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## 1.0 PURPOSE

1.1 This policy describes the minimum requirements for retaining clinical research records for all DAIDS-supported clinical research, including DAIDS-sponsored clinical research, to ensure compliance with applicable regulations, guidelines, and policies.

## 2.0 SCOPE

2.1 This policy applies to clinical research records, both paper and electronic, that are generated during the conduct of, or stored and retained following the completion or termination of, National Institute of Allergy and Infectious Disease (NIAID) Division of AIDS (DAIDS)-supported clinical research including DAIDS-sponsored clinical research. Specific requirements for DAIDS' Network clinical research sites are defined in the DAIDS SCORE Manual.

2.2 This policy applies to all contractors and grant recipients who participate in DAIDS supported clinical research, including DAIDS-sponsored clinical research.

2.3 This policy does not address other Federal record retention requirements, such as requirements related to medical devices and administrative and financial records related to funding.

2.4 This policy does not address requirements for medical records and other requirements that apply to institutions that treat patients and conduct clinical research [e.g., record retention requirements under the Health Insurance Portability and Accountability Act (HIPAA)].

2.5 This policy does not address requirements that apply to marketing authorization holders [e.g., record retention requirements established in the Good Manufacturing Practice (GMP) guidelines].

## 3.0 DEFINITIONS

For definitions, see DAIDS Glossary

## 4.0 RESPONSIBILITIES

4.1 Institutions conducting DAIDS-supported clinical research, including DAIDS-sponsored clinical research:

For those clinical research records that are the property of the awardee institution, the institution is responsible for maintaining and retaining clinical research records in accordance with all applicable regulations, policies, and guidelines.

4.2 Contractors and Grant Recipients:

The recipient of the contract or grant award (awardee) and the recipients of their sub-awards, who generate clinical research records during the course of any DAIDS-supported clinical research, including DAIDS-sponsored clinical research, are responsible for ensuring that the records within the scope of this policy are maintained and retained in compliance with this policy and all other applicable requirements.

4.3 Clinical Trial Sponsor (Sponsor):

The Sponsor, its contractors, and grantees are responsible for maintaining and retaining all required clinical research records as required by local, national, regulatory regulations; NIH, NIAID and DAIDS policies, and all applicable guidelines, such as the International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6(R2).

## 5.0 POLICY

5.1 All DAIDS-supported clinical research, including DAIDS-sponsored clinical research, falls under the clinical research record retention requirements found in the U.S. Department of Health and Human Services (HHS) regulations for Protection of Human Research Subjects delineated in 45 CFR Part 46.115(b).

5.2 Consistent with section IV of the NIAID Clinical Terms of Award, applicable contract clauses (sections H and others), the protocol signature page, and globally accepted standards for clinical trials, records must be retained in compliance with ICH E6(R2).

5.3 In addition to the requirements above, if the clinical research is subject to FDA regulations, the record retention requirements delineated in 21 CFR Parts 56.115(b), 312.57(c), and 312.62(c) must be met. Any clinical research records that are in electronic format must also be compliant with the requirements delineated in 21 CFR Part 11.

5.4 If the clinical research is subject to a non-US regulatory authority [e.g., EMA, South African Health Products Regulatory Authority (SAHPRA), etc.], the applicable regulatory authority record retention requirements must also be met.

5.5 In circumstances where multiple sets of requirements apply, the most stringent applicable retention requirement must be followed. These additional requirements include national, state, and local laws as well as institutional policies which may extend the record retention requirement.

5.6 For trials that will be submitted to a regulatory authority to support the marketing of a pharmaceutical product, the Sponsor will work with the marketing authorization holder to enable the storage and retention of clinical research records per applicable requirements.

## 6.0 REFERENCES

6.1 HHS regulations for the Protection of Human Subjects at 45 CFR 46.115(b)

6.2 FDA regulations on Institutional Review Boards at 21 CFR 56.115(b)

6.3 FDA regulations on Investigational New Drug Application at 21 CFR 312.57(c)

6.4 FDA regulations on Investigational New Drug Application at 21 CFR 312.62(c)

6.5 FDA regulations on Electronic Records; Electronic Signatures at 21 CFR Part 11

6.6 ICH E6(R2)

6.7 NIAID Clinical Terms of Award https://www.niaid.nih.gov/grantscontracts/niaid-clinical-terms-award-guidance-compliance#IIA

## 7.0 APPENDICES

Not applicable

## 8.0 REVISION SUMMARY

8.1 DWD-POL-CL-006.02 is the last effective version of the Storage and Retention of Clinical Research Records Policy published on the DAIDS Clinical Research Policies webpage prior to the implementation of the DAIDS QMS in 2018.

The scope of the policy has been modified to define the minimum requirements for retaining clinical research records for National Institute of Allergy and Infectious Disease (NIAID) Division of AIDS (DAIDS)-supported clinical research including DAIDS-sponsored clinical research. All the appendices and information from the previous version that are out of scope with the revised version of this policy have been removed.

8.2 DAIDS-OPC-A15-POL-00015 rev 01 was revised on 08/23/2022 to reflect the current document format and document numbering requirements. The policy was also modified to: 1) revise the scope to indicate that site requirements are covered in the Score Manual, 2) remove for Investigator of Record (IoR)/Principal Investigator responsibilities since this is covered in the SCORE Manual, 3) replace the term "DAIDS Collaborator" with "contractors and grant recipients".