

# MTN Good Documentation Practices (GDP) Policy

## Overview of GDP Requirements for MTN Site Personnel

*Adapted from MTN MOP Version 13.0, dated 31May2019*

*Prepared by FHI 360*

# Introduction

## MTN Good Documentation Practices (GDP) Policy

sets minimum standards for GDP compliance and applies to:

- All MTN clinical studies (biomedical or non-biomedical; IND or non-IND).
- All MTN study investigators, organizational units and functional groups involved in MTN research study development, management, communication, conduct, analysis or reporting.
- All MTN study source documents\*.

*\*Source documents are those original documents, data, recordings and certified copies of original records necessary for the reconstruction and evaluation of clinical (biomedical and/or behavioral) research studies.*

# Regulatory Requirements

- **ICH E6 Good Clinical Practice (GCP) Guidance, Sections 4.9, 5.5 and 8.0--**  
Timely, proper and thorough creation and maintenance of study records, documenting study management and data collection activities, is an ICH E6 Good Clinical Practice (GCP) requirement.
- **International Drug and Medical Device Industries Standards, referred to as Good Documentation Practices (GDP)--**  
While not law, compliance with these standards for creating and maintaining study records is expected by most, if not all, regulatory agencies; ex., Food and Drug Administration, European Medicines Agency, Health Canada and the World Health Organization.
- **DAIDS policies, DWD-POL-RA-03.00 and DWD-POL-CL-04.00, and their appendices--**  
Establish study documentation standards for all DAIDS Clinical Research Sites.

# Regulatory Consequences

- **Compliance with the documentation requirements** established by these three regulatory resources (ICH, GDP and DAIDS) is essential to establishing the integrity and reliability of any clinical research.
- **Failure to adequately and properly document a study**, in compliance with these documentation requirements can seriously impact the usefulness of the study data-- negatively impacting any regulatory agency's ability to accept the data in support of a marketing application.
- **The MTN Good Documentation Practices (GDP) Policy** sets minimum standards for GDP compliance and is intended to address and standardize issues that may be specific to MTN.

# Examples of Study Records

## Study records for sites requiring GDP compliance include, but are not limited to:

- CTU/CRS Policies & Procedures (SOPs)
- Personnel Qualification, Training Records, and Delegation
  - CVs, Training logs, DoD log
- Investigator Signature Pages
- All Regulatory Communication (IRB/IEC/ DRAs) including:
  - Submissions packets
  - Regulatory Approvals
- Contracts (all)
- Notices of IB Receipt
- Network/Site/Sponsor Communications\*
  - Notes-to-file (NTF), memos-to-file
- Study Source Data
  - ICFs, data collection materials, interview transcripts, worksheets, checklists, chart notes, etc.
  - Logs: screening and enrollment, PTID-name link, randomization
- All specimen and assay data, including repeat or reanalysis performed for a test sample
- Investigational product accountability
- Protocol Safety Physician decisions, e.g. PSRT query responses
- Monitoring/assessment/audit visit logs
- All documents required by ICH E6(R2)

*\*Relevant to significant decisions regarding study development, management, conduct, analysis and/or reporting.*

# Approval of Electronic Systems

- **Only pre-approved electronic systems/software** may be used to create, sign, date, track and/or store study records. Approval must be documented and obtained as delegated by the applicable CRS or Network organizational unit (CRS/CTU, SDMC, LC or LOC).
- **The approval of electronic systems/software**, having the potential to impact the rights, safety and well-being of study participants and/or the quality and integrity of study data, must be based on their prior successful validation and their compliance with the requirements of 21 CFR Part 11 and CPMP/ICH/135/95.
  - Certain MTN organizational units provide approved electronic systems for shared use, such as Medidata Rave, the Laboratory Data Management System and the HANC Financial Disclosure Database (see MOP Section 22 for others).
  - MTN members and Clinical Research Sites may use these systems as directed, if permitted by their institutional SOPs and policies.

# Study Record Collection and Storage

- **In the absence of an appropriate, validated electronic system**, which is compliant with 21 CFR Part 11 and CPMP/ICH/135/95 for maintaining electronic study records:
  - Study records will be collected and stored in both paper and electronic form, in a timely manner.
  - Both paper and electronic files will be maintained in secure, limited access files which are protected to the extent possible from physical damage and loss.
  - Final versions of electronic files will be routinely backed up and original date/time stamps (metadata) will be maintained.
- ✓ **TIP:** *If documents or files must be moved to a different e-address, they should be copied but not saved to the new location. “Copy” will preserve the original metadata; “saving” will change the metadata.*

# Study Record Collection and Storage

- **Maintain all study records, including paper files, electronic study data, electronic documents and audio files of interviews, on site for the entire period of study implementation and for an extended period after study completion or discontinuation according to the study protocol.**
- **Study records must be available and accessible for possible DAIDS, MTN, product sponsor or regulatory authority inspection or review.**



# Creation of Study Records

**Objective:** All study documentation will be **Attributable, Legible, Contemporaneous, Original, Accurate and Complete (ALCOA-C)**.

## **Procedures for creating and collecting study records:\***

- Collect and store records in paper and electronic form, in a secure and timely manner.
- Source documents must be hand-signed/initialed and hand-dated by the author and, when appropriate, by the person under whose authority the information has been generated (i.e. final approver).
  - Hand-written initials (rather than signature) and hand-written dates may be used, unless prohibited by DAIDS or your institution, when a Signature Log is maintained as part of the study record (*see Signature: Best Practices slide 13*).
  - If factual information has been verified by a second individual, this person also needs to hand-sign and hand-date .
  - All roles (authorship, approval, verification) should be indicated.

