1.0 PURPOSE

This policy describes the requirements for DAIDS clinical research sites (CRSs) to have written standard operating procedures (SOPs) to verify the ages and identities of potential participants before enrollment and identity throughout the duration of the study. Additionally, to preserve scientific validity and protect study participants, the SOPs will establish procedures for monitoring for co-enrollment where it is not allowed by the study protocol.

2.0 SCOPE

This policy applies to all National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS) supported and/or sponsored clinical trials except for clinical trials in which the only DAIDS involvement is providing study product.

3.0 BACKGROUND

The Division of AIDS sponsors clinical research that is compliant with the International Council on Harmonization Guidelines on Good Clinical Practice (ICH E-6 R2). Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. In accordance with ICH E-6 (R2) 5.1.1, the sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted, and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).

Eligibility criteria for protocols are developed to ensure the safety of research participants and reflect the scientific objectives of a study. Verifying participants age and identity is essential to compliance with the scientific design, legal requirements, and participant safety. In addition, verifying the identity of participants prevents co-enrollment, when it is prohibited by the protocol or in instances where co-enrollment would pose increased risk of harm based on safety, regulatory or ethical concerns.

Appropriate data sharing among DAIDS and non-DAIDS sponsored clinical research sites is essential for the prevention of study participants enrolling into prohibited clinical trials. Data sharing procedures must also be done in such a way that participants’ confidentiality is maintained.

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4.0 DEFINITIONS

**Biometric:** A method of verifying an individual’s identity based on measurements 778 of the individual’s physical features or repeatable actions where those features and/or 779 actions are both unique to that individual and measurable (FDA 21 CFR 11.3(b)(3)).

**Co-enrollment:** Concurrent enrollment of a participant in more than one clinical trial. Specifically, for this Policy the term indicates co-enrollment where it is prohibited by the entry criteria of the protocol(s). Where prohibited, co-enrollment can cause harm to the participant and can adversely impact the integrity of the studies involved. (DAIDS)

**Personally Identifiable Information (PII):** Any information about an individual maintained by an agency, including (1) any information that can be used to distinguish or trace an individual’s identity, such as name, social security number, date and place of birth, mother’s maiden name, or biometric records; and (2) any other information that is linked or linkable to an individual, such as medical, educational, financial, and employment information. (NIST)

**Validation of Computerized Systems:** A process of establishing and documenting that the specified requirements of a computerized system can be consistently fulfilled from design until decommissioning of the system or transition to a new system. The approach to validation should be based on a risk assessment that takes into consideration the intended use of the system and the potential of the system to affect human subject protection and reliability of trial results. (ICH GCP E6 R2)

See DAIDS Glossary for additional definitions.

5.0 RESPONSIBILITIES

Clinical Research Site Leader/Clinical Trials Unit Principal Investigator

The Clinical Research Site (CRS) Leader/ Clinical Trials Unit (CTU) Principal Investigator (PI) is responsible for establishing and implementing an SOP(s) for verifying potential participants’ age and identity before enrollment and throughout the duration of a study and for preventing co-enrollment when it is prohibited by the protocol(s). The processes developed for verifying participant’s...
Age and Identity Verification and Co-Enrollment Prevention

Clinical Research Sites

Clinical Research Sites (CRSs) that conduct DAIDS supported and/or sponsored clinical trials follow the written SOP(s) to verify the age and identity of each participant and to prevent co-enrollment of participants within the CRS and within the region each CRS operates.

DAIDS staff, including Office of Clinical Site Oversite Program Officers

The Office of Clinical Site Oversite (OCSO) Program Officer (PO) or designee is responsible for review and approval of the CRS’s initial SOP(s). Non-network site SOPs will be reviewed by the applicable DAIDS staff.

DAIDS Monitoring Contractor

The DAIDS Monitoring Contractor is responsible for verifying the SOP(s) is/are established and being followed at each CRS during routine monitoring visits.

6.0 POLICY

6.1 Each CRS will develop and maintain one or more SOPs to address:

1. Age and Identity Verification


6.1.1 The Age and Identity Verification SOP will describe the following:

• Steps that CRS staff will follow to verify the participants’ age and identity prior to screening and enrollment

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1 Clinical research sites that enroll children should have a written policy that addresses the actions to take when the child participant reaches the legal age of consent during his/her participation in the research. See the DAID Policy, Enrolling Children (including Adolescents) in Clinical Research: Clinical Research Site Requirements for additional information.

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Steps the CRS staff will follow to verify the participants’ identity at every visit throughout the study period.

Which CRS staff member(s) (by role) will conduct the verification process and how CRS staff will document the findings.

Which forms of identification (ID) are acceptable, such as government-issued documents, CRS-issued identification, or biometric measures.

See Appendix 1, Additional considerations for Age and Identity Verification and Co-Enrollment Prevention Standard Operating Procedures.

The Co-enrollment Prevention SOP will describe the following:

The measures put into place to prevent co-enrollment in other prohibited studies or studies that pose increased risks.

The process for obtaining co-enrollment information and how information will be disseminated about possible contraindicated clinical trials being conducted within the CRS, CTU, or among DAIDS and non-DAIDS sites and trials within the same recruitment area.

The procedures which will be used to cross-check potential participants within the recruitment area.

How the CRS will communicate enrollments with other DAIDS CRSs and non-DAIDS sites when appropriate and when allowed by local regulatory authorities.

Details on the frequency of the communication, documentation of information, and a plan to address confidentiality and privacy.
Details on inclusion of disclosure regarding co-enrollment process in the informed consent form (ICF) of each participating study.

Details on the approval requirements of the institutional review board/ethics committee (IRB/EC) for use of any electronic system.

Measures taken by the CRS for adjudication and resolution of identified cases of prohibited co-enrollment.

See Appendix 1, Additional considerations for Age and Identity Verification and Co-Enrollment Prevention Standard Operating Procedures.

6.2 The SOP(s) will be maintained as part of the CRS’s regulatory file and made available to monitors and inspectors upon request.

**7.0 REFERENCES**

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

FDA regulations on Investigational New Drug Application at 21 CFR 312

FDA regulations on Devices at 21 CFR 800-892

FDA E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry

**8.0 INQUIRIES**

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at: NIAIDOPCROPOLICYGROUP@mail.nih.gov

**9.0 AVAILABILITY**

This policy is available electronically on the

**10.0 CHANGE SUMMARY**

None

**11.0 APPENDICES**

Draft 0.10 02Aug2018
DAIDS
Bethesda, MD USA

POLICY

Age and Identity Verification and Co-Enrollment Prevention

Approval Date:         No.:  DWD-POL-
Effective Date:

Appendix 1- Additional considerations for Age and Identity Verification and Co-
Enrollment Prevention Standard Operating Procedures

12.0 APPROVAL