

National Institute of Allergy and Infectious Diseases / Division of Microbiology and Infectious Diseases/Office of Clinical Research Affairs	Policy Independent Data and Safety Oversight for DMID Clinical Research	No.: DMID Policy-010 - NCRS 1.2 v 2.0
	Effective Date: 13-JUL-2016	Version: 2.0

1.0 Purpose:

To describe the Division of Microbiology and Infectious Diseases (DMID) policy for establishing independent data and safety oversight for DMID-supported clinical research.

2.0 Scope:

This policy applies to DMID-supported clinical research studies where there are concerns about participant safety or data integrity. These types of studies require independent safety assessment.

3.0 Policy:

An appropriate safety oversight plan will be described in the protocol. If applicable, an appropriate independent safety charter for all clinical research commensurate with risks, the size, and complexity of the study will be prepared. This plan will provide a description of the review of safety and/or efficacy data to assess volunteer safety and data integrity. The plan will state the level of independent oversight necessary or that no independent oversight is required. For grant-funded clinical research that does not require a formal protocol, the awarded grant will serve as the document describing the appropriate level of oversight.

4.0 Background:

NIH policy requires that each Institute and Center (IC) have a system for managing/implementing the appropriate oversight of the conduct of clinical trials that ensures the safety of participants and the validity and integrity of the data. DMID extends this requirement to other clinical research where there are safety concerns. Data and safety oversight provides independent and objective review of the overall conduct of the study.

Data Safety and Monitoring Boards (DSMBs) review both interim safety and other clinical endpoint data, (e.g., surrogate markers). Safety Monitoring Committees (SMCs) review safety data. An Independent Safety Monitor (ISM) is a physician with relevant expertise whose primary responsibility is to provide safety oversight in a timely fashion on an individual subject basis. An ISM could be the sole independent source of safety oversight for the study. Details on the types of independent safety data and oversight are described on the DMID public web site for Clinical Research. Individuals associated with safety oversight are asked to complete a conflict of interest (COI) certification form prior to participation to attest that they have no vested interest in the outcome of studies for which they provide oversight.

These oversight committees and individuals provide recommendations to DMID and the study investigators as to the appropriateness of continuing the study as designed or described in the protocol. These recommendations address whether the study (or intervention for an individual or study cohort) should continue per protocol, be halted while additional information is gathered, be discontinued, or be modified. The DSMB, SMC, and/or ISM are advisory to DMID and their recommendations, while given careful consideration, are not binding.

National Institute of Allergy and Infectious Diseases / Division of Microbiology and Infectious Diseases/Office of Clinical Research Affairs	Policy Independent Data and Safety Oversight for DMID Clinical Research	No.: DMID Policy-010 - NCRS 1.2 v 2.0
	Effective Date: 13-JUL-2016	Version: 2.0

5.0 Definitions:

Data Safety Monitoring Board (DSMB): A committee of experts, independent of the trial investigators, pharmaceutical partners (if any), and funding agency, which periodically reviews the conduct, safety, and results of the trial and recommends continuation without change, continuation with change, or termination of the trial. These recommendations are made to DMID.

Independent Safety Monitor (ISM): A physician identified prior to the study who is independent of the study and is readily available to review and recommend actions on adverse events and other safety issues pertinent to individual subjects.

Safety Monitoring Committee (SMC): A committee of experts, independent of the trial investigators, pharmaceutical partners (if any), and funding agency, which periodically reviews the conduct and safety of the trial and recommends continuation without change, continuation with change, or termination of the trial. These recommendations are made to DMID.

6.0 Responsibilities:

Role	Responsibility
DMID Scientific Branches	<ul style="list-style-type: none"> • Consult with the Office of Clinical Research Affairs (OCRA) to determine the appropriate type of data and safety oversight for all trials • Consult with OCRA for safety oversight for studies without an investigational agent that may require independent safety oversight • Identify qualified members for the DSMB or SMC and/or ISM as appropriate
Office of Clinical Research Affairs	<ul style="list-style-type: none"> • Collect, evaluate, and maintain signed conflict of interest forms from DSMB, SMC, and ISM • Provide contract support for safety committee meetings • Consult about appropriate safety oversight mechanisms • Assist in identifying qualified members for the DSMB or SMC • Develop a charter for independent safety committees
Office of Regulatory Affairs	<ul style="list-style-type: none"> • Communicate safety oversight outcomes to the Food and Drug Administration (FDA) per ORA policy

National Institute of Allergy and Infectious Diseases / Division of Microbiology and Infectious Diseases/Office of Clinical Research Affairs	Policy Independent Data and Safety Oversight for DMID Clinical Research	No.: DMID Policy-010 - NCRS 1.2 v 2.0
	Effective Date: 13-JUL-2016	Version: 2.0

7.0 References:

[NIAID Policy on Data and Safety Monitoring Board \(DSMB\) Operations](#)

[NIAID Policy for Identifying Potential Conflict of Interest for Individuals Serving on Advisory Committees or Independent Safety Monitors Responsible for Data and Safety Monitoring of Clinical Trials](#)

[FDA Guidance: The Establishment and Operation of Clinical Trial Data Monitoring Committees for Clinical Trial Sponsors](#)

[DMID Clinical Research Policies, Guidance and Tools: Safety Oversight](#)

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
6610 Rockledge Dr.
Bethesda, MD 20892
DMIDPolicyQuery@mail.nih.gov

9.0 Availability:

This policy is located electronically at:

<http://www.niaid.nih.gov/LabsAndResources/resources/DMIDClinRsrch/Pages/safetyoversight.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	25-APR-2014	N/A
2.0	17-JUN-2016	1.0	13-JUL-2016	Administrative changes