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1.0 Purpose

This SOP defines the conventions for obtaining, controlling, and capturing data in laboratory notebooks (also referred to as lab notebooks).

2.0 Scope

This procedure applies to BDP employees who use or review lab notebooks and their Managers/Supervisors. This procedure applies to BDP employees who control and issue laboratory notebooks.

3.0 Authority and Responsibility

3.1 Lab Notebook Owners

- Requests lab notebooks from BQAD.

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- Completes all required sections of the lab notebook prior to and during its use
 - Controls the lab notebooks in their possession.
 - Protects lab notebooks from physical damage.
 - Maintains lab notebooks in a secure location.
 - Documents work (including research and development work) in a lab notebook unless the work is recorded in a controlled record such as a batch record, or QC Test request.
 - Documents work in real time
 - Routinely submits lab notebooks for peer review.
 - Prepares lab notebooks for archiving when they are complete or no longer active.
 - Returns completed lab notebooks to BQAD for archiving.
 - Prepares the lab notebooks for archival when no longer in use.
 - Surrenders lab notebooks upon request and when employment is voluntarily or involuntarily terminated. (Lab notebooks are the property of the NCI).

3.2 **Managers/Supervisors/ Project Scientists**

- Oversees the completion of the lab notebooks for the projects led and for those that report to them.
- Reviews data on a regular basis.
- Verifies lab notebook data during review and approval of technical reports.
- Assures lab notebooks are completed and reviewed in a timely manner.
- Performs a final technical review of the lab notebook.
- Prepares lab notebooks for archiving.
- Submits lab notebooks completed and reviewed to BQAD for archiving.
- Ensures that terminating employees turn in their lab notebooks for archival or reassignment.
- Trains new team members on the requirements and use of lab notebooks.

3.3 **BQAD**

- Maintains a stock of lab notebooks for users.
- Assigns lab notebook tracking numbers.
- Assigns lab notebooks to a specific owner.
- Issues the lab notebook to the requestor.
- Records all information in the database

- Archives completed or surrendered lab notebooks.
- Accesses archives when requested for reference.
- Maintains the traceability of all issued and archived Lab notebooks.
- Supports users requiring a custom lab notebook.

3.4 BQA

- Responsible for oversight of this procedure.
- Performs a monthly compliance review of lab notebooks. (see section 11.0 Audit and Reconciliation for information concerning the compliance review).

4.0 System Overview

Lab notebooks used at the BDP are the property of the NCI and are legal documents that provide a mechanism to capture critical information about experiments or processes that may be needed to reconstruct events at a later time (for example, as part of a CMC section in an IND), to serve as a foundation for future work, to transfer information from development to other departments or institutions, or to protect intellectual property. Research and development laboratory activities must be captured in a lab notebook, unless otherwise captured in batch production records.

Conventions for the management of these data are defined to ensure that appropriate data are captured, are accurate and reliable, and are retrievable. Additionally, a properly kept lab notebook is the scientist's proof of his/her discovery or invention and is frequently used as the source of information that will be needed in pursuit of a patent.

5.0 Lab Notebook Attributes

5.1 Lab notebooks must be permanently bound and include sections for:

- Notebook Number (a tracking number assigned by BQAD)
- Issue Date
- Issued To
- Project
- Department
- Returned Date
- Table of Contents

5.2 Each page should include spaces for:

- Title of the experiment
- Project Number
- Lab notebook Number
- Page From and Page to

- Recorded by and Date
- Verified by and Date

5.3 Customized Lab Notebooks

In the event a non-standard lab notebook is required for a project, the project scientist and BQAD work together to customize a design. The lab notebook design, while meeting the needs of the user, must still meet the controls of this procedure. These lab notebooks are made to order on a case-by-case basis.

