Proper Use and Maintenance of Laboratory Notebooks

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1. PURPOSE

Proper implementation and upkeep of laboratory notebooks is an essential part of good science. Laboratory notebooks should be used by all {Name of University} staff performing Research and Development (R&D) activities to properly document all written and mental activities from experiment to interpretation and ultimate understanding of physical phenomenon. The activities recorded in laboratory notebooks also represent the technical basis upon which intellectual property is developed.

2. SCOPE

This process includes the acquisition, use, control, and disposition of laboratory notebooks used at {Name of University}.

This process applies to all *laboratory notebook users* (see def.) and their management.

NOTE: All laboratory notebooks are Quality Records. All other notebooks are not quality records.

This process does not apply to sample, instrument logbooks (see def), or journals (see def). Personal journals are appropriate to log personal notes pertaining to a project; however, they should not be used to record data, original designs, or experimental processes. Notes and/or activities logged in personal journals can be included in laboratory notebooks if they support experiment documentation. Refer to the instructions for use of laboratory notebooks described in Appendix A for properly inserting photocopied journal entries, similar to inserting charts, drawings, and graphs (Appendix A, section 1.14).

3. RESPONSIBILITIES

Performer	Responsibilities
Laboratory Notebook User	Obtain, use, protect, and disposition laboratory notebooks in accordance with this procedure
Faculty Representative of Laboratory Notebook User	Acquire bound notebooks upon request Assign lab notebook numbers Ensure that all staff, educational
	appointees, and collaborators working in {Name of University} laboratory research facilities are aware of the laboratory expectation, proper use, and maintenance of laboratory notebooks, per this procedure.

4. INSTRUCTIONS

4.1 Setting Up Laboratory Notebooks

- 4.1.1 <u>Laboratory Notebook User</u>: Obtain a bound notebook from your faculty representative.
 - 4.1.1.1 <u>Faculty Representative</u>: Purchase notebooks that are bound and numbered.
- 4.1.2 Register the laboratory notebook by getting a lab notebook number assigned through the Faculty Representative.

4.2 Use of Laboratory Notebooks

- 4.2.1 <u>Laboratory Notebook User</u>: Review and implement any {Name of University} procedures that pertain to assigned laboratory notebooks.
- 4.2.2 Do not use laboratory notebooks as either logbooks or journals.

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- 4.2.3 Use Appendix A "Instructions and Best Management Practices" to ensure that research is properly recorded and controlled. (This information may be affixed to the inside cover of the laboratory notebook to aid the researcher).
- 4.2.4 Document invention disclosure and other research in laboratory notebooks. Record all other information in a "record logbook."
 - 4.2.4.1 Make entries in the laboratory notebook sufficiently complete such that a skilled researcher in the field could duplicate the results and conclusions.
 - 4.2.4.2 Record in the laboratory notebook:
 - A. experimental plans
 - B. experimental and theoretical information
 - C. data
 - D. interpretations
 - E. other information concerning research and development.
 - 4.2.4.3 Control other archival recording media by one of the following methods.
 - 4.2.4.3.1 If it is practical to do so, permanently insert other archival recording media used to record research and development data (such as data printouts and photographs) into the laboratory notebook using transparent tape or rubber cement.
 - 4.2.4.3.2 If it is not practical to permanently insert archival recording media (including computer storage media) into the laboratory notebook, store the media separately in a program or project file with the location referenced in the laboratory notebook.
 - 4.2.4.3.3 The computer storage media associated with project case files that have a permanent retention (see Section 5, Records) must also be maintained and controlled as if part of the laboratory notebook.

- 4.2.4.4 Maintain single project laboratory notebook as part of the project or program case files.
- **NOTE**: Individual laboratory notebooks may be used for multiple tasks.
- 4.2.5 <u>Laboratory Notebook User</u>: Take the necessary precautions to protect information in a laboratory notebook that may be considered classified.
- 4.2.6 Also take the necessary precautions to protect information in a laboratory notebook that may be considered controlled unclassified information (CUI).
- 4.2.7 If in doubt about whether the contents of a laboratory notebook are CUI, contact the funding organization for clarification.

4.3 Training for Laboratory Notebooks

4.3.1 <u>Facility Representative</u>: Ensure new staff, educational appointees, and collaborators working in {Name of University} research facilities are aware of the proper use of laboratory notebooks and the Appendix "Instructions and Best Management Practices". Training, if needed, may be documented as described below.

NOTE: After reading this procedure, you can receive credit for reading by completing the "Read and Sign Training Roster" found in Appendix B.

4.4 Laboratory Notebook Storage, Retention, and Disposition

NOTE: Laboratory notebooks are research and development records and are to be maintained for three years by the university or as specified by the funding organization in the statement of work.

- 4.4.1 <u>Laboratory Notebook User</u>: At a minimum, manage laboratory notebooks as quality records and are to be maintained to prevent loss, theft, or damage. Apply additional quality or other programmatic requirements specified by the funding organization, as specified in the statement of work.
- 4.4.2 Determine which of the following designations currently applies to the laboratory notebook:

