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[Home](#) > [Topics](#) > [Inventors and Inventions](#) > How to Start-and Keep-a Laboratory Notebook: Policy and Practical Guidelines

CHAPTER NO. 8.2

How to Start-and Keep-a Laboratory Notebook: Policy and Practical Guidelines

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Abstract

A laboratory notebook is an important tool that goes well beyond research management and can have important implications for issues ranging from intellectual property management to the prevention of fraud. This chapter discusses the key elements of a laboratory notebook, types of notebooks, what should be included in the notebook, ownership issues, archiving, and security. The chapter provides sample notebook pages that illustrate some of the recommended practices.

1. What is a Laboratory Notebook?

Although you may think you will remember what you did and why you did a certain experiment in a week's time, YOU WILL NOT! And nor will anyone else in your laboratory. Hence the need for laboratory notebooks. In short, a laboratory notebooks is:

- a daily record of every experiment you do, think of doing, or plan to do
- a daily record of your thoughts about each experiment and the results thereof
- the basis of every paper and thesis you write
- the record used by patent offices and, in the case of disputes, courts of law (in the event you file patents on your findings)
- a record that would enable successive scientists, working on the same project, to pick up where you left off or reproduce your results

2. Types of Laboratory Notebooks

The following items explain a few important things to know about lab notebooks and how they may be used:

- Hardbound books with numbered pages show that no pages have been deleted or added.
- In companies or institutions aimed mainly at producing patentable products, carbon copies of each page are often required. In addition, each page may have to be signed and dated both by the scientist and by an independent witness within two weeks of work being done. This scientist should be someone who is likely to be traceable in some years time, if needed, to confirm reading and counter signing. The witness should not be likely to be named as a co-inventor in a patent application. The counter-signatory should sign and date each page of the notebook to confirm that she or he has read and understood the entry and is satisfied that the entry has been accurately and correctly written.
- It is advisable to keep different notebooks for different projects or different aspects of the same project. Notebooks should be clearly identified on the outside cover.

3. What Goes into a Laboratory Notebook?

On the front cover of the notebook should be a description of what is contained in it (for example, cloning of the X gene and characterization of its product). The first and last dates of entry should also be written on the front cover.

The following items explain a few important things that need to be recorded inside the lab notebook.

Remember, everything must be written in ink or other permanent medium.

- a detailed account of every planned and executed experiment with the amount of detail that would



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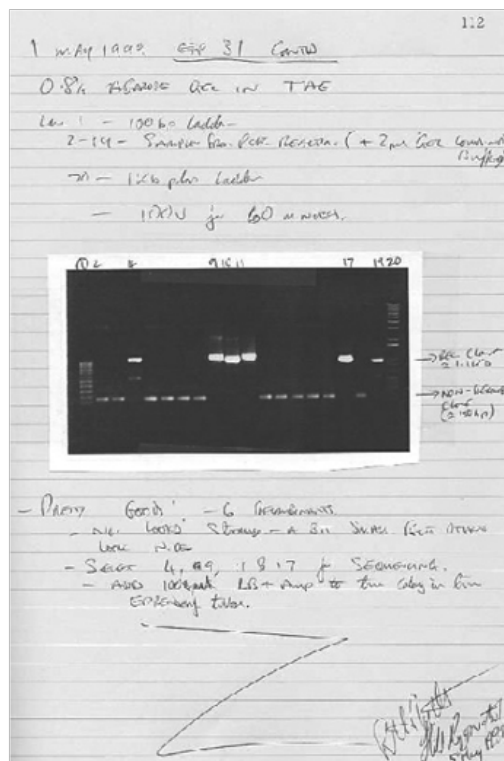
How to Start—and Keep—a Laboratory Notebook: Policy and Practical Guidelines