6.0 Issuance and Control of Lab Notebooks

- 6.1 Prior to requesting a lab notebook, a new employee should complete the training for this SOP.
- 6.2 Request a lab notebook by submitting a *Request for Lab notebook(s)* form (21408-01) to their manager who approves it and forwards it to BQAD. Sections A and B must be completed when submitted.
- 6.3 BQAD assigns a tracking number, using the following convention:
LN-YY-NN
 - LN= Lab notebook
 - YY= Last two digits of the current year
 - NN=Sequential numbers starting at 01
- 6.4 BQAD records the information in the tracking database and completes the following information in the front of the lab notebook:
 - Notebook No.
 - Issued To
 - Date Issued
 - Project/Program
 - Department
- 6.5 BQAD sets up the Signature Cross Reference Log on page 1 of the lab notebook. This table includes:
 - Title of the table "*Signature Cross Reference Log*"
 - Headers for
 - Printed Name
 - Signature
 - Initials

6.6 BQAD sets up the Document References Section on pages 2 and 3 of the lab notebook.

The table includes:

- Title of the table “*Document Cross-Reference Log*”
- Headers for
 - Document ID
 - Location
 - Lab notebook Page Number Reference

NOTE: Document locations need to be descriptive enough that your supervisor could locate documents in your absence.

6.7 BQAD sets up the inside front cover to include an area for an overview statement by the notebook owner, and the section for signature “Prepared for Archiving By and Date”

6.8 BQAD completes section C of Form 21408-01, and notifies the requestor that the lab notebook is available to be picked up.

7.0 General Use of Lab Notebooks

7.1 Documenting Type of Work

Lab notebooks may contain mixed activities, each experiment needs to be identified as “GMP/GLP” or “development”. Lab notebooks that contain only GMP/GLP activities or only development activities can be labeled on the lab notebook cover page as “GMP/GLP” or “development”.

Notebooks that are used to train staff on a technique (e.g. cell culture) are labelled as such. Reviewed copies of the notebook pages can be used as objective evidence for competency training, if competency is required.

7.2 Required Sections

7.2.1 Signature Cross Reference Section (Page 1)

Any individual working in the lab notebook should complete an entry in the log. This includes anyone entering or verifying data.

7.2.2 Document Cross Reference Section (Pages 2-3)

Documentation that is associated with lab notebook activities but cannot be included into the lab notebook (due to size, etc.), is maintained separately from the lab notebook. The location of these documents and the pages in the lab notebook that they are associated with are listed in this section. In addition to maintaining hard copies of original data, record original data from analytical instruments, captured on software and computer files that may be stored in network files or by other appropriate mechanism in the lab notebook along with the path and filename

7.2.3 Table of Contents

The Table of Contents must be updated routinely to add new experiment titles and page numbers as experiments are completed.

7.3 Optional Sections

7.3.1 Table of Abbreviations

7.3.1.1 Page 4 can be labeled “*Common Abbreviations*”. This table must include columns for “*Abbreviation*” and “*Meaning*.”

7.3.1.2 Commonly used abbreviations, symbols, code numbers, or other information that is used throughout the notebook are listed on this page to clarify the meaning of the abbreviation. Also, see **SOP 21404, *Abbreviations Used in the BDP***.

7.4 Language

All entries in the lab notebook must be in English (except commonly used abbreviations and symbols).

7.5 Using Pages

7.5.1 Consecutive Use

Pages of the lab notebook must be used consecutively. “Saving” pages to input data for an experiment to be conducted later is prohibited. Removal of pages from the book is prohibited.

7.5.2 Conventions for documenting simultaneous experiments

For periods of time when simultaneous experiments are on-going, it is acceptable to reserve sufficient pages to complete the documentation of an experiment. Pages reserved must be titled with the experiment name. As each simultaneous experiment is completed, any reserved but unused page must be “N/A’d” (and include the analyst’s signature and date).

7.5.3 New Pages

New experiments, procedures etc. must be documented starting with a new page.

7.5.4 Descriptive Titles for Experiments

A descriptive title for the work must be provided (for example, “Preparation of Reagent A”, or “Purification of X using Resin B”).

7.5.5 Page Numbering

It must be clear what pages are included in a specific experiment. For the first page of an experiment, indicate “*start*” for the “From Page No. _____” prompt (at the top left of the page). For the last page of an experiment, indicate “*end*” for the “to Page No. _____” prompt (at the bottom right of the page). For intermediate pages, complete the “From” and “To” page number prompts so this it is clear what pages document a specific experiment.

