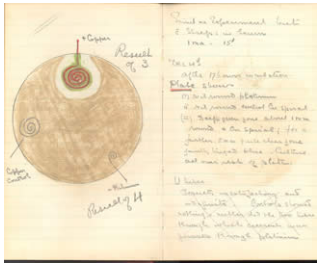
Scientific Record Keeping

Janet Clark, Ph.D.
Director, Office of Fellowship Training
NIMH DIRP

Reasons Good Record Keeping is Critical in Scientific Research



- Data analysis, writing publications, drafting presentations/posters, collaboration, peer review, data replication
- Required by NIH to meet accepted policies and standards for conduct of good science
  - Including specialized record keeping required for radioactive materials, biological materials, recombinant DNA, scheduled drugs for DEA, Food and Drug Administration (FDA), animal work
- To support intellectual property claims
  - Proof of conception of invention
- To aid in defense against false allegations of research misconduct
- Care of human subjects
  - Particularly high standards for research involving human subjects
  - Maintenance and access of records scrutinized
  - Confidentiality is key

What is data?

Definition of data:

"Factual information (as measurements or statistics) used as a basis for reasoning, discussion, or calculation." (***The Merriam-Webster Dictionary)***

For the purposes of scientific record keeping laboratory data include:

- Tangible data such as gels, slides, photographs, and computer printouts
- Calculations, statistical analyses, sample keys, etc.
- Intangibles such as observations, conclusions and next steps

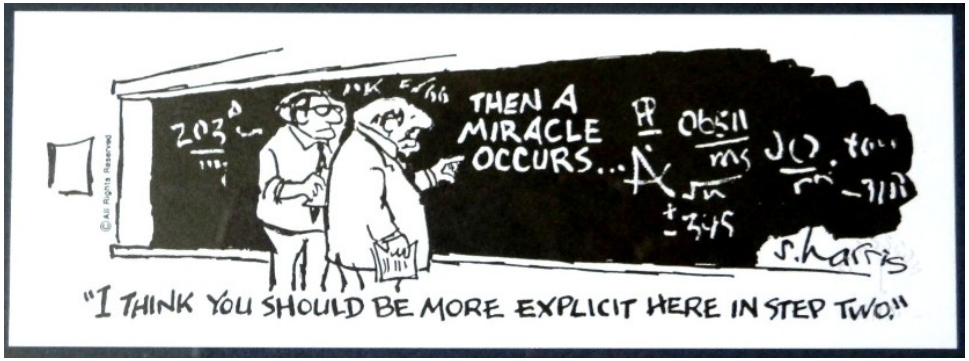
A laboratory notebook is a record of both ***physical*** & ***mental*** activities.

Scientific record keeping best practices

Scientific records can be kept in various forms.
Regardless of the form you choose to use, ***all*** records need to be:

- legible
- clear
- timely
- thorough
- complete
- secure
- backed-up
- well-organized

All entries should be in English.



Scientific record keeping best practices

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

Scientific record keeping best practices

Additional considerations for useful & good scientific research records:

- Legible (if handwritten)
- Well organized – labeled, indexed, catalogued, etc.
- Accurate & complete – include (1) original data and important study details (meta-data) and (2) successful & unsuccessful studies and activities
- Describe and date ***all*** alterations and changes to records
- Records should allow repetition of procedures and studies by yourself & others
- Are accessible to others (physically and/or electronically) both short and long term
- Are stored and backed-up properly and regularly for the short & long term (archiving)
- Are witnessed where needed to protect intellectual property rights
- Are research diaries of the researcher's work & thoughts

Research record retention

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.

Formats for scientific record keeping

- ***Bound notebook***
  - Data kept in a linear format with no skipped pages
  - Errors lined through, initialed and dated
  - Data accommodated by affixing to pages or separate storage with indexing
  - Backup requires carbon copy
  - Requires legible handwriting or affixed computer printouts
  - Affixed data and printouts should be signed across the page and data

- ***Loose-leaf notebook***
  - May be used as supplement to bound notebook to contain original data (X-ray films, photos, gels, electronic printouts, etc.)
  - Allows use of preformatted data sheets
  - Loose sheets should be dated and immediately added to binder, in chronological order, to meet standards of good science and to assure research integrity

Formats for scientific record keeping

Electronic notebook

- Collection of data files from ordinary programs
- Notebook-like-systems requiring special commercial software
- Allows for sharing of data – security an issue
- Mechanisms needed to assure no alteration of data
- Automatic and regular archiving of data needed

