# Regulation

# for Working with the Laboratory Journals of the HZI

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#### **PREAMBLE**

Scientific work is based on principles that are invariable throughout all disciplines of science and in all countries. These principles are based on being honest to oneself and others and are considered to be the foundation of good scientific practice.

On 19 January 1998, the DFG commission for 'Self-monitoring in Science' presented "Proposals for the assurance of good scientific practice". The proposals require academic and research institutions to compile binding regulations and to develop a procedure for the handling of allegations of scientific misconduct. The following guidelines are based mainly on the statements of the DFG commission and on the recommendations of the German Rectors Conference ("Hochschulrektorenkonferenz") of July 1998.

### I. Basic principles

# **Basic principle 1**

All data (with special conditions applying to GMP) must be archived for a period of 10 years (also refer to: "Regulations for the Assurance of Good Scientific Practice at the HZI and Procedures for the Handling of Scientific Misconduct," HZI Intranet).

It has to be ensured that each and any published finding including all pertinent raw data and experimental protocols can be reconstructed for a period of 10 years.

# **Basic principle 2**

The documentation shall be kept appropriately such that a knowledgeable third person can comprehend the experimental procedure and the results within a reasonable period of time without requiring additional explanations or information.

# **Basic principle 3**

Additional entries are preferable as compared to omitted entries.

# II. Organisational requirements

#### 1. General

The regulations relate to good scientific practice that is aimed at publication in a professional scientific journal.

The estimation whether or not a scientific result is patentable is at the discretion of the scientists in charge. Moreover, with regard to certain projects, the Executive Management can initiate the application of stricter standards at a level as early as the keeping of the laboratory journal. In both cases, the regulations described herein are not sufficient and more comprehensive procedures in coordination with the Technology Transfer (TT) partner of the HZI, i.e. currently Ascenion GmbH, need to be applied. Accordingly, the present regulations meet the good scientific practice, but are insufficient for evidence that is subject to patent law.

#### 2. Issuance and circulation of laboratory journals

# 2.1 Use of laboratory journals

Only HZI standard laboratory journals obtained through central procurement are approved for documentation of research work at the HZI.

# 2.2 Design of laboratory journals

All laboratory journals bear a unique serial number (printed on the cover and on each page). There is a line on the end of each page, which the author can sign and date (proof for patenting). Moreover, a field for the signature of a witness, including the date, is also printed on each page. In addition, a sheet with labels, on which the serial number is printed, is included with each laboratory journal. These are needed for the labelling of supplements (see III. 7). A table of contents is printed in the laboratory journal.

This makes the laboratory journals usable, as a matter of rule, for safe documentation for patent purposes.

# 2.3 Administration of laboratory journals

The laboratory journals are obtained through central procurement and are issued by the library conditional to provision of a signature. Accordingly, the serial numbers of all laboratory journals needed by a staff member in the course of his or her work at the HZI are assigned to the corresponding staff member. This ensures that all laboratory journals of a staff member are returned for archiving purposes.

The laboratory journals and supplement laboratory journals are archived centrally at the library. As long as a person is still employed at the HZI, the person can keep his or her laboratory journals at his or her workspace. No later than at the time a person departs from the HZI, all laboratory journals must be returned to the library. Any surrender of journals by the library to authorized persons (respective head of the organizational units) shall be conditional to the provision of a signature.

# 2.4 Obligation and responsible persons

Each laboratory journal shall be kept by a single person only and said person shall be responsible for orderly keeping of the journal.

The obligation to completely surrender all laboratory journals and supplement laboratory journals at the end of employment is stipulated in the contract of employment. The recipient of a laboratory journal confirms to have received the regulations for keeping laboratory journals on the first page of the laboratory journal. The person is then obligated to adhere to all included regulations. Upon the departure of a staff member from employment at the HZI, the central archiving department initials the surrender of all laboratory journals and supplement laboratory journals used at the HZI on the routing slip.

