

National Institute of Allergy and Infectious Diseases / Division of Microbiology and Infectious Diseases	Policy Responsibility for DMID Safety Reporting for DMID-Supported Clinical Research	No.: DMID Policy-014 – NCRS 2.3 v 2.0
	Effective Date: 13-JUL-2016	Version 2.0

1.0 Purpose:

To describe the Division of Microbiology and Infectious Disease (DMID) policy for Safety Reporting for DMID-supported clinical research.

2.0 Scope:

This policy applies to DMID staff involved with the conduct of DMID-supported clinical research when DMID has the responsibility to report to a regulatory agency.

3.0 Policy:

DMID will maintain written standards (e.g., Standard Operating Procedures (SOPs), guidelines, work instructions, and associated forms that delineate safety reporting procedures for DMID-supported clinical research. The documents will be specific in the definition and categorization of events, use of specific forms, timing of reports to comply with FDA and/or other regulatory agency requirements, and the identification of specific accountability for submission, review, and follow-up action.

4.0 Background:

In order to ensure that mechanisms and procedures are in place to protect the safety of participants enrolled in DMID-supported clinical research, appropriate written documents, such as SOPs, guidelines, and work instructions, must be in place to define and manage the responsibility for DMID Safety Reporting. These documents and associated forms are developed by the responsible DMID Office or Branch and reviewed as appropriate by DMID staff responsible for carrying out the reporting procedures.

5.0 Definitions:

Clinical Research: NIAID human subjects term indicating research conducted on human subjects or on material of human origin that can be personally identified. Policy covers large and small- scale, exploratory, and observational studies. There are three types: Patient-oriented research (investigators directly interact with study participants); epidemiologic and behavioral studies; outcomes and health services research. This term applies to both clinical trials and clinical studies.

DMID-Supported Research: Clinical research for which DMID is responsible for reporting to the regulatory agency.

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6.0 Responsibilities:

Role	Responsibility
DMID Programmatic Branches	<ul style="list-style-type: none"> Assess safety reports
Office of Clinical Research Affairs	<ul style="list-style-type: none"> Inform sites of new safety events, as appropriate
Office of Regulatory Affairs	<ul style="list-style-type: none"> Submit safety reports to the regulatory agency in the appropriate timeframe

7.0 References:

[U.S. Code of Federal Regulations, 21 CFR 50: Protection of Human Subjects](#)

[International Conference on Harmonisation. Guidance for Industry, E6 Good Clinical Practice](#)

[International Conference on Harmonisation-ICH E-2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting](#)

[International Conference on Harmonisation-ICH E-2B: Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports](#)

[45 CFR 46 Protection of Human Subjects \(HHS\)](#)

[DMID Clinical Research Policies. Guidance and Tools: Safety Reporting and Pharmacovigilance](#)

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/pharma.aspx>

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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-JULY-2014	N/A
2.0	17-JUN-2016	V1.0	13-JUL-2016	Administrative changes