1.0 PURPOSE

1.1 The purpose of this policy is to describe the requirements for the development of informed consent documents.

2.0 SCOPE

2.1 This policy applies to all NIAID (DAIDS)-supported and/or-sponsored clinical research involving human subjects.

3.0 DEFINITIONS

3.1 For definitions, see Glossary of Terms.

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, and 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, the content of the ICF must also be consistent with the requirements of ICH E6; and,

4.2.4 for clinical research under health authority oversight, the regulatory authority requirements, as appropriate (such as, 21 CFR 50 for FDA-regulated research) must also be met.

4.2.5 The ICF must be consistent with the protocol and associated documents (such as the Investigator's Brochure).

As required, the protocol team is also responsible for associated or supporting documents (e.g., assents, participant information sheets, assessment of understanding questionnaires, etc.).

4.3 Contractor or Grant Recipient:
For studies under single IRB (sIRB), the Contractor 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 and associated documents 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 supported by DAIDS that meets the NIH definition of clinical trial, the informed consent forms and associated documents must also comply with the requirements of ICH E6.

5.3 For clinical research under regulatory authority oversight, applicable regulatory authority requirements must also be followed (such as 21 CFR 50 for FDA-regulated research).

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

5.5 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 Certiciates 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 Standard Procedures Documents

6.18 DAIDS 2017 Memo Regarding New DAIDS Requirements: Informed Consent Process

6.19 DAIDS 2018 Memo Regarding Timing of Consent and Re-Consent with Updated IRB/EC/RE-Approved Informed Consent Forms

7.0 APPENDIX

Not applicable

8.0 REVISION HISTORY

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.