\* *Applies in the absence of using an approved electronic system (e.g. Medidata).*

# Creation of Study Records

**Objective:** All study documentation will be **A**ttributable, **L**egible, **C**ontemporaneous, **O**riginal, **A**ccurate and **C**omplete (ALCOA-C).

## **Procedures for creating and collecting study records:\***

- Electronically-generated source documents must be printed and certified (see *Creating Certified Copies' slide 12*).
- Electronic records will be created from paper source documents by scanning them into limited access files.
  - Multiple page documents should be scanned as a single record.

*\* Applies in the absence of using an approved electronic system (e.g. Medidata).*

# Document Versioning and Control Essentials

- **All site-created documents** should include the following components in the header or footer of each page:
  - **MTN Study #:** Where appropriate.
  - **Document Title/Name/Subject:** Full name at top of the 1<sup>st</sup> page; abbreviated name may be used in place of full name in header or footer of subsequent pages.
  - **Versioning:** Version number and effective/change date. This must be updated for every change; no matter how minor; and, all finalized versions must be maintained.
  - **Pagination:** Formatted as “page n of X” (where n is the current page number and X the total number of pages).
- **Attachments:** List all attachments by title/subject, version (where applicable), date and total number of pages.
- **Approvals:** Signed/initialed and dated by the author (*see Creation of Study Records, slide 9*).
- **Dates:** Should be consistently recorded according to the specific format designated by the policies and procedures of your institution.
- ✓ File final documents as PDF to maintain document attribution and prevent alteration.

# Creating Certified Copies

**Certified Copy:** A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature) as a true copy, having the same context, content and structure, as the original.

- Single page documents: Write a circled “C” on the copy, hand-sign and hand-date.
- Multiple page documents:
  - Write a circled “C” on each page of the copy.
  - Hand-sign, initial and hand-date the first page (incl. page n of X if needed).
  - Initial and hand-date each subsequent page (incl. page n of X if needed).
  - Each page must be certified, even when photocopied to the back of the preceding certified page.
- A “Certified” stamp may be used in place of the circled “C” if approved by the policies and procedures of your institution.
  - ✓ **Tip:** *Leave space or make a field for the certification mark/stamp and initial & date on documents that are typically certified.*

# Signature: Best Practices

Documents that require signature should include the following components:

- **Printed/typed name**
  - Underneath or next to signature. *Hand-write with black or blue ink only*
- **Title/role** (*optional*)
  - Best included if the document is not study-specific and/or the signatory is not listed on the study Delegation of Duties (DoD) log.
  - Specify authorship, verification or approval roles as applicable to the document type.
- **Hand-written signature and/or initial** as applicable for the record type
  - If the signatory is delegated on the study DoD to sign/initial the document, ensure the signature/initial matches that on the DoD log.
  - Documents circulated outside of the immediate group (i.e. those without access to the DoD) should be signed rather than initialed.
- **Date of signature**
  - Indicate the format used (e.g. DD/MM/YYYY). Never back-date.

**Examples of signed documents:** DoD, SOPs, Investigator Signature Page, NTFs, training logs, CVs, ICFs, Eligibility Checklists, Financial Disclosure Forms

# Initials: Best Practices

- Initials for all study team members should be unique; i.e. no two staff members should have identical initials.
  - Use middle initials and/or numbers as needed (e.g. “AJM” or “AM1”, “AM2”).
  - If per site practice, staff to include employee ID number with initials.
  - Include initials (and employee ID, if applicable) on DoD and use initials consistently throughout study documentation.
- Multi-page documents requiring verification on each page.
  - Sign, initial, and date first page.
  - Initial and date each subsequent page.
  - Examples: CVs, memos, certified copies.
- Examples of initialed and dated documents.
  - Bottom of each page (e.g. Paper CRFs, worksheets, eligibility checklists).
  - After each entry (chart/counseling notes) .
  - For each checklist, initial each item and ensure completion date is on each page. If a item is completed on a different day, include both initial and date beside the item.

*Hand-write with black or blue ink only*

# Modifications to Hard Copy

All modifications made to study source documents (hard copy) should be made per GCP/GDP practices:

- **Corrections:** Clear, hand written in black or blue ink, single line through original entry for a correction and include initial/date and, where appropriate, an explanation of the change. Never obscure the original entry.
- **Updates/Additions:** Initial and date new information

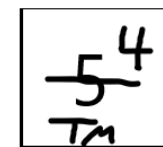
## Examples:

- Changes to a DoD
- Corrections to paper source documents including visit checklists, worksheets, chart notes, etc.
- Clinician review of lab report

Incorrect



Correct



2Jan18

# Modifications to Electronic Files

All modifications made to electronic files should also be made per GCP/GDP practices:

- **Never destroy or overwrite the original file. The original file is a permanent part of the history of the study.**
- Update the version # or add the word “revision” and include the date of the change in the header or footer.
- Provide or reference an explanation for the change, when needed; e.g., policy change, operational guidance, updated sample template.
- If the version being replaced was signed, such as for approval, authorship or verification, collect new signatures in the same format.

## Examples:

- Changes or annual updates to SOPs
- Changes to study document templates
- Changes to ICFs



# Resources

## References/Resources:

- [MTN MOP](#)-- Section 1.4, 9.2, 11.4, 13.3
- [ICH E\(R2\) GCP](#)
- [ALCOA-C Guidance](#)
- [DAIDS policies, DWD-POL-RA-03.00 and DWD-POL-CL-04.00 and appendices](#)
- [CFR Title 21](#)
- Site SOPs
- Site Quality Management Plan (QMP)

**Contact your FHI 360 CRM** with any questions or to seek advisement or review of documents for GDP compliance.

