

Laboratory Notebooks: Best Principles and Best Standards

EFFECTIVE DATE: June, 2016

Purpose

The Laboratory Notebook is the record kept of the methods and results of experiments. As such, laboratory notebooks are vital scientific documents required to preserve valuable intellectual property rights and are primary sources for resolution of many issues, including research integrity and determination of inventorship. A clear and thorough laboratory notebook allows for verification of the quality and integrity of research data, is critical to ensure that outcomes are reproducible and records are traceable, and is commonly used in the preparation of scientific papers and reports. Laboratory notebooks also play a vital role in documenting the scientific basis for intellectual property claims, e.g. patent claims. The laboratory Principal Investigator is responsible for ensuring laboratory notebooks are properly maintained by all laboratory personnel.

Ownership of Laboratory Notebooks

Laboratory notebooks are universally considered the property of the organization which employs the individual. As such, the laboratory notebooks are owned by the University of South Alabama as described in the <u>USA Data Management and Laboratory Notebook Ownership Policy</u>. Briefly, unless express written approval from the University is granted, laboratory notebooks remain with the laboratory in the event an investigator moves to another institution. At USA, this approval must come from the Dean and the Director of the Office of Commercialization and Industry Collaboration.

Determination of claims of discoveries

Laboratory notebooks provide important documentary evidence of the conception and reduction to practice of an invention. Generally a sketch and a brief written description are sufficient to establish 'conception'. However, 'reduction to practice', can be 'constructive' (by filing a patent) or 'actual' by the construction and successful testing of a prototype of the invention. In either case it requires convincing, corroborating evidence of diligence (i.e. constant progress from the conception of an invention). A clear and thorough laboratory notebook can provide such evidence if the need arises.

Laboratory Notebook Content

There are many ways to record data. The Principal Investigator of the laboratory should be involved in laboratory notebook formatting before an individual invests time in a particular method. This guide provides a recommended method for content for recording critical content in a laboratory notebook.

- 1. Notebook name
- 2. Inside cover or cover page
 - Your name and year
 - General project name
 - Laboratory mailing address

Example: Laboratory Record Patterns of Myosin Light Chain Isoenzymes in Developing Chick Skeletal Muscle David R. Caprette Department of Biochemistry & Cell Biology Rice University 211A Anderson Biology Laboratory 6100 S. Main Houston, Texas 77005 (555) 555-5555

3. Table of Contents

- Page Number
- Date
- Subject/Experiment

It is preferable to include multiple levels in the table of contents, to allow additions to the table of content as experiments and data accumulate over time. For example, indicating where a new study starts and include subheadings for specific parts of a study, methods, sets of data, etc. The idea is to enable someone to locate anything quickly. Also, list each set of entries with dates and page numbers.

- 4. Body of notebook
 - Experiment entries
 - Date
 - Title
 - Hypothesis or Goal: Brief statement of purpose
 - Background
 - How: Protocols, calculations, reagents, equipment (See Section Below)
 - Observations:
 - All that happens (planned or unplanned)
 - o Raw experimental data
 - Taped in information or reference to data location
 - Data analysis:
 - Processing of raw data, graphs, interpretations
 - Ideas for future experiments

The focal point of the experimental entry is the observation(s) made. Thus, this is where information is recorded that happens throughout the experiment. At minimum, the record of every experiment should contain the date of the start of the experiment, title of the experiment, brief statement of purpose and a description of the experiment. Record any deviation from the protocol, whether planned, accidental or an error. This is where you record any raw data collected, such as numerical readings from a piece of equipment or qualitative observations such as reporting a reaction solution that may become cloudy or change colors. Notes should be clear and thorough, as often times it is difficult to anticipate what will be important prior to analyzing the data. Any data that is printed or written on a separate piece of paper should be dated secured in the laboratory notebook (e.g. taped or stapled). For data that cannot be included in the laboratory notebook (e.g. large date sets, multiple microscope images, etc.), provide a reference in the laboratory notebook identifying where such data is recorded or stored. Many times data may need to be processed before it can be completely understood or presented. The handling of this data should also be recorded in the laboratory notebook. Lastly, be certain to reference any software that is used, as well as the location of digital files.

