

Guidelines for
SCIENTIFIC
RECORD KEEPING
in the Intramural
Research Program
at the NIH

Preface

The progress and excellence of NIH research are dependent on our vigilance in maintaining the highest quality of records for every aspect of the science conducted here. It is important that every Principal Investigator involved in research at NIH ensures that all scientific staff working with him/her read, understand, and incorporate the Guidelines for Scientific Record Keeping into everyday practice. These Guidelines set forth the general principles underlying record keeping that are necessary to support the conduct of good science and address needs arising from the rapid growth of alternative record keeping methods, the increasing complexity of research data formats, and the influx of scientific trainees with diverse backgrounds. Accordingly, the Guidelines should assist both new and experienced investigators as they work together to ensure that all research carried out in the Intramural Research Program is backed up by appropriate scientific record keeping.

The Guidelines were prepared by the intramural scientists on the NIH Committee on Scientific Conduct and Ethics in response to their recognition that not all scientists have received appropriate training in how to maintain excellent scientific records. The Scientific Directors have approved the Guidelines.



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Introduction

Good science requires good record keeping. Good record keeping promotes both accountability and integrity in research. Good records are complete, accurate and understandable to others. Records of research activities should be kept in sufficient detail to allow another scientist skilled in the art to repeat the work and obtain the same results. Each member of a research group is responsible for his/her own research records while the principal investigator has the ultimate responsibility for the laboratory's records. It is also helpful to remember that any records of research conducted by NIH scientists are the property of the NIH.

There are at least five reasons why it is important to keep good records in scientific research:

1. Good record keeping is necessary for data analysis, publication, collaboration, peer review, and other research activities.

Research records can help you to communicate with members of your research team and collaborators, brainstorm for ideas, draft or revise your research plans. When it is time to publish or present your research, you need to be able to find the data that support your conclusions and analyses. Editors and reviewers may also request additional data beyond what you submit. After publication, you may need to deposit your data in a data registry and share it with colleagues who want to repeat your experiments or examine your work more closely.

2. Good record keeping is required by the NIH to meet the accepted policies and standards for the conduct of good science.

In addition, Federal regulations governing research that includes, but is not limited to, the use of hazardous radioactive or biological materials, recombinant DNA, products regulated by the Food and Drug Administration, or animals, have additional specific record-keeping requirements. NIH investigators need to be aware of all applicable record-keeping requirements which apply to their research and comply with them.

3. Good record keeping is necessary to support intellectual property claims. If you are conducting research that may be patentable or involves intellectual property, you need records to support your patent application or to defend your patent or invention if it is challenged. Good research records can prove that you were the first person to conceive of an invention.

4. Good record keeping can help defend you against false allegations of research misconduct. Misconduct allegations commonly arise when other scientists are unable to repeat published research. Often the underlying reason for this failure is that the original research was not described in sufficient detail. While good research records cannot prevent you from ever facing allegations of misconduct, they can help you to refute them.

5. Good record keeping is important in the care of human subjects. High standards of record keeping are particularly important for research involving human subjects, be they patients or healthy controls. How investigators maintain records, particularly those involving personally identified and/or sensitive information, is also important, as are the rules/procedures that apply for access to such records. For example, Federal regulations require Institutional Review Boards (IRBs) to examine, and IRBs in turn require investigators to address before approval, how the confidentiality of records and the privacy of research subjects will be protected.

A useful resource for further information on record keeping is the *Guidelines for the Conduct of Research in the Intramural Research Program at NIH*. <http://www1.od.nih.gov/oir/sourcebook/ethic-conduct/Conduct%20Research%206-11-07.pdf>

Elements of ALL Good Laboratory Notebooks and Record Keeping

A laboratory notebook is a record of both physical and mental activity. Laboratory data include tangible data such as gels, slides, photographs, and computer printouts as well as intangibles such as observations and conclusions. Data may occur in different forms such as gels or photos of gels, scans of peaks, and quantitation of peaks, all of which are important to preserve.

