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1.0 PURPOSE

1.1 This policy describes the human subjects protections (HSP) and Good Clinical Practice (GCP) training requirements for contractors and grant recipients participating in National Institute of Allergy and Infectious Disease (NIAID), Division of AIDS (DAIDS)-supported clinical research, including DAIDS-sponsored clinical research.

2.0 SCOPE

2.1 This policy applies to contractors and grant recipients, excluding Network clinical research sites, participating in NIAID DAIDS-supported clinical research, including DAIDS-sponsored clinical research. Specific requirements for DAIDS' Network clinical research sites are defined in the DAIDS SCORE Manual.

3.0 DEFINITIONS

For additional definitions, see DAIDS Policy Glossary

3.1 **Clinical Research**: Clinical Research is research that involves human subjects and is defined by the NIH as:

a. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (i) mechanisms of human disease, (ii), therapeutic interventions, (iii) clinical trials, or (iv) development of new technologies.

b. Epidemiological and behavioral studies

c. Outcomes research and health services research

3.2 **Clinical Trial**:

HHS and NIH: 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 the interventions on biomedical or behavioral health-related outcomes.

ICH E6: Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

4.0 RESPONSIBILITIES

4.1 Contractors and Grant Recipients:

The recipient of the contract or grant award (awardee) and the recipients of their sub-awards are responsible for ensuring that:

4.1.1 all staff involved in the design, conduct, management, or oversight of DAIDS-supported clinical research, including DAIDS-sponsored clinical research, receive training in HSP and GCP, as applicable. Applicable training must be completed prior to performing any clinical research tasks/responsibilities.

4.1.2 there are documented procedures in place for HSP and GCP training requirements.

4.1.3 HSP and GCP training is completed, documented, and maintained consistent with this policy, and all applicable federal, state and local regulations, as well as applicable guidelines.

5.0 POLICY

5.1 NIAID clinical research standards require that applicable contractors and grant recipients involved in the design or conduct of clinical research, must receive training in HSP as defined in the U.S. Code of Federal Regulations (CFR) 45 CFR 46, including Subparts A, B, C, and D.

5.2 In addition to the HSP training requirements, NIAID clinical research standards also require that applicable contractors and grant recipients involved in the design, conduct, oversight, or management of clinical trials must receive training in GCP, consistent with the principles described in ICH E6(R2) [The Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)].

5.2.1 Note: HSP and GCP training requirements are in addition to other applicable training requirements.

5.3 Contractors and grant recipients are required to complete HSP and GCP training, as applicable, prior to performing any clinical research or trial tasks/responsibilities. Training should be refreshed at least every 3 years in order to stay up to date with relevant regulations, standards, and guidelines.

6.0 REFERENCES

6.1 ICH E6(R2): Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)

6.2 U.S. Code of Federal Regulations, 45 CFR 46, Protection of Human Research Subjects

6.3 NIH Policy on Required Education in the Protection of Human Research Participants Policy (June 2000)

6.4 NIH Policy on Good Clinical Practice Training for NIH Awardees involved in NIH-funded Clinical Trials (notice number: NOT-OD-16-148, Sept 2016)

6.5 NIH, Office of Extramural Research, Training & Resources, Human Subjects

6.6 NIH, Office of Extramural Research, Good Clinical Practice Training

6.7 NIH, Office of Extramural Research: Frequently Asked Questions, NIH Policy on Good Clinical Practice (GCP)(Aug 2017)

6.8 NIH Human Subjects Research Training SOP

6.9 NIAID Clinical Research Standards (May 2017)

6.10 NIAID Policy on Requirements for Human Subjects Protection (HSP) and Good Clinical Practice (GCP)Training for NIAID and Awardee Clinical Research Staff (April 2017)

6.11 NIH, Grants and Funding: Glossary of NIH Terms

7.0 APPENDICES

Not applicable

8.0 REVISION SUMMARY

8.1 POL-A-OD-003.00 is the initial version of the HSP GCP Training Requirements Policy in the DAIDS QMS. The previous version,DWD-POL-CL-03.03 is the last effective version of the HSP GCP Training Requirements Policy published on the DAIDS Clinical Research Policies webpage prior to the implementation of the DAIDS QMS in 2018.

The policy has been rewritten as a high level policy and the scope of the policy has been modified to define the minimum requirements for HSP and GCP training requirements collaborators participating in National Institute of Allergy and Infectious Disease (NIAID) Division of AIDS (DAIDS)-supported clinical research including DAIDS-sponsored clinical research.

8.2 DAIDS-OD-A-POL-00003 rev 01 is the first revision of this Policy in MasterControl. The document format and numbering were updated to reflect the current requirements. The policy was also modified to: 1) replace the term "DAIDS Collaborator" with "contractors and grant recipients", 2) revise definitions for “Clinical Research” and “Clinical Trial” to be consistent with the updated DAIDS Policy Glossary, 3) add links to references.