Provide Details of "How"

- Reagents: source, product number, lot number, expiration date, how and where stored
- Solutions and how they were made
- Cells used: type, source, passage number, growth medium
- Instruments: type, name, location, serial number
- Number and volume of washes
- Centrifuge speeds and duration of spins
- Heating rates and levels of agitation
- Time between and during steps
- Gel percentages
- Type of water used

Be as detailed as possible regarding what was used and completed. A reagent is more than just the name of the chemical or enzyme. Information recorded should include the source of the reagent and the company/laboratory/ person who provided it. Recording the product/ catalogue number will help make reordering easier. Include the lot number, expiration date and how and where the reagent is stored. When using solutions, record what is being used and how it was made. For example, if a 1X running buffer is used, how was it made from scratch and diluted from the higher-concentrated stock solution? If diluted from a stock solution, include the lot number of the stock solution or how it was made and by whom or a link to this information. Some other examples of information to record include cell type or cell line used, including source, passage number and what growth medium was used. When using instrumentation record the type, name, location and serial number if available. It may be discovered that an instrument was not working properly after the data is analyzed. Knowledge of what machine was used and when might explain anomalies.

Ethics and Laboratory Notebooks

- All data go into the notebook
 - Even "bad" data points or "outliers"
 - o Failed experiments or contradictory experiments
- No pages come out of the notebook
 - Do not take any pages out or remove any data
 - Do not skip pages in your notebook
 - Cross out any unused parts of a page
- Correct mistakes, do not remove them
 - Cross out mistakes with a single line
 - Paste in corrections without covering anything
 - Sign and date all corrections
- Honesty is the best policy

There are ethical standards that must be followed. It is essential that all data be recorded in the laboratory notebook. If an experiment fails completely, it is important to record the negative data and/or describe what happened. When keeping a laboratory notebook, remember to *correct* mistakes, but never *remove* them. The appropriate way to correct a mistake is to strike out the information with a single line and initial by the line. If incorrect data is pasted in the notebook strike it out and paste in the correct item. Do not cover up anything already included as part of the notebook. All corrections must be signed and dated for authentication purposes.

Summary of best-practices for good record-keeping

The federal Office of Research Integrity states that data should be stored in such a way that it permits a complete retrospective audit, and that it is monitored regularly to ensure completeness and accuracy. Raw data should be recorded and retained in indexed laboratory notebooks with permanent binding and numbered pages or in a dedicated electronic notebook. Completed or unused laboratory notebooks should be archived and kept for five (5) years, and disposed of only at the discretion of the Principal Investigator of the laboratory.

- 1. Recording should be done as soon as possible after data are collected. Specific notation should be made as to whether it represents the date of the recording or the date of collection, if the two are not the same. Modifications should be clearly identified and dated.
- 2. For paper records, a few pages should be kept at the front of a bound book for tables of contents.
- 3. Writing should be done in permanent ink and legibly.
- 4. Copies of original notebooks should be kept elsewhere for safekeeping.
- 5. A second loose-leaf notebook should be kept for data, such as photographs, machine printouts, questionnaires, chart recordings, and autoradiograms that cannot fit into the primary record book.
- 6. The Principal Investigator should review and sign off on notebooks to signify their completeness and accuracy. Queries should be addressed as soon as possible and changes signed by both. Some data may need to be witnessed by a colleague. Witnessing of data becomes important in commercial research laboratories.

- 7. Methodology used in an experiment should be written down or a reference to how an experiment deviated from a standard laboratory technique should be explained.
- 8. Lot numbers should be recorded and special attention should be given to the hazardoussubstance use.
- 9. Equipment calibrations need to be recorded.
- 10. Data should be noted directly into notebooks without putting it on scraps of paper or relying on memory beforehand.
- 11. All raw data should be included.
- 12. Errors should be identified by crossing out the mistakes without obscuring the initial data.
- 13. Material should be logged chronologically.
- 14. Data interpretation should be carefully written.
- 15. Areas in a laboratory notebook intentionally left blank should be indicated.
- 16. Correspondence and note conversations related to experiments should be kept.
- 17. Consent forms should be kept with raw data.
- 18. Electronic records need to be carefully monitored.
- 19. Electronic data should be backed up on a disk with a hard copy; relevant software must be retained to ensure future access, and security of data is an issue.

Sources:

Guidelines for Scientific Record Keeping, NIH Office of Intramural Training and Education RCR Data Acquisition and Management, Columbia University

Responsible Party

Vice President Office of Research and Economic Development

Next Review Date

March 2018