Pros

- Searching capabilities
- Linking between pages, studies, etc.
- Sharing of data within and across institutions with permissions
- Interoperable – can read data directly from instruments into ELN
- Audit trail recorded – with revision history and eSignatures
- Drawing tools
- Plugins
- Access of notebook from outside of the lab – without removing from the lab
- Generally customizable

Cons

- Bugs, upgrades and other digital issues
- Effort to transition
- Data storage – location (cloud or in house) – ownership
- Data security and backups – requires a reliable system
- Unsettled ELN market – survival of ELN support

Intellectual property considerations for scientific record keeping

A bound or appropriate electronic notebook should be used and must include:

- Subject matter
- Experimental details
- Sketches, diagrams
- Study descriptions
- Study results
- Explanation of results
- Succinct conclusions supported by factual data

Electronic & bound notebooks should be reviewed and entries witnessed regularly, & signed and dated by the witness

* Witness may not be a co-inventor, but should be familiar with the work

Intellectual property considerations for scientific record keeping

Bound notebook considerations:

- Sign & date inside front cover
- Sign & date each entry
- Entries made in ink – ball point
- Entries made in chronological order
- Corrections made by lining out entry, signing and dating
  - ***NO*** whiteout or erasing
- Consecutive pages used
- Photos, drawings, etc. identified, labeled, permanently affixed and both attachment and notebook page signed
- Data stored in a supplemental notebook must be indexed in the bound notebook on the appropriate page of the study

Electronic notebook considerations:

- Regularly backed up
- Entries dated and locked
- Appropriate IT security
- Authenticity and verification capabilities

Record keeping in 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 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)

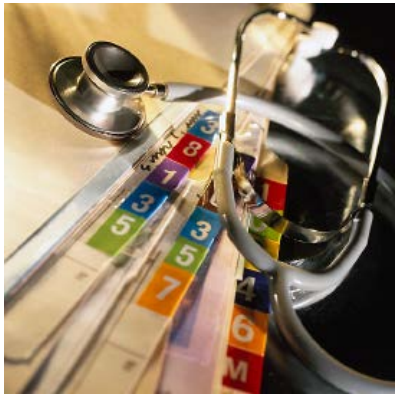
Often these records overlap

Record keeping in clinical research

Medical record/Clinical documentation

- Complete and accurate record of patient's condition & treatment with diagnosis, assessment, treatment/services, clinical course/response, adverse events
- Ensuring organization and continuity of care
- Clarifying communication between health care providers
- Providing clinical data for evaluating health care operations and use of resources
- Affording risk management and malpractice protection
- Complying with legal, regulatory, & institutional requirements

All documentation must have date/time, be legible and signed, be completed in a timely manner and avoid unacceptable abbreviations



Record keeping in clinical research

Clinical research records

- Must be handled to preserve privacy and confidentiality of research subjects
  * Can be done by removing identifiers and using identifying codes
  * Store codes safely and separately from data
- Protect in accordance with the Privacy Act
- Electronic records must be password-protected and encrypted on laptops, tablets and smart devices

Regulatory binder

- All essential documents that demonstrate the investigator, sponsor, and monitor have complied with standards of good clinical practice and all regulatory requirements
- Easy access to essential documents by trial monitor, auditor, IRB or regulatory authorities for review and/or audit

Record keeping in clinical research

Drug accountability records

- Record of administration of all study drugs even those self-administered
- Investigator is responsible for record keeping of distribution of drug, maintenance of drug accountability records (receipts/invoices from shipments and drug accountability reference forms (DARFS))

Research record retention

- All research-related records retained for at least 2 years after study completion
- Investigational new drug (IND) study records must be retained for 2 years after approval of drug marketing application or withdrawal of IND, or as indicated by sponsor
- NO NIH records may be destroyed unless consistent with NIH policies governing record maintenance and retention and applicable regulations

References

Guidelines for Conduct of Research in the Intramural Research Program at NIH (4th Edition, 2007) National Institutes of Health, Office of the Director
https://www.training.nih.gov/nih_resources

Guidelines for Scientific Record Keeping in the Intramural Research Program at the NIH (1st Edition, (2008) National Institutes of Health, Office of the Director
https://www.training.nih.gov/nih_resources

Guidelines for Responsible Data Management in Scientific Research
Clinical Tools, Inc. (2006; Funded by ORI, DHHS)

A Review of Electronic Laboratory Notebooks Available in the Market Today
Rubacha, M. et. Al. (2011) JALA, 16: 90.