7.6 Use of Worksheets

7.6.1 Developing and using worksheets to guide the organization and documentation of activities can be helpful. Worksheets enhance the consistent presentation of information and prompt for appropriate experiment data.

7.6.2 Worksheets can be developed for commonly performed processes (for example, cell splitting or reagent preparation) and designed to prompt for required information (for example, equipment numbers, reagent lot numbers, incubation times, etc.). Worksheets are permanently affixed into the lab notebook with permanent tape or glue. The analyst must initial and date across the splice between data sheet and lab notebook page.

7.7 Documentation at Time of Performance

Experiments must be documented on the day work is performed, as soon as it is practical to record entries into the lab notebook. As experiments or procedures are completed, the Table of Contents is updated to reflect this new information.

7.8 Good Documentation Practices

Good Documentation Practices must be followed at all times (see also **SOP 21409, *Good Documentation Practices***) including:

- Use of blue or black ink.
- Legibility of all entries.
- Real time recording of data, concurrent with the activities
- Proper practices for corrections
- Accurate signatures and dates for work.
- Use of lines and/or "NA" (with initials and date) to justify blank spaces in the lab notebook.

7.9 Data Integrity

Data contained in BDP lab notebooks must be attributable, by identifying individuals who performed/recorded the work, legible, contemporaneously recorded, original (first capture of information), and accurate. Data must be reliable and credible (refer to the **SOP 21910 *Integrity of BDP Data***). It is not acceptable to record data on pieces of paper that will be discarded after the data is transcribed in the lab notebook.

8.0 Experimental Data

8.1 Work must be recorded in lab notebooks in sufficient detail so that the experiment or procedure can be reconstructed later and to provide traceability of materials, reagents and equipment that was used. Document the following information:

8.1.1 Purpose of the experiment

8.1.2 Method or procedures used

Routinely performed procedures may be described once and then cross-referenced when used to conduct later experiments. Specific information (equipment used, materials, process information, etc.) must still be provided for each specific experiment.

8.1.3 Equipment, materials, and reagent traceability

8.1.3.1 Raw material/reagents

Include brand, catalog number, lot number and expiration date. Record the BDP raw material release number (R number) and BDP part numbers if provided.

8.1.3.2 Reagent preparation data.

8.1.3.3 Equipment used, including any standardization of the equipment that was performed to prepare the unit for use. If standardizations or preparation is documented elsewhere, include the cross-reference (such as to an equipment log book).

NOTE: The use of equipment “MEF” (Master Equipment File) number is encouraged in addition to the equipment description since this number allows traceability back to the specific piece of equipment. Use of an MEF number or an equipment serial number is required for GLP/GMP activities.

8.1.4 Location

Document the area in which the procedure was performed. If the area is not under a routine environmental monitoring schedule, include any environmental monitoring that was performed during the time period of the experiment.

8.1.5 Process Information

Document process information that will be needed to reproduce the experiment exactly at another time, for example:

- Times (for incubation, mixing, holding, etc)
- Temperatures (for incubation, mixing, holding, etc)
- Flow rates
- Sampling points

8.2 Raw Data

Raw data must be adequately identified and maintained.

8.2.1 Raw data include data such as HPLC tracings, testing results, reports, etc.

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- 8.2.2 Raw data must be appropriately labeled to indicate sample number (or ID), date, technician name, lab notebook page cross reference, etc., and be **SIGNED** and **DATED** by the analyst or scientist. Include any explanations of the data that would be helpful to another person reviewing it at a later date.
- 8.2.3 Affix raw data into the lab notebook using permanent tape or glue. The analyst must initial and date across the splice between data sheet and lab notebook page.
- 8.2.4 Alternately, raw data may be maintained separately from the lab notebook (for example, if the data is too large to fit into the lab notebook). The location of this data must be indicated on the lab notebook page pertaining to the experiment and must be included on the Document Cross-Reference Log.
- 8.2.5 Electronic files must be protected by saving the files to a network server or other appropriate means. Locations storing electronic raw data must be backed up to protect inadvertent loss of data. A hard copy of the raw data should be maintained when possible. The location of this data must be indicated on the lab notebook page pertaining to the experiment and must be indicated on the Document Cross-Reference Log.

