1. PURPOSE

1.1 The purpose of this Policy is to establish the standards for Human Subject Protection (HSP) training in Human Subject Research funded and sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), Division of Microbiology and Infectious Diseases (DMID).

2. SCOPE

2.1 This Policy applies to awardees for all Human Subject Research funded by and/or supported by DMID, including investigators and clinical research staff at research sites conducting, managing, and/or overseeing research (e.g., coordinating centers).

2.2 HSP requirements for DMID staff are covered under a separate policy (DMID-QM-POL-00004).

2.3 HSP requirements for vendors are covered under a separate policy.

3. DEFINITIONS

3.1 Human Subject Research: A human subject is "a living individual about whom an investigator (whether professional or student) conducting research: Obtains information or biospecimens; or through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

For additional definitions, see DMID glossary.
https://www.niaid.nih.gov/research/dmids-clinical-research-glossary

4. RESPONSIBILITIES

As defined under Policy.

5. POLICY

5.1 NIH policy requires that all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects must have education on the protection of human research participants.

5.2 NIAID policy states that all awardee staff who are involved in the conduct, oversight, or management of clinical research should demonstrate a basic knowledge in HSP, prior to performing their clinical research job functions/oversight.

5.3 Decision making authority:

5.3.1 Activities outside of DMID that are funded by grants including cooperative agreements must comply with the NIH Grants Policy Statement (NIHGPS) and any terms and conditions in the Notice of Award (NoA).

5.3.2 Activities outside of DMID that are funded by contracts must comply with the contract statement of work (SOW) and any other conditions specified in the award/contract.

5.3.3 All funding from the NIH require compliance with NIH policies including the NIH and NIAID HSP policies.

5.3.4 The DMID policy (below in 5.5) is written to align with NIH HSP policies. In the event the policy below contradicts the terms of the grant or contract, the grant or contract will take precedence.

5.4 The requirements for HSP training depend on the type of trial and funding mechanism.

IND/IDE Clinical Trials

Type of Trial	Grant	Cooperative Agreement	Contract
IND/IDE held by DMID	See 5.5.1	See 5.5.1	See 5.5.1
IND/IDE held by another entity	See 5.5.2	See 5.5.2	See 5.5.2

Non-IND/IDE Clinical Trials and Clinical Studies

Type of Trial/Study	Grant	Cooperative Agreement	Contract
Clinical Trial: High Resource	See 5.5.3	See 5.5.3	See 5.5.1
Clinical Trial: Low Resource	See 5.5.3	See 5.5.3	See 5.5.1
Clinical Study (not a trial): Higher Risk Procedure	See 5.5.5	See 5.5.5	See 5.5.6
Clinical Study (not a trial): Not High Risk	See 5.5.5	See 5.5.5	See 5.5.6

5.5 DMID policy on HSP training:

5.5.1 For DMID sponsored IND trials:

- All staff who require GCP training must also have HSP training. This includes all staff that are involved in the design, conduct, oversight, or management of clinical trials including:
  - The Principal Investigator(s) (PI) / Project Director(s) (PD) as listed on the grant or contract award.
  - The PI of the clinical trial (if different than above).
  - Any sub-investigators listed on the Form FDA 1572.
  - Any sub-investigators or associate investigators listed on the IRB application.
  - Any staff on a delegation log in a role that interact directly with trial participants.
  - Any staff performing recruitment (discussing details of the trial), consent, and evaluation of inclusion/exclusion criteria.
  - Any staff who are responsible for study coordination, data collection, and data management.
  - Other staff involved with the trial that obtain information or specimens for the purpose of research.
  - For other staff, the site PI / PD should consider local and institutional policies and whether HSP training would be helpful in protecting the rights of trials participants. The site PI / PD is responsible for identifying other staff that need HSP training.

5.5.2 For non-DMID sponsored IND trials, the IND sponsor has the responsibility of determining which clinical staff, in addition to the clinical investigator, need documented HSP training. At a minimum, however, if GCP training is required by the sponsor then HSP is also required.

5.5.3 For non-IND trials funded by grant or cooperative agreement:
- the PI / PD as listed on the grant or cooperative agreement must have HSP training.
- the PI / PD is responsible for determining which additional staff need HSP training.

5.5.4 For non-IND trials funded by contract, HSP training requirements will follow those specified for DMID sponsored IND trials above. (5.5.1)

5.5.5 For clinical research (not a clinical trial) funded by grant or cooperative agreement:
- the PI / PD as listed on the grant or cooperative agreement must have HSP training.
- the PI / PD is responsible for determining which additional staff need HSP training.

5.5.6 For clinical research (not a clinical trial) funded by contract all staff that are involved in the design, conduct, oversight, or management of the clinical study require HSP training including:
  - The PI / PD as listed on the contract award.
  - Any investigator(s), sub-investigators, or associate investigators listed on the IRB application.
  - Any staff performing recruitment (discussing details of the trial), consent, and evaluation of inclusion/exclusion criteria.
  - Any staff who are responsible for study coordination, data collection, and data management.
  - Other staff involved with the trial that obtain information or specimens for the purpose of research.
  - For other staff, the site PI / PD should consider local and institutional policies and whether HSP training would be helpful in protecting the rights of trials participants. The site PI / PD is responsible for identifying other staff that need HSP training.

5.6 Renewal of HSP training is not required per NIH policy, however, periodic (i.e., every 3 years) HSP refresher training is encouraged.

5.7 HSP training requirement may be fulfilled through a class, course, or academic training program. Any HSP training is acceptable. If training is needed, good quality recommended HSP trainings include:

5.7.1 HHS Office of Human Research Protections

5.7.2 The Association of Clinical Research Professionals
- Free option without contact (continuing education) hours is acceptable.

5.7.3 Collaborative Institutional Training Initiative (CITI)
- Biomedical Comprehensive or Biomedical Foundations, or Biomedical Refresher.

5.7.4 HSP trainings from other sources may be acceptable. Contact the OCRA to discuss acceptability of other options.

6. REFERENCES

6.1 NIH Policy on Required Education in the Protection of Human Research Participants

6.2 NIAID Clinical Research Standards (internal NIH only)

6.3 NIAID HSP and GCP Policy

6.4 NIH definition of Human Subject Research

7. APPENDICES

Not applicable

8. REVISION HISTORY

- Revision 1, effective 8 January 2024, was rewritten from the prior policy DMID Policy-017 NCRS-3.1 v 3, and is the original version in the eQMS.
- Revision 2 reformatted the table in 5.4 for Section 508 compliance.

9. ADDITIONAL INFORMATION

9.1 Document Lead: Associate Director for Clinical Research

9.2 Posting externally: Yes