- a detailed account of every planned and executed experiment with the amount of detail that would enable a scientist “*skilled in the art*” to determine what had been done, why it had been done, and what the results were
- dates accompanying every entry, account, or record
- protocols, reagents, lot numbers in each entry, and where appropriate, sketches, descriptions, and so on
- explanations of the significance of each experiment, as well as the observations, results and conclusions of the experiment
- details of each experiment (Remember, what may seem trivial or obvious at the time your experiment was conducted, may later be of critical importance.)
- personal comments (It is a living document, so stamp it with your own personality. Comments such as “*SUCCESS AT LAST!! THIRD TIME LUCKY!*” are highly appropriate. However, do not make sweeping statements, such as, “*This procedure is worthless*” or “*We infringe X’s patent with this procedure.*” Statements like this could affect the future patentability of your research.
- photographs, computer generated data, and so forth should all be stuck into your notebook in such a way that they will not come loose (see Figure 1). If the format of these data is too large for your laboratory notebook, sign and date such data and file them in a loose-leaf ring file that can clearly be identified. Record the location of these documents in your notebook.

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**FIGURE 1: EXAMPLE OF A GEL PHOTOGRAPH
PASTED INTO A LABORATORY NOTEBOOK**



- cross-references (If you have already described an experiment earlier, or if you have used a standard protocol and have not deviated from the previous descriptions of the experiment for your current one, you may reference the earlier information instead of writing it out again. For example, if you are starting a new experiment on page 48 and are using the same protocol as already described on page 22, write on page 48, “*following the protocol as described on page 22 of this laboratory notebook.*”)
- using preprinted forms can save time, if your experiments involve common, standard procedures (see Figure 2)

FIGURE 2: USING A PREPRINTED FORM FOR STANDARD REACTIONS SAVES TIME

111
1 MAR 1999 GP 31

PCR of colonies from exp 30 - 1st Recombinant clones

- To see when clones are recombined, will do PCR using primers to MCS outside insert - will get a 182bp fragment if no insert - and a 1.1kb fragment if 900bp insert is present.

- Screen colonies for blue color - Transfer to 20µl water in 96-well plates (only 18 plates).

PCR Reaction setup	Exp. No. - 31	Date - 1-10-99	No. Reactions - 18
Buffer	5x - 10µl	2	3.0
dNTPs	10mM - 0.5µl	1	0.5
MgCl ₂	25mM - 0.5µl	1	0.5
Primer 1	10µM - 1µl	1	1.0
Primer 2	10µM - 1µl	1	1.0
Taq	5U - 0.2	1	0.2
Water		4.8	9.0
TOTAL VOLUME		10	18.2

Reactions set up in 96-well plates (above) and 1 µl of each colony.

PCR Conditions

92°C	- 5 minutes
92°C	- 10 Sec.
58°C	- 20 Sec.
72°C	- 60 sec.
72°C	- 10 minutes
15°C	- 10 min.

Reactions Screened @ 10:53 - Estimated yield @ 12:47

Robert Williams
3/10/99

- information with regard to any data that has been electronically captured (These data should be accessible to any scientist "skilled in the art." Such electronic data should be backed-up and archived weekly.)

Corrections must be made by drawing a single line through the entry (see Figure 3). If you leave more than four lines at the bottom of a page, cross through the area to indicate that those lines were unused (see Figure 4). Never use Whiteout.

FIGURE 3: IF YOU MAKE MISTAKES, CORRECT VERY CLEARLY

100
30-APR-1999 - exp 30

Cloning of PCR products (exp 28)