8.3 Calculations

Show all calculations and include units and conversion factors.

8.4 Data Analysis and Conclusions

Include any conclusions that can be drawn from the data. Discuss any explanations for the observed results. Include additional activities planned.

8.5 Analyst Signature

The analyst/scientist must sign and date the bottom of each page at the time the page is completed.

9.0 Review of Lab notebooks

9.1 Review of Lab notebooks **must** be done by the manager/supervisor or a peer that has not participated in the work but would be able to understand the work documented.

9.2 For routine development activities, the reviewer should assure that:

- Sufficient information has been captured so that the experiment conducted can be repeated exactly at another time.
- Good documentation practices were used.
- The review is timely (within 30 days).
- Reviewers are NOT required to re-check calculations or to evaluate the science or conclusions of the experiment.

9.3 For GMP or GLP activities, the reviewer should assure that:

- Sufficient information has been captured so that the experiment conducted can be repeated exactly at another time.
- Good documentation practices were used.
- All data captured are confirmed as accurate, complete, and comply with established procedures (for example, equipment numbers, lot numbers, expiration dates, calculations, etc).
- Conclusions drawn from the activity are appropriate (especially for test results).
- The review is timely (**within 30 days AND** before any final result is formally reported).

9.4 For a potentially patentable development:

The initial review should be the same as for routine development activities, but the employee and/or reviewer alerts BDP Management who may require an additional review/evaluation to protect the invention.

10.0 Storage

- 10.1 Issued lab notebooks are maintained in a manner to protect them from physical damage and to maintain security.
- 10.2 Store lab notebooks in a secure area.
- 10.3 Approval to remove any active lab notebooks off-site must be made at the Director level and be in writing. A copy of this approval is provided to BQAD prior to removal. BQAD is again notified when the lab notebook is returned to the site.

11.0 Audit and Reconciliation

Monthly, a random sampling of 5% of all active lab notebooks are recalled by BQA for review, reconciliation, and audit. Audits of the process include compliance to this SOP for issuance, archival, as well as data integrity and peer review compliance. Training competency may be reviewed during the audit. BQA works with BQAD and the lab notebook owner to address any issues. The reconciliation, observations and action items are documented in the eQMS.

12.0 Reassignment

When an employee terminates employment, or moves to another department, any lab notebook(s) assigned to that employee must be returned to BQAD. The lab notebooks can be reassigned (if appropriate) to another person. The supervisor or manager decides who the lab notebooks are reassigned to. Prior to reassignment, the lab notebook must be peer reviewed.

13.0 Archival

13.1 General

- 13.1.1 Inactive lab notebooks that are no longer required within the department must be archived. A lab notebook is considered inactive if:

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- The lab notebook is completed
 - The work or project is complete
 - No entries have been made for two years
- 13.1.2 Completed lab notebooks must be prepared for archiving according to the requirements below, and provided to BQAD. In the event the notebook is needed for reference, the notebook can be signed out to a requestor. The requestor's name and the date is noted, and the status is changed in the tracking database.
- 13.2 Preparation of Lab notebook for Archiving by Lab notebook Owner
- 13.2.1 Data Completion and Review
- Ensure that each completed page has been signed by the owner and either peer or supervisor reviewed and both signatures are on each page.
- 13.2.2 Overview Statement (Lab notebook Cover Page)
- Add a short statement or paragraph on the general topic of the activities included in the lab notebook, and whether the lab notebook is a continuation of work captured in other lab notebooks. If this lab notebook is a continuation of work, the lab notebook number(s) for the previous work must be identified. If available, additional information can be added to the overview, this includes the goal of the activities, project number, stage of the project and where other related information can be found.
- 13.2.3 Blank Pages
- Mark any unused lab notebook pages with an "X" and "NO INFORMATION ON THIS PAGE". Sign and date the bottom of the page. For lab notebooks with many unused pages:
- Mark the first and last blank page of the lab notebook prominently in the body of the page with "*Page # (first blank page #) through page # (last blank page #) have been intentionally left blank as of (current date)*". The person making this statement will sign and date these pages.
 - Following the last entry in the Table of Contents, indicate "*Page # (first blank page #) through page # (last blank page #) have been intentionally left blank as of (current date)*".
- 13.2.4 Ensure that the following are complete and up to date
- Table of Contents
 - Signature Log
 - Document Cross-Reference
- 13.2.5 Verify any document or raw data that is stored outside of the lab notebook (included in section 8.2) is retrievable. Referenced documentation that is part of other official BDP records must remain in the original, official file.