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- A. Working Laboratory Notebook. This notebook is not yet complete and is currently being used to record information.
- B. Active Laboratory Notebook. This notebook is completed, but is needed as a reference to conduct current business.
- C. Inactive Laboratory Notebook. This notebook is completed and is no longer needed for ready reference.
- 4.4.3 Maintain/Control/Store laboratory notebooks as follows:
 - 4.4.3.1 If the notebook is working or an active laboratory notebook, protect it from loss, theft and damage. The laboratory notebook should be stored in a locked area with limited access to prevent loss, theft, damage or unauthorized users from tampering with the laboratory notebook.
 - 4.4.3.2 If the laboratory notebook is inactive, turn it over to your Faculty Representative for inclusion in the appropriate project file. The inactive laboratory notebook should also be stored in a locked area with limited access to prevent loss, theft, damage or unauthorized users from tampering with the laboratory notebook.
- 4.4.4 Before you graduate, are transferred or no longer working on the research, relinquish working and active laboratory notebooks to the Faculty Representative.
- 4.4.5 <u>Faculty Representative</u>: If a laboratory notebook has been relinquished, either reassign the notebook or include it in the appropriate project file and store it as specified in section 4.4.3.1.
- 4.4.6 <u>Faculty Representative/ Laboratory Notebook User</u>: Retain the laboratory notebook at the university and maintain the laboratory notebook for a minimum of three years or as specified by the funding organization in the statement of work.

5. RECORDS

All laboratory notebooks are considered quality records and are to be controlled, maintained and retained by the university in accordance with section 4.4.3.

6. **DEFINITIONS**

Journal. A personal record of occurrences, experiences, and reflections kept on a regular basis.

Laboratory notebook. A controlled, registered, and bound record with consecutively numbered pages used for recording and interpreting data or information concerning research and development work. Laboratory notebooks provide a permanent written record of a researcher's mental and physical activities from experiment and observation through to interpretation and ultimate understanding of physical phenomenon. Laboratory notebooks also provide corroborative evidence for patent and other intellectual property claims made by the university and serve as a reference for subsequent research projects. Laboratory notebooks remain the property of the funding organization.

Laboratory notebook user. An individual performing research and development work, which includes staff; academic appointees, student interns; and subcontract engineers, scientists, and technicians.

Logbook. A bound collection of record pages used to provide chronological documentation of routine analytical functions and laboratory operations. Logbooks are used to provide sample analysis traceability and use histories for laboratory equipment and processes. Logbooks differ from laboratory notebooks in that they are not used to document research and development activities or data interpretation, and are not personspecific.

7. APPENDIXES

Appendix A, Laboratory Notebook Instructions and Best Management Practices

Appendix B, Read and Sign Training Roster

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Appendix A

Research and Technical Notebook Number:
TITLE:
REQUESTER/RESEARCHER:

- SETTING UP A LABORATORY NOTEBOOK Obtain a bound notebook from your Faculty Representative
- Print this appendix A and affix it inside the front covers of the laboratory notebook.
- Register the laboratory notebook by Getting a Lab Notebook Number assigned from the Faculty Representative.
 The title should reflect the project or task that will be recorded in the Laboratory Notebook.

LABORATORY NOTEBOOK INSTRUCTIONS AND BEST MANAGEMENT PRACTICES

- 1. Instructions for Use of This Laboratory Notebook
 - 1.1 Assign the notebook ONLY to a person performing research and development work.
 - 1.2 Use this notebook to keep complete research records, which can include:
 - a statement of the objective and description of the work to be performed, or a reference to an approved planning or implementing document
 - B. identification of method(s) and computer programs used and any changes to them
 - C. identification of samples or measuring and test equipment used
 - D. description of the work as it was performed and the results obtained.
 - 1.3 Use this notebook for all original data, calculations, notes, and sketches.
 - 1.4 Safeguard this notebook from loss, theft, damage, unauthorized use or tampering.
 - 1.5 Include this notebook in records storage when designated as an inactive laboratory notebook.
 - 1.6 Relinquish working laboratory notebooks and active laboratory notebooks to the Faculty Representative upon graduation, transfer or re-assignment.
 - 1.7 Write all entries in indelible ink that can be copied using conventional xerography and photographic processes.
 - 1.8 Make all laboratory notebook entries in chronological order.
 - 1.9 Include a date and signature on each page that has data in the notebook.
 - 1.10 Make alterations or amplifications of previous entries as new entries, with the current date and cross referenced to the previous entries.
 - 1.11 Make corrections by a single line through the entry, with initials and date.
 - 1.12 Do not obscure any information, or obliterate or backdate previous entries.

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- 1.13 Do not remove pages from the laboratory notebook.
- 1.14 Glue or otherwise securely fasten in place charts, drawings, and graphs drawn on special paper; include a date and signature for each.
- Designate each blank page that will not be used or unused portions of a page with a line or "X" through the unused portion to indicate that portion of the page as being intentionally left unused.

2. Best Management Practices

- 2.1 It is recognized that some types of original records (such as computer printouts and chart recordings) cannot be inserted into the laboratory notebook because of their size. Such records should be signed and dated and reference should be made in the notebook to their existence and current storage location.
- 2.2 As deemed necessary to support an invention disclosure record, specific pages of the laboratory notebook should be reviewed, signed, and dated by a witness who is a knowledgeable peer, with a written statement that the individual has "read and understood" the entries.
- 2.3 It is advisable to preface each new item (e.g., heat treatment, process, or machine) with a very brief description of the purpose and planned approach.
- 2.4 The description of a development that is considered to be an invention or discovery should be complete enough to be understood by anyone skilled in the art.
- 2.5 Reference to a name or catalogue number should be made when standard items are being discussed (such as "Westinghouse pump, Model No."); the source of unconventional materials should be given in more detail.
- 2.6 In cases where work is conducted in collaboration with other persons, conferences and telephone conversations should always be entered in the notebook giving the date, who was involved, and if possible, an outline of the subjects discussed, even if the information is recorded elsewhere.

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Appendix B

Read and Sign Training Roster

Title: Proper Use and Maintenance of la	Date:	
Print Name (Last, First, MI)	Signature	