1.0 Purpose:

To describe the Division of Microbiology and Infectious Disease (DMID) requirements for Human Subjects Protections (HSP) training for awardee clinical research staff.

2.0 Scope:

This policy applies to all site personnel involved in the design, conduct, or oversight of DMID human subjects research.

3.0 Policy:

Awardees must comply with the NIH Required Education In The Protection Of Human Research Participants policy and NIAID Clinical Terms of Award that are incorporated in their grant Notices of Award or contract. The training requirement extends to study staff responsible for the design, conduct, or oversight of the clinical research. The Principal Investigator (PI)/ Project Director (PD) as listed on the grant or contract award will maintain training records for all relevant personnel and make the records available to DMID upon request. It is the PI's responsibility to document that new employees receive the required training prior to assuming study responsibilities and all relevant personnel maintain certified or updated training as per their contract, grant, or institution's requirements.

DMID expects awardees to have a working knowledge of the U.S. Federal regulations and any local regulations that address HSP. DMID may also require additional training, such as Good Clinical Practices (GCP), if DMID services are provided to support the execution of a clinical protocol.

4.0 Background:

The primary considerations in the conduct of human subjects research are protecting the safety and rights of the persons who volunteer to participate and assuring the integrity of the study data. The NIH and NIAID policies for extramural awards require senior/key personnel involved in the design and conduct of clinical research to have completed training in HSP before contract or grant funds are awarded. Responsibilities associated with human subjects research include oversight of a DMID award or participation in the conduct of a project that includes human subjects research or the development or review of clinical trial protocols. Individuals at the awardee institution become involved in human subjects research when they (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes.

HSP training includes ethical principles and their historic foundation, federal regulations, state/country and local laws, professional standards, and institutional policies relevant to the protection of human subjects.

HSP training may be conducted in many different ways, including classes or training material provided by the awardee's institution. Additionally, both the NIH and NIAID offer on-line training modules that may assist investigative staff in meeting HSP training requirements; these are identified in the Resources section (8.0) of this policy.

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.

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.

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Human Subjects: Legally defined term for living persons about whom an investigator obtains specimens or data through direct interaction or intervention or through identifiable, private information.

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 identifiable private information.

Note: the terms Clinical Research and Human Subjects Research are used synonymously in this policy.

6.0 Responsibilities:

Role	Responsibility
Principal Investigator/ Project Director	• Ensure that staff with human subjects research responsibilities or oversight functions receive initial and renewal training, as appropriate
DMID Scientific Branches	• Review documentation of training and assure the site staff are adequately trained for the planned studies. For DMID clinical contract sites, contact the contract COR for follow up with site staff on reports from the review of training documentation

7.0 References:

21 CFR 50, Protection of Human Subjects (Informed Consent)

45 CFR 46, Protection of Human Subjects

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

NIH Required Education in the Protection of Human Research Participants Policy

NIAID Clinical Terms of Award Guidance

Good Clinical Practice Training for NIAID and Awardee Clinical Research Staff

8.0 Resources:

HSP Training:

- English: National Institutes of Health (NIH) Protecting Human Participants in Research on-line training
- Spanish: Oficina de NIH para Investigaciones Extrainstitucionales: Protección de los Participantes Humanos de la Investigación

HSP and GCP Training:

- NIAID Online GCP Training course, which contains modules for both GCP and HSP
- NIAID Human Subjects Research portal

9.0 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@mail.nih.gov

10.0 Availability:

This policy is located electronically at: .

https://www.niaid.nih.gov/sites/default/files/hsptraining.pdf

11.0 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/AUG/2013	N/A
2.0	20/JUN/2015	Version 1.0	01/JUL/2015	Administrative edits
3.0	06/JUL/2017	Version 2.0	14/AUG/2017	Biennial review; administrative edits; specified DMID contact for clinical contract sites