1. PURPOSE

1.1 The purpose of this policy is to establish the standards for clinical research training requirements in trials funded 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:

- Clinical trials where DMID is the IND/IDE or equivalent sponsor (regardless of funding type).
- Non-IND Clinical trials funded under contract.

2.2 For non-IND clinical trials funded under cooperative agreement, the Program Officer (PO) may require adherence to this policy.

2.3 For clinical studies (that are not clinical trials) funded under contract, the Contracting Officer's Representative (COR) may require adherence to this policy.

3. DEFINITIONS

For definitions, see DMID glossary.

4. RESPONSIBILITIES

4.1 Principal Investigator (PI) responsibilities:

4.1.1 Adhere to DMID clinical research training policy by ensuring that staff are appropriately trained for their delegated responsibilities with regards to clinical research training modules.

4.1.2 Maintain training records for all staff and provide these records at the request of DMID staff or DMID-contracted staff (e.g., monitor or auditor), site management staff, or FDA/regulatory agency inspector.

4.2 DMID responsibilities:

4.2.1 Ensure adherence to training requirements as documented by each site. The DMID delegate (e.g., the clinical monitoring team or site management organization) will review training records for compliance during scheduled site visits or as needed.

4.2.2 Training deficiencies will be communicated to CPM/COR/PO and the OCRA NC as Action Items from a site visit.

5. PROCEDURE

5.1 Initial Training Requirement

5.1.1 After award and prior to site activation, the following trainings must be completed by relevant staff and documented:

Table 1: Required Training Modules

Reference	Training Topic	Applicable for:
DMID Policy	Human Subjects Projections (HSP)	See: DMID-SM-POL-00001 "Human Subjects Protection Training for awardees" for applicable staff
DMID Policy	Good Clinical Practice (GCP)	See: DMID-SM-POL-00002 "Good Clinical Practice Training for awardees" for applicable staff
DMIDCROMS Clinical Training Modules	Study Product Management	For interventional studies only: PI, Pharmacists, anyone delegated responsibility for activities regarding study product (including ordering, receipt, handling, preparation, administration, and accountability)
	Source Documentation Standards	PI, quality manager, study staff who record data on source documents or transcribe data from source documents
	Regulatory Document File Guidelines	PI, quality manager, person responsible for essential documents, person responsible for ethics filings
	Investigator Responsibilities	PI, person(s) delegated investigator responsibility
	Federal wide Assurance (FWA)	Required for any site that does not have an FWA at the time of award/site selection
	FDA Inspection Preparedness	For interventional studies, if an inspection by a regulatory agency (e.g., FDA or EMA) is scheduled: PI, regulatory contact, others as needed to prepare for the inspection. This training may also be helpful in preparation for an audit conducted by DMID (often in anticipation of a possible inspection).
	Essential Regulatory Documents	PI, quality manager, regulatory contact
	Clinical Quality Management	PI, quality manager
	Adverse Events/Serious Adverse Events	PI, sub-investigators (who will assess AEs or if listed on 1572 and assigned responsibility) [other roles assigned responsibility and listed on 1572
Other	Biohazardous Materials training	Staff delegated with shipping of samples

5.2 Renewal/Refresher Training

5.2.1 HSP refresher training is not required (per policy DMID-SM-POL-00001).

5.2.2 GCP refresher training is required every three years (per policy DMID-SM-POL-00002).

5.2.3 DMID CROMS Clinical Research Training modules must be completed at a minimum every five years.

5.2.4 Biohazardous materials training must be completed every two years.

5.3 Training resources

5.3.1 DMID CROMS Clinical Research Training modules can be accessed via DMID-CROMS website (https://www.dmidcroms.com/_layouts/15/LMS/SSO.aspx). Contact the DMID CROMS Training group via training@dmidcroms.com for questions regarding access to the training modules available in the DMID-CROMS Learning Management System.

5.3.2 Biohazardous Materials training that meets this requirement must address federal regulations under 49CFR172. International Air Transport Association (IATA) training meets this standard.

- Shipment of biological materials is subject to the regulations for the shipment of infectious substances, biological substances, patient specimens, and dry ice.

6. REFERENCES

6.1 Transporting-Infectious-Substances-Safely Guide: https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2022-06/Transporting-Infectious-SubstancesSafely.pdf

6.2 49CFR172: https://www.ecfr.gov/current/title-49/subtitle-B/chapter-I/subchapter-C/part-172?toc=1

7. APPENDICES

Not applicable

8. REVISION HISTORY

   8.1 DMID-SM-POL-00004 rev 01 is the original version of this policy within the eQMS. It is a revision and replacement of DMID-OCRR Policy-008.

9. ADDITIONAL INFORMATION

   9.1 Document Lead: OCRR

   9.2 Posting externally: Yes