Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Maintaining Laboratory Books**		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
Final v 1.0	10/11/09	Annual Review	Final v 1.0
Final v 1.0	20/10/11	Annual Review/ Update following MHRA GCP Inspection	Final v 2.0
Final v 2.0	21/08/2012	Periodic Review	Final v 3.0
Final v 3.0	23 October 2014	Periodic Review	Final v 4.0
Final v 4.0	19 December 2016	Periodic Review	Final v 5.0

1. Purpose

This Standard Operating Procedure (SOP) is designed to provide guidance to all researchers for the maintenance of laboratory books for all research studies.

2. Introduction

Proper record keeping is important for research. The Good Laboratory Practice Regulations (GLP) 1999 specifies that researchers need to ensure the performance of a study is recorded and that the raw data is stored and maintained as part of that study, and that archiving of the same takes place.

Maintaining a detailed laboratory book provides the evidence for validating study results. They are a vital record for detailing, for example, dates of conception of an invention, demonstrating that an invention works and the ownership of Intellectual Property Rights. They are also a key aid when preparing a manuscript, thesis or presentation.

3. Scope

This SOP applies to all members of University staff; both academic and support staff as defined by Statute 1 and including honorary staff and students who are conducting research within or on behalf of the University.

4. Responsibilities

4.1 Chief Investigator

The Chief Investigator is responsible for all aspects of the study and it is important that they ensure records are appropriately maintained. Where the research is student led, it is the Supervisor's (Chief Investigator's) responsibility to review the laboratory book and countersign entries.

4.2 Investigator

The investigator is responsible for ensuring that permanent, complete and continuous records are made for each research study conducted in a laboratory. These entries should be made in a permanent bound, hard-backed notebook, with numbered pages.

The investigator is responsible for ensuring the safe keeping of the laboratory book during the research study and for ensuring that it is appropriately archived, within the University, once the study is complete.

5. Procedure

5.1 Laboratory Book

Each laboratory book issued to a member of staff or student remains the property of Queen's University Belfast and not the holder.

A new laboratory book should be started for each new research study. The holder should sign and date the inside cover.

A laboratory book should be a permanently bound, hard-backed notebook with numbered pages. Queen's University laboratory books are available from the member of staff responsible for the laboratory within which you are based.

The first pages of the book should be used as an index, this can include acronyms, codes, laboratory jargon and trade-names being used.

Where more than one laboratory book is used for an individual study, these should be numbered in format of 1 of 3, 2 of 3, 3 of 3.

5.2 Entries

Entries into the laboratory book must be:

- In consecutive date order;
- Written in ink, preferably one that does not smudge;
- Written in English;
- Completely legible;
- Blank gaps between entries should be avoided, where they do occur draw a line through the blank gap to prevent subsequent entries;
- Incorrect entries must have a single line put through them. They should remain legible and therefore must not be crossed out or correction fluid used;
- Entries must not be modified at a later date. If data is omitted, enter it under a new date and cross reference it to a previous entry;
- Be consistent;
- Each entry must be signed and dated.

5.3 Detail to be recorded

Laboratory notebooks must contain enough information so that an independent reviewer, who has the technical knowledge, can understand what has been done. Therefore it is necessary to record:

- Experiments that have been performed and observations from them;
- The reasons for undertaking new experiments;
- Outline the experimental design, operation conditions and controls;
- Include the materials and methods used such as reagents and apparatus. Any raw data from recording instruments, computer printouts, drawings etc must be permanently glued or taped into the laboratory book, signed and dated;
- Include all results;
- State the conclusions drawn from the experiment;
- Record, as they arise, details of ideas for future experiments, discussions and suggestions from colleagues in laboratory meetings, collaborators or others. In addition, capture the names of those persons involved in the discussion. This may be particularly important in determining inventorship or ownership of any Intellectual Property produced.
- State reasons for not working on a study for any period of time, e.g. because of annual leave, bank holiday, sick leave etc.
- Where laboratory work relates to patients, there must be no patient identifiable information recorded/retained in the laboratory books.

5.4 Electronic Laboratory Books

Until electronic records are accepted by the courts, a hard copy of all data should be maintained. If electronic data is generated then an official procedure should be adopted, using the following guidelines:

- Generate permanent electronic records;
- Back up and write protect electronic data;
- Reference this data in a signed and dated handwritten notebook;
- Store electronic records in a safe repository retained with custodians who could vouch for their authenticity;
- Electronic or digital signature software may be employed to enhance the credibility of the electronic records;
- Use hardware or software that prevents the ability to edit original research descriptions;
- Create records that show the development of the research;
- Ensure security to prevent unauthorised access to the system;
- Password protect the system and data;
- Limit system access to authorised personnel.

6. References

None.