

Checklist of Scientific Record Keeping Best Practices

Scientific records can be kept in various forms – Bound notebook, Loose-leaf notebook, electronic notebook (ELN) – PIs should specify to scientific staff and trainees their preference.

All notebooks and data are owned by the NIH, but may be copied (without personal identifiers if human data) at the discretion of the supervisor.

Regardless of the form of record keeping employed, ***all*** records need to be:

- Dated, at least month and year
- legible
- well-organized
- clear
- timely
- thorough & complete
- secure & backed-up

All entries should be in English

Useful & good research records should include the following detail:

- What you did – experimental protocol
- When you did it - date
- Why you did it – objective
- How you did it – methods
- Who you are (the person creating the record)
- What project(s) this work was part of
- Who conceived of the study (if not yourself)
- Special materials & instruments utilized
- Source of materials & instruments
- Discussion of data – results – expected and unexpected

- Data handling and analyses
- Data interpretation by yourself (and others if pertinent)
- Next steps based on reported results

Special considerations for documentation of Clinical Research:

- Clinical studies regulated by the Food and Drug Administration (FDA) must follow Good Clinical Practice and adhere to specific guidelines found in 21 CFR parts 11, 50, and 312
- Patient privacy and confidentiality must be kept with civil and criminal penalties for violating the Privacy Act
- Principal Investigator is responsible

Clinical Research Practice requires:

1. Documentation of clinical care rendered to subjects and clinical findings
(medical records)
2. Documentation of research procedures and results (research records)
Often these records overlap