

### ***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