulations and DMID requirements.

- The respective site will be notified of the review findings and asked to address the findings necessary.
- Documents are deemed acceptable by the EDCO once all issues have been resolved.

5.2.3 Once the protocol documents required for submission to the US FDA for a DMID held IND/IDE have been deemed acceptable, copies will be provided to the Office of Regulatory Affairs designee for the protocol.

5.3 Activation

5.3.1 A formal Site Activation notice approved by DMID is required before study activities may begin at a site according to the DMID Site Activation SOP.

5.3.2 The designated EDCO reviews all site essential documents to ensure they are complete, accurate, and in compliance with applicable regulations and the DMID requirements then notifies the appropriate DMID representatives (CPM/ COR and possibly the OCRA NC if necessary).

5.3.3 All required site essential documents required for activation must be provided to DMID for the Sponsor Files prior to activation.

5.3.4 Upon approval by DMID representatives, the EDCO will send the DMID Clinical Site Activation notice via email authorizing the respective site to begin study-related activities.

5.4 Maintenance

5.4.1 During the conduct of the trial, the EDCO is responsible for tracking the expiration status of required essential regulatory documents and providing DMID with current protocol and site-specific essential documents.

5.4.2 The EDCO is responsible for providing DMID with documents within 30 days of approval.

5.4.3 The EDCO is responsible for the review of the documents provided to DMID for the sponsor files at a minimum annually.

5.5 Study Close Out

5.5.1 Some final documents may be collected during the Close Out Visit (COV) and provided to DMID by the monitors as described in the monitoring plan for the study. The designated EDCO should ensure that if these documents require updates, that DMID receives any updated documents.

5.5.2 The designated EDCO will collect the required site close out documents following the conduct of the close out visit and conduct a quality review of the documents submitted for the DMID files.

5.5.3 The site must be notified of any missing or discrepant documents, as appropriate.

5.5.4 The EDCO will track the pending documents until the final closure document is provided to DMID and will inform their study specific DMID representatives once all documents have been collected so the protocol can be closed.

6. REFERENCES

6.1 ICH GCP (R2) Guidelines

6.2 DMID-TD-POL-00001, Trial Master File (TMF)

7. APPENDICES

Not applicable

8. REVISION HISTORY

8.1 DMID-SM-SOP-00006 rev 01 is the original version of this procedure within the eQMS.

9. ADDITIONAL INFORMATION

9.1 Document Lead: OCRA

9.2 Posting externally: Yes