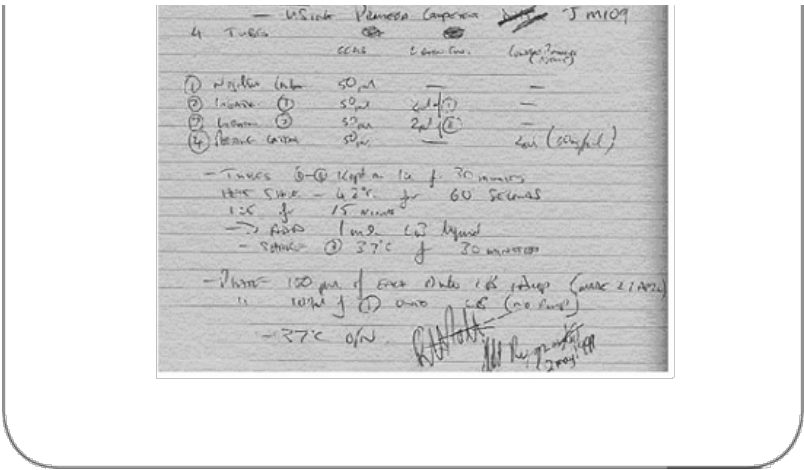
- Clean PCR products will be cloned into pCR2.1 using B-Terra and BamHI

1. Screen Reactions

PCR product	10µl	100µg B-Terra
PCR product	1µl	1µl
2x B-Terra Buffer	1µl	1µl
16 µM B-Terra	1.7µl	1.7µl
Water (to 10µl)		0.2µl

- Reactions @ 37°C for 30 minutes
then 65°C for 2 minutes.

T. Williams



**FIGURE 4: DRAW A LINE TO
FILL EMPTY SPACE**

www.iphandbook.org/handbook/ch08/p02/

4. Who Owns the Notebook?

The person or organization who is paying the bills owns your laboratory notebook. In most cases this will be the company, university, or research institute who employs you or your supervisor.

In the case of universities, you will probably find that employees enter into a contract that stipulates

that all inventions developed while employed are the property of the university. Universities, and some companies, have agreements that income generated from discoveries

made by employees and/or students, will be divided between the institution and the discoverers.

5. How Do You Keep Copies of Laboratory Notebooks?

Some laboratory notebooks come equipped with carbon copies. These types are the best and safest. If your notebook is not of this type, you should make photocopies of the complete notebook. But why do you need copies?

- Once you have completed a laboratory notebook, your supervisor will probably want to keep the original. You will therefore need copies to help you in completing your research. You will often need to check back on what you did a few months ago.
- You might leave your institution before you have time to write up your research for publication or patenting. You will need a copy of your notebook to enable you to do this. Your supervisor will also need a copy to ensure correctness of data and interpretation. (The latter is just one reason why it is so important for you to comment on your data in your lab notebook, making suggestions, interpretations, and so forth.)
- Another scientist might have to take up where you left off. Although your supervisor will have your lab notebook, your successor will also need to have a copy to help her or him continue your work. It will be essential that your results can be repeated.

6. How Do You Archive Your Laboratory Notebook?

Archiving means keeping your notebooks in a system that allows easy access. Your supervisor or institute will probably have an archival system in operation for this purpose. Here are some recommendations for archiving:

- The best option is a lockable bookcase, or cupboard, or a locking file cabinet.
- Label your notebook along the spine with your name, the project, and the start and end dates for the notebook.
- Make sure your supervisor knows where your notebooks are stored!

7. How Do You Protect Your Lab Notebook?

It is essential to protect the security of your records. Here are some important practices to follow:

- When you leave the lab each day always leave your lab notebook where your supervisor can find it, preferably in the same place. It is not necessary to lock it away every night, although it is a good habit to form.
- Lock your lab when you are the last person to leave. If you are not sure whether anyone else will return to the lab, play safe and lock it. People will soon learn to keep their keys with them!
- If your supervisor allows you to keep past notebooks, make sure she or he knows where they are.

8. Conclusions

A laboratory notebook is an important tool that goes well beyond research management, and keeping good records has implications for issues ranging from intellectual property management to the prevention of fraud. Institutions should have a comprehensive policy that should be rigorously implemented (see Box 1 for guidelines for a notebook policy).

