

Policy
Good Documentation Policy (GDP)

Effective Date: 03/23/21

Document No.: **POL-A15-OPC-014.00**

1.0 PURPOSE

1.1 This policy describes the standards for good documentation practices for National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS) sponsored clinical research conducted by DAIDS-funded HIV/AIDS clinical trial networks.

2.0 SCOPE

2.1 This policy applies to all clinical research - conducted by DAIDS-funded HIV/AIDS clinical trial networks for which DAIDS serves as the clinical trial/regulatory sponsor

3.0 DEFINITIONS

For additional definitions, see the [DAIDS glossary](#).

3.1 ALCOA+: Attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available.

3.2 Good Documentation Practices (GDP): Documentation that presents a clear set of work instructions that when followed prevents mix-ups and misbranding or adulteration of regulated materials and documents. Such measures that collectively and individually ensure documentation, whether paper or electronic, is attributable, legible, traceable, permanent, contemporaneously recorded, original and accurate.

3.3 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH): Is an initiative that brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical product development and registration. As it relates to GCP, ICH provides a unified standard for the European Union (EU), Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.

4.0 RESPONSIBILITIES

4.1 All individuals creating and executing clinical trial documents: Good documentation practice is the responsibility of all individuals involved in the creation and execution of clinical trial documents. These individuals are responsible for ensuring that all clinical trial documentation generated by them meet good documentation practice standards.

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- 4.2 Principal Investigator (PI)/Investigator of Record (IoR):
In addition to the responsibilities listed in 4.1, the PI/ IoR are responsible for ensuring that the site has a standard operating procedure (SOP) in place for good documentation. For electronic records, the PI/IoR is responsible for developing and maintaining a list of all authorized data originators, ensuring that access to electronic documents is password protected and that an audit trail of changes and deletions to electronic version of documents is maintained.

5.0 POLICY

- 5.1 Good Documentation Practice has been described in the form of ALCOA+ - attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available (known as ALCOA+). The European Medicines Agency has also included additional qualities (credible and corroborated) to describe good electronic source documentation. These attributes apply to both paper and electronic records and represent the foundation of data integrity (ICH E6 R2).
- 5.2 In addition to the requirements noted above, for electronic documents, each data element in an electronic record needs to be associated with an originator type, otherwise known as an authorized data originator. An authorized data originator could be a person, a computer system, a device, or an instrument that is authorized to enter, change, or transmit data into the electronic record.

6.0 REFERENCES

- 6.1 [E6 \(R2\) Good Clinical Practice: Integrated Addendum to International Conference of Harmonization \(ICH\) E6 \(R1\)](#)

7.0 APPENDICES

- 7.1 APP-A15-OPC-007 Good Documentation Policy Job Aid

8.0 REVISION HISTORY

- 8.1 POL-A15-OPC-014.00 is the original version of this policy.