## 1. PURPOSE

1.1 The purpose of this policy is to describe the requirements for records management and retention to support clinical research on behalf of National Institute of Allergy and Infectious Diseases (NIAID), Division of Microbiology and Infectious Diseases (DMID).

## 2. SCOPE

2.1 This policy applies to:

2.1.1 Clinical trials where DMID is the Investigational New Drug (IND)/ Investigational Device Exemption (IDE) sponsor or equivalent (regardless of funding type).

2.1.2 Non-IND/IDE clinical trials funded under contract.

- For non-IND clinical trials funded under cooperative agreement, the Program Officer (PO) may require adherence to this policy.

2.1.3 For clinical studies (that are not clinical trials) funded under contract, the Contracting Officer's Representative (COR) may require adherence to this policy.

## 3. DEFINITIONS

3.1 **Source Documents:** Are described as "Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subject diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial)."

3.2 **Essential Documents:** Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced (e.g., trial master file, informed consent forms, protocol amendments).

3.3 **Trial Master File (TMF):** The collection of essential documents that allows the conduct of a clinical trial to be reconstructed and evaluated. It includes both the sponsor and investigator files.

3.4 **Good Clinical Practice (GCP):** An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.

3.5 **Institutional Review Board (IRB)/Independent Ethics Committee (IEC):** An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial.

For other definitions, see DMID glossary.

## 4. RESPONSIBILITIES

4.1 **The Office of Regulatory Affairs (ORA) staff** is responsible for oversight of clinical trial records management for DMID Sponsored IND / IDE studies submitted to the US Food and Drug Administration (FDA).

4.2 **The Office of Clinical Research Affairs (OCRA) staff** are responsible for oversight of copies of essential documents that are maintained on behalf of DMID as part of Sponsor responsibilities.

4.3 **The Office of Clinical Research Resources (OCRR) staff** is responsible for communicating record retention requirements to funding recipients for contracts or cooperative agreements.

4.4 **The Clinical Research Site (CRS)** is responsible for effectively managing the records collected throughout the course of their clinical studies.

4.5 **DMID clinical research support contractors** are responsible for effectively managing the records collected throughout the course of the study and the life of the contract.

4.6 **DMID Clinical Project Manager or Program designee** serves as the point of contact for the CRS staff and facilitates communication regarding record retention in accordance with this SOP.

## 5. POLICY

5.1 Records Management

5.1.1 DMID will ensure the collection and maintenance of Sponsor documents and records in support of a clinical study when DMID is the sponsor of the IND/IDE or equivalent in accordance with the Code of Federal Regulations (21 CFR part 312.57, 45 CFR part 46, 21 CFR 50, 21 CFR 56, and 21 CFR 812.140), International Council for Harmonization (ICH) E6, Good Clinical Practice (GCP) Consolidated Guidance and NIH policy.

5.1.2 DMID will ensure that CRS maintain accurate records for their clinical studies, in accordance with applicable regulations (21 CFR part 312.57, 45 CFR part 46, 21 CFR 50, 21 CFR 56, and 21 CFR 812), ICH GCP guidelines, and NIH policies for record-keeping and retention.

5.1.3 All essential documents at DMID sponsored sites and clinical research support contractors shall be collected, maintained, and retained as per this policy.

- During a DMID-sponsored study, the DMID site monitor confirms that the site maintains such documents in accordance with the monitoring plan for the study.

5.2 Record Retention

5.2.1 DMID will retain records and reports supporting clinical research for a minimum of two years after a marketing application is approved for the investigational product or device

- If a marketing application is not approved for the product or device, records shall be retained until (two years after shipment and delivery of the product for investigational use is discontinued and the US FDA has been duly notified.

5.2.2 All study documents retained by the DMID sponsored CRS (e.g., signature sheets, investigational product accountability records, IRB safety notifications) must be maintained by the CRS as per federal and local regulations and ICH guidelines for sponsors, clinical investigators, and IRBs.

5.2.3 At the conclusion of a CRS award, the clinical investigator or designee should contact the responsible clinical site COR/PO, who will discuss with ORA, OCRR, and OCRA records disposition.

5.2.4 For studies conducted international or submitted to regulatory authorities outside of the US (e.g. European Medicines Agency (EMA), record retention requirements may be longer than those in the U.S. Record retention must follow all applicable regulations.

5.2.5 Documents to be retained for clinical trials conducted under a DMID-sponsored IND/IDE application or international equivalent are described in the ICH GCP, the DMID Regulatory Document Guidelines, or the study specific Trial Master File (TMF) Index as applicable.

5.2.6 A combination of paper and electronic records is acceptable to meet the record requirements outlined in regulations and ICH guidelines for the CRS and Sponsor.

5.2.7 Electronic records may be archived in non-electronic media such as microfilm, microfiche, and paper or to a standard electronic file format, such as PDF as per 21 CFR Part 11, regarding Electronic Records and Electronic Signatures.

5.2.8 The CRS must have a process in place to certify that the electronic copy is an accurate representation of the original with the same attributes and information.

5.3 Destruction of Records

5.3.1 A CRS must contact the protocol specific relevant program staff (e.g., Programmatic Branch CPM or Program Officer (PO)), the Director of ORA or designee, OCRR, and OCRA before destruction of any documentation related to DMID sponsored studies as defined in this policy.

5.3.2 DMID staff must verify if/when licensure of the product or device in question occurred, and if no licensure, follow-up with the manufacturing partner to seek confirmation that no licensure or change of the indication is intended.

5.3.3 The DMID COR/PO must also ensure that any agreement deliverable retention timelines are met when applicable.

## 6. REFERENCES

6.1 FDA Code of Federal Regulations 21 CFR Part 312 -Investigational New Drug Application (IND)

6.2 FDA Code of Federal Regulations 21 CFR Part 11 - Electronic Records; Electronic Signatures

6.3 International Council for Harmonization (ICH) E6, Good Clinical Practice (GCP) Consolidated Guidance

6.4 International Council for Harmonization (ICH) E8(R1) General Considerations for Clinical Studies

6.5 Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers

6.6 European Medicines Agency (EMA) Guidelines Annex VI

6.7 FDA Guidance on Clinical Trial Data Monitoring Committees

6.8 NIH Policy on Data Sharing

## 7. APPENDICES

7.1 Not applicable

## 8. REVISION HISTORY

8.1 DMID-TD-POL-00003 is the original version of this procedure within the eQMS. It replaces REG-Guidance-001 and REG-Guidance-003.

## 9. ADDITIONAL INFORMATION

9.1 Document Lead: Office of Regulatory Affairs (ORA)

9.2 Posting externally: Yes