Records may be kept in bound or unbound notebooks, electronic files, or other formats. Any human subjects records kept and retrieved by personal identifier must meet the requirements of the Privacy Act and other NIH policies applicable to such records as well as IT security requirements. You should check with your supervisor or lab/branch as to the preferred format. Many disciplines use a combination of paper and electronic records. Although styles and forms of record keeping vary among different disciplines, some common principles apply to all. **Records should be legible, clear, timely, thorough, complete, secure, backed-up, and well-organized. All entries should be in English.**

Records should describe or explain:

- Who did it (the person making the record).
- What you did.
- When you did it (clearly stating month, date and year).
- Why you did it.
- What project the research was part of.
- How you did it (including the methodology).
- What materials were used.
- The findings.
- Your interpretation.
- The next step.

Data should be recorded in ways that cannot be altered. Records also should be protected from destruction (ranging from fading caused by sunlight or flooding to computer crashes).

The original records should be retained in accordance with the guidance provided in the *Guidelines for the Conduct of Research in the Intramural Research Program at NIH*, as well as applicable regulatory and record retention requirements. All notebooks and data are owned by the NIH, but may be copied (without personal identifiers) at the discretion of the supervisor.

The Bound Notebook

One format for a lab notebook is a bound volume with numbered pages. Data not easily accommodated in this format (tissue sections, original microscope photos, computer printouts, X-ray films) may be kept in separate storage, clearly indexed to the lab notebook. A Table of Contents listing experiments and a list of abbreviations should be included at the beginning. Data should be kept in a linear fashion without skipped pages (except for the pages initially left blank at the beginning for the Table of Contents). Errors should be lined through with a single line, never erased or obliterated. If corrections are made to previous entries, they should be initialed and dated.

Advantages:

- Easily portable.
- Simple tools (e.g., book and pen).

Disadvantages:

- Not easily searchable.
- Requires reference to other data storage places such as those for sequence data, slides, and microscope photos.
- May not have backup unless copied on routine basis or carbon-copied.
- Requires legible handwriting.

The Loose-leaf Notebook

The use of a ring binder and loose-leaf sheets is another acceptable form of laboratory notebook for many academic investigators. Loose-leaf notebooks may also be used as a supplement to bound notebooks in order to contain original data – e.g., X-ray films, data sheets and electronic printouts. Using a loose-leaf notebook as an adjunct to a bound notebook necessitates appropriate and perhaps redundant references or keys to link the data and experimental protocols. **Loose sheets should be dated and immediately added to your binder, in chronological order, to meet the standards of good science and assure research integrity.**

Advantages:

- Allows for the use of pre-formatted data sheets, which helps to keep data consistent over time, and makes for easy retrieval and comparison of information.
- Allows primary data (X-ray films, pictures, gels, “reader” print-outs) to be kept adjacent to experimental entries, using heavy weight plastic sheet protectors and/or reinforced paper that can be inserted into notebooks in close proximity to experimental protocols.

Disadvantages:

- Not easily searchable.
- May not have backup unless copied on routine basis or carbon-copied.
- Requires legible handwriting.
- Pages may “fall out” – this can be remedied by the use of “reinforced hole” paper.

The Electronic Notebook

An electronic notebook is a system to create, store, retrieve and share electronic records. Instead of recording information on paper, the sketches, text, equations, images, graphs, and other data are recorded electronically. Adding to an electronic notebook can involve input from keyboard, other program output, imaging equipment, microphone, and directly from scientific instruments. Electronic notebooks can range in capability and complexity from the simplest types, that use ordinary software (word processing, spreadsheet, graphics) on one's computer to annotate and keep track of data files, to more notebook-like systems, to special commercial software for authentication.

Electronic notebooks allow easier input of scientific data, uniform formats for data recording, and the ability for collaborators to share and add to the record. Commercial electronic notebook software varies in how much it “looks and feels” like a paper notebook, but includes all functions of a paper notebook. If personally identifiable and/or sensitive data are involved, appropriate Privacy Act and IT security standards must be met.

