1. PURPOSE

1.1 The purpose of this document is to convey the NIAID Policy "Requirements for Human Subjects Protection (HSP) and Good Clinical Practice (GCP)Training for NIAID and Awardee Clinical Research Staff" and to include this policy within DMID's eQMS.

2. SCOPE

2.1 Per the original document, "This policy applies to individuals involved in the conduct, management, or oversight of clinical research and clinical trials under the auspices of the NIAID (including NIAID staff, contractors, and awardee staffs)."

3. DEFINITIONS

3.1 Electronic Quality Management System (eQMS) - Software program that automates and centralizes Quality Management System (QMS) processes and procedures required to achieve effective quality management.

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

4. RESPONSIBILITIES

4.1 As defined under Policy.

5. POLICY

5.1 The NIAID GCP HSP Training Policy identifies training requirements and guidelines regarding human subjects protections (HSP) and Good Clinical Practice (GCP) for NIAID and awardee staff.

5.2 All NIAID and awardee staff must follow the NIAID GCP training Policy.

5.3 DMID will develop processes within the DMID QMS (policies, SOPs, etc.) to meet the requirements specified in the NIAID HSP GCP policy and describe how it is applied to the type of trials and types of funding utilized by DMID and to DMID staff.

6. REFERENCES

6.1 NIAID GCP HSP Training Policy

7. APPENDICES

7.1 Not applicable

8. REVISION HISTORY

8.1 This is the original version of this policy.

9. ADDITIONAL INFORMATION

9.1 Document Lead: DMID Associate Director of Clinical Research

9.2 Posting external: Yes