# III. Keeping the laboratory journal

#### 1. Documentation

The performance and the results of experiments shall be documented in timely manner in the laboratory journal.

The experiment ID must be unambiguous to any knowledgeable reader. It must be feasible to unambiguously associate associated electronic data with the experiments ("computer search ability"). Any research work shall be documented completely and comprehensively without omissions in chronological order. The format of the documentation can be designed freely.

#### 2. Legibility of the documents

All hand-written entries made in the laboratory journal shall be clearly legible. Black or blue ballpoint pens shall be used exclusively for any entries made in the laboratory journal. Printouts and copies shall be clearly legible. Heat-sensitive paper (thermal printer!) must always be photocopied before gluing it into the laboratory journal, since the original printouts fade over time. All data glued into the laboratory journal must be signed on the corresponding page with the signature continuing onto the page such that it can be traced afterwards if any printouts have come off the page and fallen out.

#### 3. Correction of incorrect entries

It is not permitted to erase or paint over errors. Instead, the incorrect entry shall be crossed out with a single line such that the corresponding word or sentence remains legible. Any changes of content shall be entered, initialed and dated. As before, original entries shall be crossed out such that they remain legible.

#### 4. Cross-references

If more than one person participates in the experiments, cross-references (minimal information: HZI name ID and date) to the corresponding laboratory journals of the other participants need to be recorded.

If the work on one experiment cannot be documented on contiguous pages, it needs to be entered at the site of interruption on which page the document is continued. Laboratory journals must include unambiguous cross-reference to any additional material that is archived in a supplement laboratory journal.

#### 5. Printable enclosures

Anything that is legible and can be printed out with a reasonable effort should be glued into and/or archived in the supplement laboratory journal (see 7. Supplement laboratory journals). Data that cannot be printed out is to be archived by electronic means.

#### 6. Table of contents

The table of contents of the laboratory journal shall be kept in comprehensible manner by the responsible individual.

#### 7. Supplement laboratory journals

Large-sized and bulky materials and data sheets that cannot be glued easily into a laboratory journal must be stored in a supplement laboratory journal (any storage system that is suitable for the pertinent materials, e.g. document file, cardboard box, etc.). For this purpose, a label describing the supplementary material and the place where this material is stored is to be glued to the site of cross-reference in the laboratory journal. The same label is also to be attached to the material itself. Each supplement in a supplement laboratory journal must be numbered unambiguously and such that it cannot be changed (e.g. the serial number of the laboratory journal, the date of the experiment

and the page number of the laboratory journal to which reference is made). Supplement laboratory journals shall be surrendered to the library together with the corresponding laboratory journals for central archiving.

# 8. Responsibility of the directors of the organisational units

The heads of divisions, departments and research groups are responsible for compliance with the present regulations for the keeping of laboratory journals and for the safekeeping of the data in their organizational units, in particular for the archiving of data generated by staff members leaving employment such that the data can be recovered correctly. These directors have to instruct their staff members accordingly and check them in regular intervals and create suitable organizational conditions for compliance with the present regulations.

#### IV. Safekeeping of electronic data

#### 1. Central data security

All primary data that is available in electronic form and the results derived from this data must be archived centrally on an HZI server.

The same applies to all material that is stored on mobile data media (e.g. CD, DVD, etc.).

Data material that was produced up to ten years before the present regulations took effect must be archived at the HZI in the form of a legible copy of the data media. This copy must be labelled appropriately such that it can be assigned unambiguously to the associated experiments and publications and can be archived centrally.

# 2. Discoverability of stored data

Since no meta-data of the archiving are recorded at the current time, the staff members storing data need to make sure that their data remain discoverable (i.e. by creating a table of contents and/or list of keywords). As a minimal requirement, data need to be stored together with the name of the workgroup and the initial used inhouse at the HZI.

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f. Dr. Dirk Heinz	 Silke Tannapfel

(English copy valid without signature. The relevant document is the German one.)