



Standard Operating Procedure Research Governance

Title:	Maintaining Research Record including Laboratory Books		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

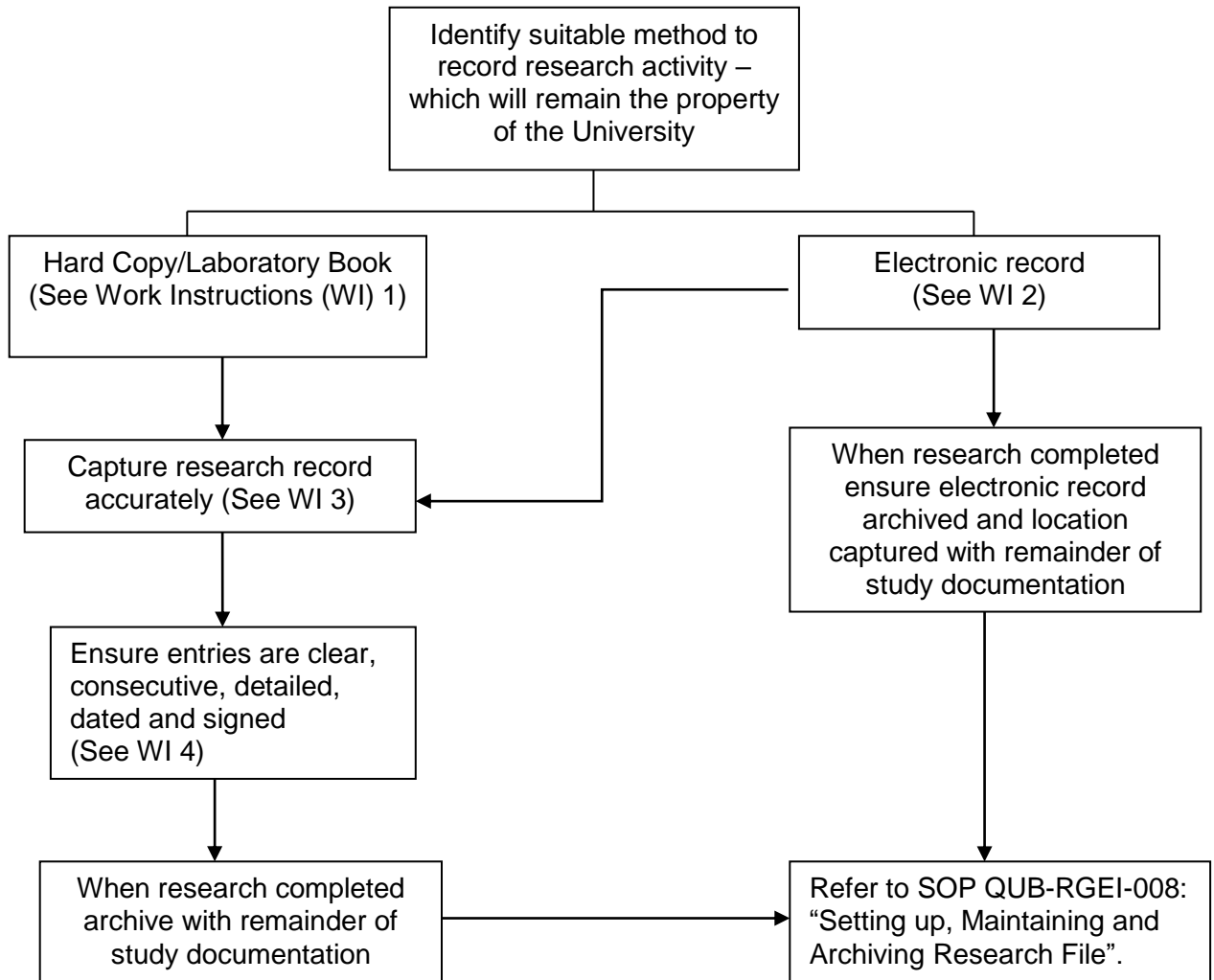
1. Purpose

This Standard Operating Procedure (SOP) is designed to provide guidance to all researchers for the maintenance of their research record, including laboratory books used for the collection of data in their research studies. Its purpose is to ensure the raw data is captured, stored and maintained as part of the study and that this appropriately archived at the end of the study.

2. 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.

3. Procedure



4. References

None.

5. Appendices

- Work Instruction 1 – Hard Copy book
- Work Instructions 2 – Electronic Copy
- Work Instructions 3 – What to Include
- Work Instructions 4 – Record Entries

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Work Instructions 1 – Hard Copy book

1. Each hard copy research record/laboratory book should be permanently bound, hard-backed with numbered pages.
2. A new research record/laboratory book should be started for each new study.
3. The inside cover should be signed and dated by the holder.
4. The first pages should be used as an index which can include acronyms, codes, laboratory jargon and trade-names being used.

Work Instructions 2 – Electronic Copy

Until electronic records are accepted by the courts, data should be retained in a manner that can allow the generation of a hard copy for evidence purposes.

1. Generate permanent electronic records;
2. Back up and write protect electronic data;
3. Reference this data in a signed and dated handwritten notebook;
4. Store electronic records in a safe repository with a named custodian which is usually the CI;
5. Electronic or digital signature software may be employed to enhance the credibility of the electronic records;
6. Use hardware or software that prevents the ability to edit original research descriptions;
7. Create records that show the development of the research;
8. Ensure security to prevent unauthorised access to the system;
9. Password protect the system and data;
10. Limit system access to authorised personnel.
11. Ensure that any transfer of the electronic records is in accordance with legislative requirements such as GDPR, Export Control etc.

Work Instructions 3 – What to include

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:

1. Experiments that have been performed and observations from them.
2. The reasons for undertaking new experiments.
3. Outline the experimental design, operation conditions and controls.
4. 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.
5. Include all results.
6. State the conclusions drawn from the experiment.
7. 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 inventor or ownership of any Intellectual Property produced.
8. State reasons for not working on a study for any period of time, e.g. because of annual leave, bank holiday, sick leave etc.
9. Where laboratory work relates to human participants, there must be no identifiable information recorded/retained in the laboratory books.

Work Instructions 4 – Record entries

Entries must be:

1. In consecutive date order.
2. Written in ink, preferably one that does not smudge.
3. Written in English.
4. Completely legible.
5. Blank gaps between entries should be avoided, where they do occur draw a line through the blank gap to prevent subsequent entries.
6. 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.
7. 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.
8. Be consistent.
9. Each entry must be signed and dated.