BOX 1: LABORATORY NOTEBOOK POLICY

The following policy is a document originally prepared by SWIFFT at Cornell University in the context of its collaboration with the centers of the Consultative Group on International Agricultural Research (CGIAR). The policy itself is based on actual policies that are in effect in several leading research centers and companies, but has been adapted to reflect the specific needs of public sector research institutions.

BACKGROUND

Many public organizations are entering a new era and are considering protecting their own inventions and engaging in research with other organizations, both public and private. These new relationships, often based on collaborative research agreements, may require precise documentation of certain activities and results. Laboratory and research practices will frequently need to be carefully formalized and noted in ways that will allow future IP auditors to review the authenticity of results and certify the dates of occurrences. Such practices are important for potentially patenting possible discoveries made by these institutions or by their collaborators, especially when seeking patent

How to Start—and Keep—a Laboratory Notebook: Policy and Practical Guidelines

discoveries made by these institutions or by their collaborators, especially when seeking patent protection in the United States.

Recording procedures are generally spelled out with respect to standard laboratory notebook practices. These procedures inform all staff about the process for daily establishing and maintaining of laboratory records that could become primary evidence for the resolution of disputes or litigation. In court, dates of invention, description of an invention, and research techniques can be established through carefully kept laboratory notebooks.

In order to achieve the goal of maintaining court-ready documentation, a bound laboratory notebook, in whatever format, must be:

- an honest representation of the research work done by the researcher
- regularly written (daily recording is normally recommended)
- routinely witnessed (at least weekly) by another scientist
- duplicated when completed, if the researcher would like a working copy
- archived in a secure place and/or by a secure method.

The policies and procedures outlined below can be modified to suit almost any organization’s needs and existing IP policies and to harmonize the lab notebook policy with other institutional tools. It is essential, however, that any laboratory notebook policy be consistent with other laboratory procedures, that all research staff be well trained in the execution of the policy, and that the adopted policies be systematically enforced.

LABORATORY NOTEBOOK POLICY

The purpose of this policy is to ensure that the institution is sufficiently protecting its inventions, research, and products, so that discussions or allegations during disputes or litigation are based on documented fact. This includes such things as the date of an invention or a description of the invention or research, the dates or research techniques that were used, and the like. In order to do this, the laboratory notebook, in whatever format, must be an honest representation of the research work done by the institution, and must be acceptable to a court, the U.S. Patent and Trademark Office, and other offices whose charge is regulating statutory protection of IP. Therefore, certain standards apply to each type of notebook.

GUIDELINES

1. General

All ideas and data must be entered into the laboratory notebook. Entries must be complete enough that another scientist would have little or no trouble understanding and repeating the experiments.

Each page must be signed, and dated each day, by the scientist running and recording the experiment, and signed and dated by a witness, if not immediately, then at least within one week of the scientist’s signature.

In deciding the exact procedures to follow, it is important to keep in mind that any type of laboratory notebook must achieve two goals:

1. Reflect its own integrity
2. Corroborate information independent of the person doing the research

Thus, the condition of the laboratory notebook must reflect that it is a clear and accurate representation of activities that have taken place in the lab and that none of the information has been falsified: any changes made to the recorded information should be clear and obvious and the new information should be able to be compared with the old; and the notebook should be completely in tact, with no pages missing or illegible. A witness who has not been involved in the experiment, by signing and dating the notebook, must attest (by virtue of signing) that the information, experimentation, and/or ideas that occurred were recorded on the date indicated.

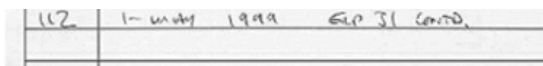
2. Types of laboratory notebooks

1. Hardbound notebook

- Laboratory notebooks are checked out from the designated librarian in the department or office specified and returned to the designated technician immediately upon being filled, to be microfilmed.
- When signing out a new laboratory notebook, the researcher will notice that the laboratory notebook is numbered, is permanently bound, has index pages (Figure 5) and that all pages are prenumbered.