The security of electronic records, including access to a particular electronic notebook, its contents, and authentication of entries in a notebook, is a fundamental issue that must be addressed. Every electronic notebook has a list of authorized users, one of whom should be the NIH supervisor. A group notebook may be set up for collaboration on a project. Mechanisms to ensure that data are not altered after entry are important. In commercial software this can be done automatically and the signature can be digitally authenticated. If notebooks use common software that does not provide for automatic archiving, the notebook should be stored on a secure NIH server with daily backups for archival purposes. IP issues are then addressed with periodic printouts of important data that are signed and witnessed so that in the event

the data become the subject of a patent dispute, they can be more easily authenticated to the satisfaction of a court or administrative body. Unwitnessed data are more likely to require later testimonial corroboration in the event of a patent dispute.

Advantages:

- Searchable.
- Legible.
- If appropriately backed up, cannot be misplaced, lost, or accidentally destroyed (see Electronic Data Storage and Accession, p.10).
- Easier to incorporate computer files, plots, images, movies, etc.
- Can collect data directly from lab instruments.
- Enormous amounts of data can be stored in a small space.
- Can be password protected as well as meet other security requirements, such as encryption, if data are sensitive or personally identifiable.
- Lab members can use a uniform system of records.
- Can be shared by a group of researchers at NIH
- Can be accessed remotely.

Disadvantages:

- Requires access to a computer and ability to use software programs.
- Requires encrypted laptop for easy portability to places of data collection.
- Risky in environments subject to thefts or spills.
- Data entry by keyboard is subject to transcription errors.
- Data can be lost/erased if not backed up.
- Data may become inaccessible due to discontinuance of software/media.

Electronic Data Storage and Accession

More and more, data collection and handling generate electronic files (digital photographs, data spreadsheets, output of statistical, mathematical and other modeling programs). Regardless of what type of laboratory notebook is used, it is essential to keep the original electronic data as well as the modified electronic files. Two important issues that need to be considered are the type of media used and indexing of the files.

Media

Files can be kept on internal or external hard drives, CDs or DVDs, tapes, or flash drives – no one knows what the favorite media will be tomorrow. It is recommended that there be more than one copy, stored in different approved places. NIH has remote sites that accept archival material. Whatever medium is chosen, it is important to make sure that the medium is reliable and that files can still be read at a later date.

Indexing

A record of data locations must be maintained. That can be accomplished by entering the information in a database (which also needs to be maintained and backed up properly). Some new versions of modeling packages self-index the files that are created. There are commercial database systems where the backup may be done automatically.

Record Keeping in Clinical Research

The principles guiding record keeping in clinical research are the same as those guiding record keeping in preclinical research, although their practical implementation may vary. In particular, paper and electronic records generated by 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. In contrast to pre-clinical data, clinical data carry the additional responsibility of patient privacy and confidentiality as well as the civil and criminal penalties associated with violations of the Privacy Act. The principal investigator of a study has ultimate responsibility for the clinical research records.

Two types of records must be maintained in clinical research practice:

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

These two types of records often overlap.

Source documents are the original “raw” data that document the existence of the subject, what was done or observed, by whom, when, and with what effect.

Medical Record/Clinical Documentation

The purposes of clinical care documentation include:

- Providing a complete and accurate record of the patient’s condition and treatment, including diagnosis, assessment, treatment/services, clinical course/response, and adverse events.
- Ensuring organization and continuity of care.
- Clarifying communication among 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, and institutional requirements

All patient encounters and clinically relevant information should be documented in the medical record. This ensures that good practices are followed AND that source documentation is available as needed for data abstraction, a monitoring visit, or an audit. All documentation must include the date and time, be legible and signed, be completed in a timely manner and avoid unacceptable abbreviations. Procedures for charting in the NIH Clinical Center medical record can be found in the Medical Records Handbook (<http://intranet.cc.nih.gov/cc/mrh/>).

