1. PURPOSE

1.1 The purpose of this Policy (POL) is to describe the use of the Study Product Management Plan (SPMP) template and associated modules in specifying clinical research site processes and procedures with respect to study product and pharmacy management within the National Institute of Allergy and Infectious Diseases (NIAID), Division of Microbiology and Infectious Diseases (DMID) sponsored clinical sites.

2. SCOPE

2.1 This policy applies to all clinical trials sponsored or funded by NIAID DMID for Investigational New Drug Applications/ Investigational Device Exemptions (INDs/IDEs) trials under DMID-held INDs/IDEs.

2.2 The policy also applies to trials without INDs/IDEs but when a licensed product is prepared other than as described in the labeling and/or a non-commercially available dummy/placebo or dummy/placebo that is manufactured specifically for the clinical trial.

3. DEFINITIONS

For other definitions, see DMID glossary.

4. RESPONSIBILITIES

4.1 **Office of Regulatory Affairs (ORA)** is responsible for oversight of the content of the Study Product Management Plan (SPMP) document.

4.2 **Director/Deputy Director, ORA** is responsible for responding to any questions regarding this policy.

4.3 **Product Support Team (PST)** is responsible for review of the site-specific SPMPs submitted directly to the DMID Point of Contact (POC)/Contracting Officer's Representative (COR) and the DMID Product Support Team (PST) for acceptance.

5. POLICY

5.1 Each DMID-funded clinical research site has institutional policies and/or standard operating procedures (SOPs) in place to govern the management of clinical investigational products.

5.2 Each DMID clinical research site must complete and submit to the DMID Point of Contact (POC), Contracting Officer Representative (COR), Clinical Project Manager (CPM), and Product Support Team (PST) a SPMP (see references for template location on the DMID Clinical Research Operations & Management Support (CROMS) website) that describes their processes and procedures for the management of investigational products.

5.3 The SPMP is based on the expectations outlined in the DMID Guidelines for Clinical Study Product Management and International Conference on Harmonization (ICH) E6: Good Clinical Practices Guidelines and Code of Federal Regulations Title 21 Part 312.

5.4 The SPMP ensures all required elements specified in the DMID Guidelines, International Standards and regulatory requirements are addressed in a consistent and objective manner.

6. REFERENCES

6.1 Code of Federal Regulations Title 21 Part 312:
http://www.ecfr.gov/cgi-bin/text-idx?SID=08353c1dd96739e7f073274a3f41b026&mc=true&node=pt21.5.312&rgn=div5

6.2 United States Code 21 Part A Section 353a: Pharmacy Compounding:
https://uscode.house.gov/view.xhtml?req=compounding&f=treesort&fq=true&num=20&hl=true&edition=prelim&granuleId=USC-prelim-title21-section353a

6.3 Code of Federal Regulations Title 21 Part 812:
http://www.ecfr.gov/cgi-bin/text-idx?SID=9126b1f4cc88d366ac2d937624655975&mc=true&node=pt21.8.812&rgn=div5

6.4 Code of Federal Regulations Title 45 Part 46:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

6.5 International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6: Good Clinical Practices (GCP):
https://www.ich.org/

6.6 DMID Guidelines for Clinical Study Product Management:
https://www.dmidcroms.com/SitePages/Guidelines.aspx

6.7 DMID Study Product Management Plan Template:
https://www.dmidcroms.com/_layouts/15/WopiFrame.aspx?sourcedoc={d8f8f9dc-9518-4114-9057-c34efd890a7a}&action=default

7. APPENDICES

Not applicable

8. REVISION HISTORY

8.1 DMID-IP-POL-00001 revision 01 is the original version of this procedure within the eQMS and is an update to PST-Policy-003, DMID Clinical Study Product Management Plan Requirements for Clinical Research Sites.

9. ADDITIONAL INFORMATION

9.1 Document Lead: ORA Director

9.2 Posting externally: Yes