1. PURPOSE

1.1 This document describes the Division of Microbiology and Infectious Diseases (DMID) policy for storage of clinical biospecimens at the DMID Clinical Materials Services (CMS) facility.

2. SCOPE

2.1 This policy applies to:

- All clinical trials where DMID is the IND/IDE sponsor.
- Non-IND/IDE clinical trials and clinical research protocols funded under contract, unless otherwise specified in a written agreement or by contract language.

3. DEFINITIONS

- **Primary Research Biospecimens:** Biospecimens collected for research purpose and would not be collected if a person was not participating in the research. The testing of these biospecimens is specified in the primary study protocol.
- **Repository Research Biospecimens** *(previously referred to as "Future Use")*: Biospecimens collected with the intent to store for additional research (i.e., biospecimens collected beyond those needed for primary research).

For other definitions, see DMID glossary.

4. RESPONSIBILITIES

4.1 Responsibilities are delineated in the policy.

5. POLICY

5.1 Biospecimens collected in trials covered within the scope of this policy, other than clinical laboratory evaluations used to assess inclusion/exclusion criteria and/or safety, must be stored at the DMID CMS (referred to as "central storage") until shipped to an investigator/institution for per protocol analysis or secondary research (as applicable).

5.1.1 Repository Research Biospecimens for clinical trials conducted under cooperative agreement or grant can be stored at the collecting site or other facility with the written permission of the program officer. This does not apply to Primary Research Biospecimens.

5.2 Short-term storage (as delineated in the study manual of procedures) is permitted at the specimen collection site/facility (referred to as "on-site storage") to allow for batch shipments.

5.3 Prior to shipment for central storage, all biospecimens must be labeled by the specimen collection site and entered into a specimen tracking system to establish the chain of custody and ensure tracking. The system must be accessible to DMID. Specimen labels must not contain personally identifiable information.

5.4 Specimens collected from clinical trials and clinical research funded under contract (within the scope of this policy) are the property of NIAID unless otherwise specified in a written agreement.

5.5 Specimens collected from clinical trials where DMID is the IND/IDE sponsor and funded under grant or cooperative agreement are the property of the awardee but are held by DMID until the end of the clinical trial implemented under IND to ensure DMID fulfills its regulatory obligations in testing endpoints specified in the trial.

5.5.1 After closure of the clinical trial and after the clinical study report has been finalized, these biospecimens are returned to the grantee unless continued storage is requested by the grantee and approved by the OCRR Director and the ownership of biospecimens is transferred to DMID.

5.6 Exceptions from this policy are permitted but must be approved by the OCRR Director and documented in the appropriate protocol documents (e.g., protocol, informed consent, manual of operations).

6. REFERENCES

Not applicable

7. APPENDICES

7.1 Policy exception request form

8. REVISION HISTORY

8.1 DMID-LB-POL-00002 rev 01 is the original version of this Policy within the eQMS. It replaces DMID-OCRR Policy-003, which was revised prior to incorporation into the eQMS.

9. ADDITIONAL INFORMATION

9.1 Document Lead: Office of Clinical Research Resources

9.2 Posting externally: Yes