

RECORDING OF LABORATORY DATA

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Scope

This Policy on Recording of Laboratory Data applies to faculty, staff, predoctoral researchers, summer scholars and applicants ("Covered Individuals") of The Graduate School of the Stowers Institute for Medical Research ("The School").

Purpose

The purpose of this policy is to set forth rules, guidelines and procedures for recording scientific data for promoting the responsible conduct of research, protecting the intellectual property, and promoting scientific integrity.

In addition to intellectual property concerns, complete and accurate recording of scientific data promotes scientific integrity, thereby permitting examination for the purpose of replicating research, responding to questions that may result from unintentional error or misinterpretation, establishing authenticity of the data, and confirming the validity of the conclusions.

Intellectual property developed at the Institute can represent a significant financial opportunity for the Institute and for the inventors of the intellectual property. One important aspect in the development of valuable intellectual property is the "trail of evidence" created in laboratory notebooks, which is used to support the patent applications and issued patents resulting from research carried out at the Institute. In particular, the data in laboratory notebooks can significantly affect the Institute's ability to assert its rights in important intellectual properties. Laboratory notebooks may eventually become important evidence in litigation where high-quality laboratory notebooks can give the Institute an advantage in defending discoveries made by its members.

The School is included in the Stowers Group of Companies ("SGC") Organizations and has adopted the following policy as its own.

Policy

Definition

- "Scientific data," as used in this policy, refers to data resulting from the conduct of research activities, including but not limited to quantitative data (e.g., graphs, recorded numbers, instrument output of any type, including photographic materials from which measurements can be made), qualitative data (e.g., notes of any type and some types of instrument output, including photographic media), and research tools (e.g., protocols in

any form, computer software). In some cases there may be original samples in (e.g., biological specimens, slides) that should be documented in order to connect them to the data described above.

- Scientific data is owned by the Institute, not the individual, and is subject to the oversight outlined in this policy.
- This data can take the form of 1) a physical notebook, 2) an electronic file/notebook, or 3) supporting data.

Maintenance of Laboratory Data

All laboratory data must be permanently recorded in a laboratory notebook, electronically stored, or identified as supporting data and referenced within the lab notebook or electronic file. Physical laboratory notebooks will be scanned to create electronic versions once the notebook is full, a member leaves or when the notebook is no longer used for capture of scientific data and is “closed” out. For electronic laboratory data that is stored on a Stowers Network Data Share, it is considered scanned upon creation. For programming code, the scanning equivalent is deposition into Bitbucket. Supporting data can be electronic, paper, written or medium of any form.

General Rules for Maintaining Data

- Electronic lab notebooks and/or bound lab notebooks are required.
- Members must use physical lab notebooks provided by library services.
- The handwritten entries must be legible.
- All entries must be in the English language.
- Both positive and negative research results should be recorded. Entry of both types of results verifies the legitimacy of the research record.
- Lab notebooks must 1) be kept in a timely manner, 2) include the dates associated with the entered work, and 3) be signed and dated by the author after the last entry before scanning.
- The principal investigator should maintain a master log that catalogues who is working for the investigator and the specific project assigned to each individual.
- If collaboration by more than one lab occurs, a log directed to the collaboration should be maintained.

Suggestions for Notebooks

- Entries should follow an internal standardized format and should be organized such that someone not familiar with the specific experiment can retrieve all the pertinent details.
- The first several pages should be reserved for a table of contents in which is listed the experiments and the pages on which the data is located.
- If successive bound notebooks are used, the volumes should be numbered sequentially or a log kept to identify the sequential books.
- All entries, including corrections, should be in ink or other indelible, permanent medium. When possible, the same color ink or other medium should be used.

- Data should be entered on every page. All unused portions of a page should be crossed out if a new page is started for a new entry.
- Print-outs or data sheets of raw data should be affixed to the laboratory notebook. In the event this is not possible, explicit instructions as to where this “supporting data” can be found (e.g., location of disks, samples, specimens, etc.) should be included in the laboratory notebook.
- Corrections should be made by drawing one line through an erroneous entry, and not “whited out” or otherwise obscured. Pages or portions of pages must not be removed for any reason. A correction must be initialed and dated by the individual making such correction. If needed, a brief explanation for the cancellation should be made in the margin.
- Extrinsic data, such as photographs, sketches, charts, graphs and other supporting materials, should be permanently affixed with glue or tape to the page. It must not be stapled or paper clipped, which appear to be temporary insertions.

Procedures for Scanning Lab Data Recordings

Physical notebooks will be scanned to create electronic copies that will be stored on a Network drive. These electronic files can also be provided to exiting members as appropriate (described below). Notebooks need to be scanned 1) when full, 2) upon exit of the responsible member, or 3) when the notebook will no longer be used for capture of scientific data and is “closed” out.

Library Services is responsible for scanning.

Production of Written Reports Related to Lab Data

Each principal investigator has an obligation to produce written reports describing the results of research being conducted. Normally, this is accomplished in the course of preparing and submitting manuscripts for publication in peer-reviewed journals. If research results may constitute valuable intellectual property, the principal investigator has an obligation to prepare and file a written invention disclosure with the Office of General Counsel.

Notebook Storage and Retention

Bound notebooks should be stored in a secure, cool, dry place on the Institute’s premises away from potentially damaging light, corrosive agents and organic fumes. Retention and long-term storage of laboratory notebooks is governed by 610R – Records Retention and Management of Scientific Data.

The lab notebooks and the intellectual property they contain are the property of the Institute, but a Covered Individual may request an electronic copy of his/her lab notebook(s) from Library Services upon his/her departure from the Institute. If the Principal Investigator supervising the Covered Individual approves the request for a copy, Library Services will provide the Covered Individual with a copy as soon as is practical

This policy was approved by the GSSIMR Board of Directors on September 5, 2018.
This policy was last updated by the GSSIMR Board of Directors on November 09, 2020.
This policy will be reviewed by the GSSIMR Board of Directors in 2022.