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1.0 PURPOSE

1.1 This policy describes the requirements for the development of informed consent documents.

2.0 SCOPE

2.1 This policy applies to all NIAID (DAIDS)-supported clinical research, including DAIDS-sponsored clinical research, involving human subjects. Specific requirements for DAIDS' Network clinical research sites are defined in the DAIDS SCORE Manual.

3.0 DEFINITIONS

For definitions, see DAIDS Glossary

4.0 RESPONSIBILITIES

4.1 Institutional Review Board (IRB)/Ethics Committee (EC)/Regulatory Entity (RE)/Regulatory Authority (RA)

The reviewing IRB/EC/RE/RA is responsible for performing their functions as outlined in 45 CFR 46.108- 113, 45 CFR 46 Subparts B, C, and D, 21 CFR 50 Subpart D, 21 CFR 56 Subpart C, and other applicable requirements.

4.2 Protocol Team

The Protocol Team is responsible for:

4.2.1 developing the protocol and ICF(s) that will be used either,

(a) as is, for single-site studies, or

(b) to develop sample ICFs for multi-site studies;

4.2.2 ensuring that the content and format of the ICF meet the requirements of 45 CFR 46;

4.2.3 for clinical research that meets the NIH definition of a clinical trial, ensuring that the content of the ICF is also consistent with the requirements of ICH E6;

4.2.4 For U.S. FDA-regulated IND clinical trials, 21 CFR 50 requirements must also be met;

4.2.5 for clinical trials under non-U.S. national health authority oversight, including IND clinical trials conducted internationally, ensuring that in-country regulatory authority requirements are followed, as appropriate;

4.2.6 ensuring that the ICF is consistent with the protocol and associated documents (such as the Investigator's Brochure).

4.2.7 developing associated or supporting documents (e.g., assents, participant information sheets, assessment of understanding questionnaires, etc.), as appropriate.

4.3 Contractors and Grant Recipients

For studies under single IRB (sIRB), the contractors or grant recipient either directly or working with Protocol team will obtain sIRB approval of the ICF.

5.0 POLICY

5.1 All informed consent forms for clinical research supported by DAIDS must comply with the requirements of 45 CFR 46, as well as all other applicable regulations, laws, and institutional policies and procedures.

5.2 In addition, for clinical research that meets the NIH definition of clinical trial, the content of the informed consent forms must also comply with the requirements of ICH E6.

5.3 For U.S. FDA-regulated IND clinical trials, 21 CFR 50 requirements must also be met.

5.4 For clinical trials under non-U.S. national health authority oversight, including IND clinical trials conducted internationally, in-country regulatory authority requirements must be met.

5.5 When multiple requirements apply, the most stringent law, regulation, guidance, and/or policy(ies) must be followed.

5.6 The ICF(s) must be revised to incorporate any changes to the protocol and any significant new findings and information learned during the research study that may impact a participant's willingness to join or continue in the study.

6.0 REFERENCES

6.1 HHS regulations for the Protection of Human Subjects at 45 CFR 46

6.2 HHS Office for Human Research Protections (OHRP) Informed Consent FAQs

6.3 FDA regulations on Institutional Review Boards at 21 CFR 56

6.4 FDA regulations for the Protection of Human Subjects at 21 CFR 50

6.5 FDA: Guidance for Industry Investigator Responsibilities —Protecting the Rights, Safety, and Welfare of Study Subjects

6.6 FDA Draft Guidance: Informed Consent: Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors (July 2014)

6.7 FDA Guidance: Institutional Review Boards Frequently Asked Questions - Information Sheet

6.8 FDA's Role: ClinicalTrials.gov Information-Required Informed Consent Language

6.9 Genetic Information Nondiscrimination Act (GINA)

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

6.11 NIH Certificates of Confidentiality-General Information

6.12 NIH Certificates of Confidentiality-Example Informed Consent Language

6.13 NIH Policy and Regulation on ClinicalTrials.gov Registration and Reporting-General Information

6.14 NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

6.15 NIH Genomic Data Sharing (GDS) Policy

6.16 NIH Guidance on Consent for Future Research Use and Broad Sharing of Human Genomic and Phenotypic Data Subject to the NIH Genomic Data Sharing (GDS) Policy

6.17 DAIDS Clinical Research Policies and Other Information

6.18 Data Management and Sharing Policies

7.0 APPENDICES

Not applicable

8.0 REVISION SUMMARY

8.1 POL-A15-OPC-005.00 is the initial version of The Requirements for Informed Consent Form and Process Policy submitted to the DAIDS QMS as version 00.

The Requirements for Informed Consent Form Policy replaces The Requirements for Informed Consent Development Policy published on the DAIDS Clinical Research Policies webpage prior to the implementation of the DAIDS QMS in 2018. The Informed Consent Form Policy updates the requirements for informed consent, including information about the informed consent process, revised Common Rule, and ICH E6.

8.2 DAIDS-OPC-A15-POL-00005 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) revise the scope to indicate that site requirements are covered in the Score Manual and 2) add links to references.