13.2.6 The lab notebook owner signs the inside front cover of the lab notebook: "Prepared for Archiving by: (signature / date)". In the event the owner is no longer at the BDP, the supervisor assumes this responsibility.

13.2.7 Submit the prepared lab notebook to the supervisor.

13.3 Supervisor Review of the Lab notebook

13.3.1 After preparing the lab notebook for archiving, the lab notebook (and any associated raw data that was filed separately) must be examined by the scientist's supervisor to ensure that all data is available and has been reviewed and signed. The Supervisor documents their review by signing the inside front cover of the Lab notebook: "Reviewed / Approved for Archiving by: (signature / date)".

After review by the Supervisor, the Cover Page will be amended with the statement "This Lab notebook Completed By [Name]. No Marked Entries After [Date]."

Entries into the lab notebook after this date are prohibited.

13.3.2 The supervisor then submits the prepared lab notebook to BQAD for archival.

13.4 Archiving of Lab notebooks by BQAD

13.4.1 BQAD receives the lab notebook from either the owner or the supervisor.

13.4.2 BQAD confirms that the lab notebook has been prepared for archival appropriately by seeing if the lab notebook owner and supervisor have signed the inside front cover of the lab notebook stating that it was reviewed and approved for archival. BQAD returns any lab notebooks that have not been properly prepared for archival back to the owner or supervisor for remediation.

13.4.3 BQAD completes the Returned on date. If the notebook is intended to be stored off site, the owner or supervisor completes the ***Archival Request*** form 21402-01.

13.4.4 BQAD stores the lab notebooks. Generally, lab notebooks for projects that are still active will be stored on-site as space permits. As needed, commercial archival services are used for off-site storage.

13.4.5 BQAD maintains traceability information for all lab notebooks.

14.0 Archived Lab notebooks for Reference

14.1 To retrieve an archived lab notebook for reference, contact BQAD via email to the BQAD group email. The requestor is responsible for the care of the archived lab notebook from the time the lab notebook leaves the archives until the time it is returned to BQAD.

14.2 Archived lab notebooks may only be used for reference. No data may be entered into an archived lab notebook. Any data entered after the completion date is considered void.

15.0 Competency Training for Lab notebooks

Those that routinely use lab notebooks are required to show competency in this procedure. Competency is verified by the supervisors, and evaluated during internal audits.

16.0 Exceptions to Peer Review and Archival Procedures

Lab notebooks Assigned for Training purposes only should have a label placed in the inside front cover with the following statement: "This lab notebook is to be used for training purposes only and not used for experiments for GMP, GLP, or BDP-project directed R & D work."

17.0 Records

The following records are generated as part of this SOP

- Lab Notebooks
- Completed **Request for Laboratory Notebooks** form (21408-01), are included in the project files and maintained by BQAD.
- Records of Active notebooks sent to the Managers quarterly, is an email record that is maintained per NIH email retention requirements.

18.0 Reviewer Responsibilities for Lab notebooks (Managers/Supervisors)

BQAD provides each manager with a list of active lab notebooks (or inactive lab notebooks held within their department) quarterly. The reminder includes a note that the quality of the lab notebooks is the ultimate responsibility of the department supervisor/manager.

19.0 References and Related Documents

21402	<i>Document Storage and Archival Process</i>
21409	<i>Good Documentation Practices</i>
21910	<i>Integrity of BDP Data</i>
24413	<i>Preparing BDP Technical Reports in PDF format for Regulatory Submissions</i>
21408-01	<i>Request for Lab Notebook</i>

"Guide for Keeping Laboratory Records, Do's and Don'ts" National Institutes of Health, December 18, 2017.



20.0 Change Summary

