1.0 Purpose:

To describe the Division of Microbiology and Infectious Disease (DMID) policy on Food and Drug Administration (FDA) inspections of DMID as a sponsor.

2.0 Scope:

This policy applies to DMID staff who would be involved with the conduct of an FDA inspection of DMID as a sponsor.

3.1 Policy:

The Office of Regulatory Affairs (ORA) Director has the responsibility for coordination of:

a) DMID's preparation for FDA inspections;

b) DMID's activities during an FDA inspection; and

c) DMID's response to FDA inspections.

Should any DMID staff become aware of an impending FDA inspection, the ORA Director will be notified immediately.

4.0 Background:

The FDA conducts inspections of sponsors to determine if the sponsor met their regulatory obligations. DMID must permit FDA investigators to access, verify, and reproduce any records pertinent to DMID's role as a sponsor. In order to be prepared for an FDA inspection, procedures must be in place to assure that appropriate information is readily available.

5.0 Definitions:

Inspection: The act by a regulatory authority (ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority (ies) to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority (ies).

6.0 Responsibilities:

The DMID ORA Director has the responsibility to implement this policy and is the point of contact with the FDA.

7.0 References:

U.S. Code of Federal Regulations, 21 CFR 50: Protection of Human Subjects

U.S. Code of Federal Regulations 21 CFR 312: Investigational New Drug Application

U.S. Code of Federal Regulations 21 CFR 812: Investigational Device Exemptions

International Conference on Harmonisation, Guidance for Industry, E6 Good Clinical Practice

8.0 Inquiries:

Questions or comments regarding this policy may be directed to:

Associate Director for Clinical Research
Division of Microbiology and Infectious Diseases (DMID)
NIH / NIAID
5601 Fisher Lane, Rm. 7E60
Bethesda, MD 20892
DMIDPolicyQuery@niaid.nih.gov

9.0 Availability

This policy is located electronically at:
http://www.niaid.nih.gov/labsandresources/resources/dmidclinrsrch/Pages/recordretention.aspx

10.0 Change Summary

Version Number	Date of Revision: DD-MMM-YYYY	Replaces	Effective Date: DD-MMM-YYYY	Description of Revision/Retirement
1.0	N/A	N/A	01-JUN-2014	N/A
2.0	17-JUN-2016	1.0	13-JUL-2016	Administrative changes