Figure 5: An Index at the Back Makes your Notebook More useable

<u>INDEX TO BOOK ONE</u>			
Page No.	EXPT. No.	Date	DATE
109	30 APRIL 1999 - EXP. 30		
110	1 - MAY 1999 - EXP 30 - CONT		
111	1 - MAY 1999 - EXP 31		



- The researcher should enter a new experiment in the index each time a new experiment is started.
- Use each page in order. Leave no blank pages between experiments.
- Record enough information so that a scientist “skilled in the art” could pick up your laboratory notebook and easily determine what had been done, why it had been done, and what the results were. Entries should include procedures, reagents, lot numbers, where appropriate, sketches, descriptions, and so on. The purpose and significance of the experiment as well as observations, results, and conclusions should be made clear. Remember, what may seem trivial or obvious at the time experiments are conducted, may later be of critical importance.
- If procedures have already been described in an earlier experiment or have used a standard protocol, and the researcher has not deviated from the previous descriptions of the experiment for the current one, the researcher may reference the earlier information instead of writing it out again. For example, if the researcher was starting a new experiment on page 42, and was using the same protocol as already described on page 25, he or she could write on page 42, “Following the protocol as described on page 25 of this laboratory notebook.”
- All data should be entered, in ink, directly into the laboratory notebook.
- Corrections should be made by drawing a single line through the entry. Erasers or whiteout should never be used. The researcher should initial each lineout, and if possible, add next to each lineout a note of explanation, such as, “*wrong data.*” The researcher should never tear pages out of the laboratory notebook. Pages may be copied for the researcher’s own use, but never removed.
- At the end of each day the researcher should put a line or a cross through any unused space on that day’s page(s) in the laboratory notebook. If a blank line is left between paragraphs, there is no need to lineout the one line, but if a number of lines have been left at the bottom of the page, they should be marked through. This could prove it was impossible to enter additional information in the laboratory notebook, in those empty spaces, at a later date.
- If additional information, such as a machine-generated table or graph, an original photo, or autorad, is part of the experiment and is small enough to be attached in the notebook, the information should be attached using a permanent adhesive or nonremovable tape. The researcher should sign his or her name over the border of the attachment, crossing over onto the laboratory notebook page. Signing in this way would clearly show, if at any time in the future the attachment had been removed.
- If the additional data is too large for the laboratory notebook (for example, a computer printout that is a few pages long), such additional data can be signed and dated; countersigned and dated by the witness; and given an appropriate ID number. The researcher should note on such additional data which laboratory notebook and which page number the additional data is referenced. Then, in the laboratory notebook the researcher should reference the additional data’s ID number and note the secure-storage location where the additional data is being held. Preferably, a drawer with a set of files that are always used to store oversized information should be used. A summary of the data can be placed in the laboratory notebook. The same sort of procedure should be followed with any samples that are to be kept.
- Each original page of the laboratory notebook must be signed and dated by the researcher and by a witness. A witness should be someone who has read each entry, who is competent to understand what he or she has read, but who is not a co-inventor. Each research group should designate a person who is responsible for assigning permanent witnessing partners. However, if the assigned witness is not available when needed, another person who fulfills the appropriate criteria may be used.
- If any changes are made after pages are signed or witnessed, the changes must be initialed and dated by both the researcher and a witness. Care should be taken to use the current date when signing or witnessing a laboratory notebook.
- Ideas should be recorded in the laboratory notebook, as these may be important in determining a date of invention.
- It is important to return completed laboratory notebooks to the designated person as soon as possible to ensure a duplicate copy of the laboratory notebook is captured on microfilm or other permanent media. This process will be expedited so that the notebook can be returned quickly to the researcher. A laboratory notebook can be retrieved at any time during the microfilming process, if needed. Upon completion of the microfilm process, the laboratory notebook will be returned to the researcher, for use as reference in the laboratory, or put into permanent storage at the researcher’s request. One microfilmed copy will be kept in the library for access at any time. One other copy of the microfilm copy will be

put into secured storage in the designated location.