Clinical Research Records

Clinical research records must be handled and retained in a way that preserves the privacy and confidentiality of research subjects. One way of helping to protect the confidentiality of patients is by deleting personally identifying information as much as possible and identifying records by codes with a key stored separately and known only to the investigators. Records with identifying codes, identifiers or other sensitive information about subjects should be protected in accordance with Privacy Act standards. Electronic records should be password-protected and encrypted if on laptops. The principal investigator of a study has ultimate responsibility for the clinical research records.

Regulatory Binder:

The regulatory binder or file organizes all essential documents that demonstrate that the investigator, sponsor, and monitor have complied with the standards of good clinical practice and with all applicable regulatory requirements. This central binder/file also allows research team members to reference information and provides easy access to essential documents by the trial monitor, auditor, IRB, or regulatory authorities for review/audit purposes. The principal investigator is ultimately accountable for the maintenance of the regulatory binder.

Drug Accountability Records:

For regulatory purposes, the administration of all study drugs, including those that are self-administered, should be documented in the subject's medical record. The principal investigator is also ultimately accountable for record keeping related to the investigational drug/product, including recording the distribution of drug, and maintaining accurate drug accountability records such as receipts of drug shipment/invoices and drug accountability record forms (DARF). These responsibilities may be delegated to appropriate pharmacy staff.

Research Record Retention:

In general, all research-related records should be retained for at least two years after the study has ended. However, many investigators retain records indefinitely to allow for review or reanalysis of data. For investigational new drug (IND) studies, records must be retained for two years after the drug marketing application has been approved or the IND withdrawn, or as indicated by the Sponsor. No NIH records may be destroyed unless consistent with the NIH policies governing record maintenance and retention and applicable regulations.

**Record and
Data-keeping
for
Intellectual
Property
Purposes**

The standards for acceptable laboratory notebooks to protect intellectual property claims are more stringent, as described below, and in the event of a patent dispute, researchers and NIH may find it more difficult to defend their intellectual property rights by not adhering to these standards.

A bound or appropriate electronic notebook should be used.

A bound notebook should be signed and dated on the inside front cover to indicate the first day the recipient started using the notebook. Each entry should be signed and dated. Entries must be made in ink, in chronological order. Entries should not be erased or “whited out.” Any correction to existing data must be initialed and dated after lining through erroneous information. If insufficient space exists to make a correction, the correct information should be placed in the next available space, with an indication of where the error is. Consecutive pages must be used. Photos, drawings, etc., should be identified and permanently attached. Attachments such as graphs or computer printouts should be permanently affixed in the notebook, and both the attachment and the notebook page signed and dated. If the attachment cannot be stapled, it should be placed in an envelope and the envelope stapled to the notebook page. The envelope and page should then be signed and witnessed,

making reference to the attachment being placed in the envelope. Alternatively, documents should be identified by book and page number and stored in a separate loose-leaf notebook.

An electronic notebook must have backup, dating, appropriate IT security, and authenticity and verification capabilities.

Both bound and electronic notebooks must include the subject matter, experimental details, sketches, diagrams, test descriptions, control conditions, test results, an explanation of the results, and photos or sketches of the results or the test device. Conclusions should be short and supported by the factual data.

Periodically someone should look at and witness the entries electronically or by applying signature and date. The witness should have an understanding or familiarity with the inventor's work, but not be a co-inventor. Generally, laboratory technicians who were not involved in the conception of the invention, but were involved in its reduction to practice, make good witnesses. Other potential witnesses include a scientist, student, or technician who performed experiments under the inventor's direction, or a coworker or supervisor who actually observed the inventor's work. The witness should preferably be a person who is available or can be easily reached for the next several years.

It is instructive to go back to one's own old notebook and evaluate how complete and comprehensible the entries are. Can you easily repeat the experiment based on the information provided?

Final Notes

Ideally, each laboratory should maintain a catalogue of notebooks in whatever form they are maintained.

