
Guidelines for Establishing Good Research Practices in Research Laboratories

PURPOSE

The purpose of this document is to provide guidelines to research teams at the University of Miami (UM) for implementing good research practices in laboratories that facilitate acquisition of high quality, reliable and reproducible data.

Due to the diversity in research conducted at UM, not all processes discussed below are applicable to each laboratory. The general principles of ensuring reliable, reproducible data and maintaining data integrity are applicable to all research and, therefore, appropriate measures should be implemented.

Researchers in UM laboratories are encouraged to review these guidelines and to implement similar processes, where applicable, to maintain data integrity and security.

ABBREVIATIONS

CV	Curriculum vitae
ELISA	Enzyme Linked Immunosorbent Assay
HPLC	High Performance Liquid Chromatography
LIMS	Laboratory Information Management System
UM	University of Miami

RESPONSIBILITY

It is the responsibility of all personnel conducting research in UM research laboratories, including laboratory directors, research associates, students, etc to:

- Protect human and animal subject safety
- Ensure and maintain data integrity
- Ensure data reliability and reproducibility
- Protect and secure research records (both paper and electronic format)
- Protect UM's intellectual property

Guidelines for Establishing Good Research Practices in Research Laboratories

WRITTEN PROCEDURES

It is understood that in a research laboratory, procedures are modified as part of the research; however, there are instances in which established procedures will be routinely repeated.

Established procedures and processes should be written and available to all researchers in a given laboratory. For example, procedures may be saved in BOX or One Drive and printed and pasted into laboratory notebooks whenever used to demonstrate the method that was followed.

Written procedures should be available for, but not limited to, the following, as applicable:

- Solution preparations
- Assay procedures
- Instructions for use of analytical equipment

SAMPLE TRACKING & REAGENT INVENTORY

Laboratories should have a system in place to log the samples and reagents received and to document their storage temperature and location.

A tracking system may consist of any of the following:

- paper log sheets
- spreadsheets in electronic format
- database such as LIMS (Laboratory Information Management System)

EQUIPMENT

Calibration and Maintenance:

To ensure that laboratory equipment is working properly and generating reliable results, a calibration and maintenance schedule should be established for all equipment.

The frequency of calibrations may vary for different types of equipment depending on the sensitivity of the equipment and the frequency of use.

Documentation of calibrations and any maintenance performed should be maintained. It is recommended to place calibration stickers on equipment to note the date of calibration and the next due date.

Guidelines for Establishing Good Research Practices in Research Laboratories

Defrost freezers on a regular basis or as needed. This may require making arrangements to move items into a temporary cold room or alternative freezer while the defrost cycle is in effect.

Equipment Verification:

For critical steps or solution preparations, it is a good practice to verify the accuracy of equipment such as balances, pH meters and pipettes prior to use, even if the equipment has already been calibrated.

Temperature Monitoring:

Establish acceptable temperature ranges for refrigerators, freezers, liquid nitrogen tanks and incubators. These refrigerators, freezers, liquid nitrogen tanks and incubators (while in-use) should be monitored to ensure that the correct temperature is being maintained.

Temperature monitoring may be continuous via the use of data loggers or min/max thermometers.

Alternatively, a manual process can be used whereby the temperature is read by personnel on a daily schedule. For example, temperature readings may be taken twice daily.

Note: When using a data logger, research personnel should review the data being captured to ensure that unacceptable temperature excursions have not been occurring.

All temperature excursions should be evaluated for their impact on each product stored in the respective equipment, based on the duration of the excursion and the available stability data of that product.

Alarm System:

It is recommended that critical equipment such as refrigerators, freezers, liquid nitrogen tanks and incubators that are used to store or incubate critical samples/cells be connected to an alarm system and back-up power.

SOLUTIONS AND REAGENTS

In addition to UM's Environmental, Health and Safety requirements, prepared solutions and reagents should be labeled with the minimum following information:

Guidelines for Establishing Good Research Practices in Research Laboratories

- Name of solution
- Concentration
- pH value (if applicable)
- Date of preparation
- Expiration date
- Storage condition
- Name/initials of investigator/person who prepared it

PROCEDURE QUALIFICATION

To demonstrate that an analytical procedure is reproducible:

- Establish an acceptable quantitative range for the control samples.
- Perform the procedure a minimum of three (3) times using standards and control samples.
- Repeat the procedure using different operators to test for inter-operator reliability.

Documentation of Procedure Qualification:

Maintain all documentation of the qualification effort in an area accessible to all researchers of the given laboratory. Documentation should include the following:

- Written assay procedure that was followed
- Name of operators
- Preparation of solutions and reagents
- Concentration of prepared standards and control samples
- Raw data printouts/electronic files from analytical equipment (e.g. ELISA reader)
- Tabulated results and conclusion

SAMPLE ANALYSIS DOCUMENTATION

When analyzing samples, document the procedure that was followed and the samples that were analyzed. It is a good practice to record the solutions that were used if they were not prepared fresh on the day of analysis.

Sample analysis source /raw data generated by equipment such as ELISA reader, gel documentation system, HPLC, etc. should be maintained in electronic files saved to a shared drive and printed to be maintained with associated documentation in laboratory notebooks, etc.

Guidelines for Establishing Good Research Practices in Research Laboratories

RECORD RETENTION

Each laboratory should implement a system to store all research documentation in a secure and retrievable manner.

Lab Notebooks should be stored in a locked fireproof and waterproof cabinet. Lab Notebooks should be retained for a minimum of 15 years, after which permission to destroy them must be obtained from the Department Chair and Vice Provost for Research.

Points to Consider:

In order to protect all research data and to make it accessible for review by fellow researchers, consider scanning completed lab notebooks and storing the files on a shared drive. Back-up copies can also be made and saved onto discs.

Data in Lab notebooks should be entered in such a manner that anyone, including an external auditor, can understand and reconstruct the research. An excellent guide to maintaining lab notebooks can be found in:

- *At the Bench* by Kathy Barker, 2005, Cold Spring Harbor Press

Off-site storage at a facility such as Iron Mountain allows for the safe-keeping of records as their facility has fireproof and waterproof storage. In addition, records can easily be retrieved within 24 to 48 hours.

Electronic Files:

A naming convention for electronic files should be established to ensure records are organized and easily found. File names should facilitate easy identification and retrieval (e.g., assay name_operator name_YY_MM_DD), should not be too long, and should conform to file-naming requirements of common operating systems (e.g., Windows and Macintosh)

TRAINING

A training file for each member of a laboratory should be maintained to document his/her qualification and experience. Each file should contain, at minimum, the following:

- Current CV
- Current job description
- Copies of certifications or licensure
- Training documentation such as training logs used to document all training received:
 - initial training for new members to a lab
 - training on new or revised procedures

Training records should be readily available for any [inspection](#).

Guidelines for Establishing Good Research Practices in Research Laboratories

SIGNATURES

Prepared by: _____ Date: _____
Signature on file *20 Jul 2017*
Helen Miletic, MA, CHRC, RQAP-GCP
Quality Assurance Manager, RCQA

Approved by: _____ Date: _____
Signature on file *28 Jul 2017*
John L. Bixby, Ph.D.
Vice Provost for Research