Medizinische Fakultät



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## Keeping a Research Notebook – Recommendations of the Faculty of Medicine Tübingen

A carefully kept research documentation in paper-based protocol books or digital lab notebook systems and the correct storage of primary data are integral parts of good scientific practice (see the DFG "Safeguarding Good Scientific Practice", 2019) and are mandatory for **all research**, whether in the form of experimental, clinical, population-based or theoretical studies and trials. They allow other researchers to reproduce your results and, if kept properly, can document your own scientific contribution and establish intellectual property or priority of invention in case of conflicts over patent or copyright issues.

Junior researchers are responsible for making sure their supervisors, who should have the German *Habilitation*, instruct them in the proper use of a research notebook when they begin their research project. Supervisors of research projects in turn are obliged to instruct all project members in the proper documentation of research results.

Paper-based log books with bound and numbered pages are used for documentation. Protocol books or "Research Notebooks" in the University's corporate design are available at the UKT from the central warehouse in Weilheim (order numbers 60200814: UKT Research Notebook L - 288 pages A4, 60203354 UKT Research Notebook M - 144 pages A4, 60203355 UKT Research Notebook S - 96 pages A4). At present, the doctoral office also issues research notebooks to registered doctoral candidates of the faculty. Additionally, digital lab book systems which are recognized by the DFG are also suitable. The faculty issues licenses for "Labguru" on request and offers information events on the introduction and use of this system via Patrick Moritz (Patrick.Moritz@med.uni-tuebingen.de)

### What need to be considered maintaining a paper-based research notebook?

- Each research notebook is kept by a **single person in legible handwriting**. This person is responsible for the orderly maintenance of the notebook. If more than one person is involved in an experiment, make cross-references to the research notebook(s) of the other involved person(s).
- Entries in a research notebook must be made in **chronological order**.
- Use **ball point pens or indelible ink** never pencils! Data analyses and original data may be pasted into the notebook. Printouts on thermal paper should first be copied onto permanent paper to avoid rapid fading.
- You may **never remove pages** from the notebook. If you have made a mistake or need to make corrections, please put a thin line through the passage in question so the **original entry remains legible**, and note when and why corrections were made. Or simply made a new (chronological) entry referring to the original entry and explaining the corrections.
- Always **record your entries during or immediately after an experiment** in order to avoid errors in documentation.

### Required entries in your research notebook

At the very least, your research notebook must record the following:

- Your name, address and laboratory
- Table of contents (will be generated over the course of time as you record your research)
- Date and project title for each new entry

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- Title of each research step (for example, a short title and possibly a code number for the experiment), your working hypothesis, and the appropriate cross-references when experiments are repeated
- If patient samples are used in experiments or patient data are entered in the research notebook, you may only record pseudonymized data (patient number, sample number) which cannot be directly linked to an individual. The project or trial leader is responsible for keeping the identification key with which data or samples can be traced back to individual patients.
- Precise descriptions of experimental set-ups and procedures, with measurement protocols (lab protocols with exact quantities, processing times, etc., sketches or photographs of experimental set-ups)
- Where applicable, planning of statistical analysis before data are gathered (justification for sample sizes, primary end points, analysis methods)
- Where applicable, precise measurement points and endpoints (particularly in clinical trials)
- Where applicable, any queries used for literature searches
- Where applicable, guidelines for qualitative studies such as interviews, focus groups, etc.
- Where applicable, the equipment used (purchasing source, device numbers, etc.)
- Where applicable, materials used (samples, reagents, controls), including type, origin, batch numbers (where applicable) and storage details
- Original (raw) data from the samples and controls (e.g. gel images, data curves or a detailed description of where the raw data have been stored; see below) or links to the (digital) storage location of questionnaires or data entry forms or databases (e.g. registers or other secondary data sources).
- Calculated data (including calculation and statistical methods and the software used), including intermediate results. Each statistical evaluation should be documented by archiving an original printout from the statistics package used (including version number and any analysis scripts used)
- Comments and conclusions about your results
- Data backup procedures

### What needs to be considered when keeping a digital lab notebook?

- In terms of content, the same guidelines apply for digital documentation as for the paper-based record book! However, the digital lab notebook takes over many little tasks automatically (date, project assignment, table of contents, references to repetitions, ...) or simplifies the documentation (master data of samples and devices, documentation templates, ...)
- To get the maximum benefit from the digital lab notebook, data should be stored and saved in a way that is not searchable. Scanned handwritten notes may technically fulfill the minimum requirement for research data documentation, yet they are not practical either.
- Uploaded files should use standard formats if possible (Office files, common image formats, text files, etc.). When uploading proprietary file formats, please note that these may no longer be readable if the necessary special software is not available.
- Uploading large amounts of raw data (e.g. from imaging, sequencing, mass spectrometry, structure elucidation, ...) to the digital lab notebook is possible, but not practical. Extensive raw data should be stored in the local network and the storage location should be noted/linked in the digital lab notebook.

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# Your documentation must complete without gaps, and it should be so detailed and accurate that another person can reproduce your results.

Additional data storage can also be used for original data (such as notebooks or digital media) if the quantity or format of the data require it (for example, video recordings, extensive questionnaires, imaging data, DNA sequences, etc.). In the paper-based or digital research notebook, you must then describe exactly where the original data can be found and formulate summaries and conclusions from the results.

#### When does the research notebook need to be countersigned?

Documentation in the research notebook should be entered regularly, particularly where there are potentially patentable results, and entries should be dated and signed by the experimenter and countersigned by a second person (independent witness, supervisor), who confirms that he or she has seen and understood the entries.

#### Where is the research notebook kept?

Research notebooks and thr digitally stored documentation, including any additional primary data storage, must be stored so that they are publicly accessible, and they belong to the institution in which the work was carried out. The institution is responsible for archiving the protocols and data for a period of at least ten years (cf. DFG rule 7 for "Safeguarding Good Scientific Practice").

As long as the researcher remains in the department, the research notebooks may be kept at his or her work station. When the experimenter leaves the institution, all notebooks and data must be turned over to the supervisor. Copies of research notebooks may be made by the author of the notebook for his or her personal use.

The following persons worked together to draw up the first version of these guidelines: Professor Peter Rodemann (ombudsman of the Faculty of Medicine Tübingen), Professor Wolfgang Bethge (head of the Center for Clinical Trials ZKS), Professor Peter Martus (director of the Institute for Clinical Epidemiology and Applied Biometry), Dr. Heidrum Sturm (Institute for General Practice and Interprofessional Care) and Dr. Achim Siegl (Institute for General Practice and Interprofessional Care), please contact Dr. Inka Montero, Office of Doctoral Affairs, Faculty of Medicine Tübingen.

The current version has been expanded with the support of Dr. Iwan Grin (Laboratory Manager and Project Coordinator, Section Cellular and Molecular Microbiology) to include the use of digital laboratory notebook systems.