# 

# A PURPOSE

# To define acceptable Good Documentation Practices (GDP) for completion of research records in accordance with federal regulations and Good Clinical Practice.

# B. SCOPE

# This procedure applies to documentation associated with any medical research study at the University of Arizona.

# 

# C. RESPONSIBILITY

# Principle Investigator as well as research staff involved with obtaining and recording documentation for study trials should follow the requirements of this SOP.

# D. DEFINITIONS

**GDP**: Good Documentation Practice

# 

# E. PROCEDURE

# Types of documents requiring GDP include but are not limited to:

|  |  |  |
| --- | --- | --- |
| Hospital records | Informed Consent Forms | Laboratory results / notes |
| IRB Correspondence | HIPAA Authorization forms | Test results (X-Ray, MRI, etc) |
| Subject diaries | Visit / Contact notes | Questionnaires |
| Evaluation checklists | E-Mail | Surveys |
| Clinical and office charts | Certified copies | Sponsor correspondence |
| Case report forms - only if data are entered directly | Pharmacy dispensing records | Medical records supplied by the subject |
| Medical records created throughout the study | Memoranda | Recorded data from automated instruments |

# Key Attributes of Good Documentation Practice (ALCOA-C)

# Attributable: It should be clear who has documented the data.

# Legible: It should be readable, and signatures should be identifiable.

# Contemporaneous: Information should be documented in the correct time frame, along with the flow of events. If a clinical observation cannot be entered when made, chronology should be recorded. Acceptable amount of delay should be defined and justified.

# Original: The first record made by the appropriate person.

# Accurate: It should be accurate, consistent, and a real representation of facts.

# Complete: Research team should maintain adequate, accurate and complete source documents.

# 

# Documentation Problems

# Common documentation errors include:

# Missing data / documentation

# Missing dates

# No initials or signature (who documented data)

# Missing subject identifiers

# Scribbled out / white out

# Illegible.

# No explanation for changes

# Documentation Best Practice

# If correction is necessary, draw a single line through the error. Ensure that the original data remains clear, visible and legible. No information should be obscured by any means. In addition, the correct data should be written next to the incorrect data along with initials, date, and a brief explanation of the reason for change. Do not change data without knowledge that the change is correct.

# All entries should be made with black or blue ball point pen.

# Correction fluid (e.g., white-out) or equivalent, is not permitted.

# Explanations in records relating to deviations or violations must be explicit and attributable.

# All sections of the document must be completed or include an explanation as to the reason why a section was not completed

# Any areas that are not applicable should have ‘N/A”.

# All spaces of the document should be completed.

# Avoid writing in borders or margins.

# Hand written amendments to controlled documents (protocol) are not permitted.

1. Do not reuse scrap paper or post-it notes for recording any data.
2. If any document/page must be changed due to legibility, it can be reissued, and the original page should be retained with the file note that the document has a “duplicate page.”
3. Entries should never be post-or pre-dated.

# Where check initials are used rather than a signature, a record should exist to demonstrate who the initials belong to (i.e. delegation log).

# Reasons for corrections can be stated with a short simple justification, such as:

|  |  |  |
| --- | --- | --- |
| Recording error | Technical error | Spelling error |
| Late entry | Wrong date | Dosing error |
| Calculation error | Transcription error | Malfunctioning equipment |
| Erroneous entry | Repeated data | Miscalculation |
| Not legible | Original entry ok | Clarity |

# F. REFERENCES

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

<https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf>

Guidance for Industry Electronic Source Data in Clinical Investigations

<https://www.fda.gov/downloads/drugs/guidances/ucm328691.pdf>

Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects

<https://www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf>

Bioresearch Monitoring Clinical Investigators and Sponsor-Investigators

<https://www.fda.gov/downloads/iceci/enforcementactions/bioresearchmonitoring/ucm133773.pdf>

# G. HISTORY

|  |  |  |  |
| --- | --- | --- | --- |
| **Effective**  **Date** | **Version #** | **Authors** | **Description** |
| 04/01/2018 | 000 | Blanca Pernic | New procedure describing GDP |
|  |  |  |  |