Guidance: Good Documentation Practices

Overview

Conducting ethical and compliant human subject research depends on multiple factors, one being the ability to collect accurate, reliable, and reproducible data. To ensure a good dataset, members of the research team should be educated on Good Document Practices (GDP) to remain compliant with the approved IRB protocol.

This document details items to consider when implementing Good Document Practices (GDP).

Definition

GDP is essentially good recordkeeping practices to help ensure the data's quality, accuracy, and integrity**.** Although more commonly referred to in biomedical settings (e.g., pharmaceutical, laboratory, etc.), these practices apply to all types of research, including social, behavioral, and educational research.

Key Elements of GDP

The key principles detailed below guide the research team on how data should be recorded, retained, and modified/

Accurate & Attributable
Study documentation should be correct, free from errors, consistent, and a representation of facts. This ensures that research h documents are a reliable source of information. Documents should include the individual; who recorded the data and/or information and when the event occurred.

Auditable: ensure all missing data points are noted and explained in the protocol file.

Clarity & Completeness: Study documentation should be precise, complete, and comprehensive. Research documents, including signatures, should be legible and identifiable.

Consistent: Follow a process that is consistent among all members of the research team.

Continuous Improvement: Implement periodic quality assurance checks to ensure processes are consistent and members of the research adhere to GDP. Modify practices when necessary and implement them after the modification receives approval. Report any inconsistent practices to the IRB as they are identified.

Protected and Secured: All research documents are to only be accessible by authorized individuals. Consider where material is stored and anyone outside the research team will have access to the confidential documents.

Timely: Documents should be up-to-date and information recorded as it happens. Do not pre- or backfill dates. All events are to be recorded in real-time by the originator.

Traceable: In the event modifications to documents are needed, ensure that these corrections are made, and a memo is included in the protocol file for documentation and to serve as an audit trail of edits. The changes should not obscure the original entry. Draw a single line through the incorrect information, correct it accordingly, and initial and date the document. Do not white out, cross out entirely, or remove the original data recorded.

Retention and Destruction: Adhere to the approved protocol and retain identifiable documents only for the allowable period and destroy documents securely when they are no longer needed,

References & Resources

CITI Course – Biotility: Good Documentation Practices
Exploring good documentation practices (PandaDoc blog)
NIH (NCI): Good documentation practices SOP, 101 Good documentation practices, SOP
The Ohio State University
University of Rochester, OHSP