2. Hardbound notebooks containing electronically captured data

- At laboratories where a large amount of data are generated and stored in the computer, a written laboratory notebook, with all of the guidelines referred to above, is still required. In this setting, however, much of the data referred to in the laboratory notebooks may exist in electronic files. The laboratory notebooks should contain a summary of the information in those files and also give the name of the file (and format) in which the data are stored.
- The electronic data should be backed up and archived weekly. A new and separate file should be provided as a place to store data. Details of these files and the back-up procedure should be described to all researchers and managers in a memo. These backed-up files should never be opened except for litigation or U.S. Patent Office matters.

3. Hardbound notebooks generated by computers

- The same guidelines apply to hardbound notebooks generated by computers as for hand-written laboratory notebooks. The difference is that rather than purchasing a laboratory notebook and writing in it, research activity is documented electronically. The documentation is printed out on a regular basis and then bound to form a laboratory notebook. The printed material should be clearly labeled with the information that will appear on the front of the bound book and sent to the appropriate person or department for binding. Once bound, the laboratory notebook will be assigned a number, recorded, and returned to the researcher or archived, upon request.
- Each experiment is to be described and each page should be numbered and signed, countersigned, and dated. Each week these experiments are to be saved in the special data file as described in a memo. Also, as with hardbound notebooks, data such as small graphs, photos of gels, and so on, which can be attached to the laboratory notebook page should be attached using the same methods as described above.
- Even though it may be a convenient way of recording experiments, electronic documentation is not the recommended way, for a variety of reasons. If a number of experiments from different days are printed on one page, for example, and the page is only signed and dated after the last entry, it may be difficult or impossible to pinpoint dates of specific activity, especially an exact date of invention.

Endnotes

All referenced Web sites were last accessed between 1 and 10 October 2007.

Thomson JA. 2007. How to Start—and Keep—a Laboratory Notebook: Policy and Practical Guidelines. In *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org.

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The University of Kansas encourages the commercial development of intellectual property to enhance the research capability of KU and to serve the public good. Although university research is not specifically undertaken to develop commercial products, important marketable discoveries can result from basic research. The technology transfer (TT) process moves research discoveries from the research laboratory to the marketplace by recruiting commercial partners to help develop new products that benefit the public.

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Ownership of intellectual and tangible property (IP/TP) rights in agricultural biotechnology (ag-biotech) and transgenic plants has become critically important. For scientists in all institutions, whether industrialized or developing country, public or private sector, an understanding of IP/TP rights is fundamental to both research and development. Transgenic plants and ag-biotech products include

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fundamental in both research and development. Transgenic plants and ag-biotech products embody numerous components and processes, each of which may have IP/TP rights attached. To identify these rights, a transgenic plant or ag-biotech product must be dissected into its essential components and processes, with each 'piece' analysed under the IP/TP 'microscope'. This product deconstruction is an integral step in product clearance (PC) analysis leading to freedom to operate (FTO). To facilitate a PC analysis, the following points are important: knowing what one has and where it's from, organizing material transfer agreements and licences, researching scientific and patent databases and relevant literature, instituting a laboratory notebook policy, keeping track of ownership of germplasm and plant genetic resources, and promoting ongoing IP/TP management, awareness and training. However, a FTO opinion does not solve the IP/TP issues of releasing a transgenic plant or ag-biotech product; rather, it is a management tool for assessing the risks of litigation. When transferring transgenic plants or ag-biotech to developing nations, scientists from industrialized countries have the heightened responsibility of verifying that IP/TP issues are fully addressed and documented. Successful technology transfer goes beyond research, development and licensing; it is an holistic package leading to long-term partnerships in international development. Managing IP/TP requires capacity-building in scientists and technology transfer of offices, in both industrialized and developing countries.

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