

National Institute of Allergy and Infectious Diseases / Division of Microbiology and Infectious Diseases	Policy Clinical Research Data Management	No.: DMID Policy-013 – NCRS 2.2 v2.0
	Effective Date: 13-JUL-2016	Version: 2.0

1.0 Purpose:

To describe the Division of Microbiology and Infectious Disease (DMID) policy on management of data from DMID-funded clinical research projects.

2.0 Scope:

This policy applies to individuals and organizations responsible for the management of DMID-supported clinical research data.

3.0 Policy:

In order to ensure the integrity of data generated from DMID-supported clinical research, systems must be in place to assure that data are collected, processed, analyzed, and reported in a reproducible manner that protects the integrity, authenticity and confidentiality of the data. For all clinical research supported by DMID, data collection and data management responsibilities are divided between the Principal Investigator and the data manager/data management center. The Principal Investigator (PI) and the clinical sites are responsible for determining their need for complying with HIPAA provisions.

4.1 Background:

Depending on the type and complexity of the clinical research, data management responsibilities may include:

- Generating a data management plan that includes, but is not limited to: standard operating procedures, descriptions of data sources, data collection and handling processes at the site, data transfer formats and procedures, data management QC/QA procedures, and data security measures
- Training staff
- Restricting data access to authorized personnel
- Responding promptly to queries
- Developing case report forms
- Developing a data analysis/statistical plan which clearly delineates objectives, endpoints, and statistical approach
- Data reconciliation
- Preparing reports as requested
- Timely data recording

In addition, the following should be included for clinical trials:

- Database validation documentation or confirmation of use of a commercial validated data collection program
- Any electronic data management system that will be consistent with the US Code of Federal Regulations 21 CFR 11

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- Data managers collaborate with the study statistician in the development of the analysis plan
- Transfer upon request databases and documents needed to recreate the analysis to DMID or pharmaceutical partners.

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.

Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Clinical Study: Clinical research that does not meet the definition of a clinical trial.

Data: A piece of information acquired by observation, measurement, or experiment and used as a basis for calculation or reference.

Data Coordinating Center: An entity responsible for providing data coordinating services for one or more clinical research projects.

Human Subjects Research: A systematic investigation designed to develop or contribute to generalizable knowledge that involves a living individual(s) about whom an investigator obtains data through intervention or interaction with the individual or involve identifiable private information.

5.0 Responsibilities: refer to policy section 3.0 and 4.0

6.0 References:

[Health Insurance Portability and Accountability Act of 1996 \(HIPAA\)](#)

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

[International Conference on Harmonisation \(ICH\) M-5: Data Elements and Standards for Drug Dictionaries](#)

[NIAID OMB Clearances and Clinical Exemptions](#)

[NIH Clinical Research and the HIPAA Privacy Rule](#)

[Privacy Act of 1974](#)

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U.S. Code of Regulations:

[21 CFR 11: Electronic Records and Signatures](#)

[21 CFR 50: Protection of Human Subjects \(FDA\)](#)

[21 CFR 56: IRB \(FDA\)45 CFR 46: Protection of Human Subjects \(HHS\)](#)

7.0 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

8.0 Availability:

This policy is located electronically at:

<http://www.niaid.nih.gov/research/dmid-data-management>

9.0 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