Expectations for Best Practices in Research Supported by Academic Core Facilities

1. Background

The recommendations outlined in this document have been developed by a working group of members and stakeholders of the EQIPD consortium, the largest private-public partnership completely dedicated to improving data quality in preclinical research.

These recommendations are intended to improve the robustness, reliability, traceability and integrity of the data obtained from the research activities supported by academic core facilities (CF).

By sharing these recommendation, they aim to:

- clarify communication between CF and the users of the services and infrastructure provided by the CF in respect to best practices,
- minimize bias and errors in the collection, reporting or representation of data, and
- create reliable scientific and supporting evidence in resulting publications, presentations, reports, patents and other types of research output.

The experimental record is the ultimate source of information and documentation regarding the experiment. Therefore, the contents of the experimental record must be accurate and traceable to permit the reproduction of the work. The experimental record is the official data record for each experiment and the primary source of data. It is expected that the recommendations outlined in this document will be applied to experimental planning, record-keeping procedures and reporting, to the fullest extent possible.

Recognizing the diversity of environments and settings in which core facilities operate, the current recommendations can be used in two modes - “Regular Service” and “EQIPD Service”.

It is expected that CF and their users discuss both types of services, any ambiguities or conflicts regarding the recommended practices, and ensure alignment and understanding prior to the start of the experiments.

Core Facilities provide the users with information about research practices recommended by EQIPD (link) and offers to support best research practices.

The user has the choice between two different types of service

**Regular Service**

- The Core Facility decides how information about research practices recommended by EQIPD is shared with the users (e.g., made part of a training program, shared as a written summary in paper or electronic form).
- Unless requested by the users or otherwise enabled, the Core Facility does not assume any further role in supporting or monitoring the implementation of recommended practices for the user.

**EQIPD Service**

- The Core Facility has implemented the EQIPD recommendations to enable support of EQIPD-compliant research to the user.
- Together with the user (and supervisor/PI if necessary), the Core Facility identifies the best solutions to implement specific recommendations for the user’s research.
- Core Facility assumes responsibility over spot checks (requires acceptance by the user if certain recommendations are implemented on the user’s side)
- Core Facility confirms to the user that the study was conducted as “EQIPD compliant” or not (e.g. to be stated in the report or in a publication)
2. Recommendations

Training - link

• Users must be trained by CF members in order to be eligible to use the CF.
• Users should seek support from CF to design experiments in due time and with the optimal rigor.

Experimental Record - link

• Unique study identifiers must be used and defined by the future owner of the raw data for each experiment. Unless this is the CF, the owner of the raw data should communicate the unique study ID to the CF.
• Each experimental record should include, directly or by reference, the names of all scientists involved, objectives, ethical approval/number, procedures, methods, materials, equipment, dates, and any other details considered necessary for reproducibility and reconstruction.
• All raw and any processed data must be retrievable and traceable, directly or by reference. No raw data should be erased.
• An experimental record must describe any significant changes and deviations from the original study protocol.
• An experimental record must provide an explanation and justification for exclusion of any data points from analysis.

Rigor in Study Design - link

• For every study, there should be a study protocol prepared prior to the study being conducted.
• The study protocol must include:
  o Title
  o Study hypothesis
  o Ethical approval number and the name of approving body (for research involving animals)
  o Statement / information about controls (with choice justification if necessary)
  o Description of sample size calculation
  o Inclusion / exclusion criteria
  o Description of animal resources, reagents and materials (as applicable)
  o Study design overview for complex studies
  o Detailed description of experimental procedure(s) (or references to standalone descriptions if available)
• The study protocol should include:
  o Statement whether study is undertaken with the intention to inform a formal knowledge-claim
  o Statement about choice of experimental methods
  o Detailed description of measures against risk of bias (randomization, blinding) (or references to standalone descriptions if available)
  o Description of raw data analysis
  o Section for amendments (or use versioning)
• It is advisable to:
  o Include in the study protocol references to relevant literature
  o Conduct risk assessment and reflect (document) it in the study protocol
  o Preregister the study protocol
Analyses of Experimental Data - [link](#)

- Experimental / data analysis record and study report (e.g. publication) should include sufficient detail to reconstruct any analysis performed and record all process steps and calculations used.

Data Storage and Traceability - [link](#)

- Experimental records should be kept in an audit-trailed, version-controlled, safe storage environment such as an appropriate bound-paper laboratory notebook with permanent ink or an electronic laboratory notebook (ELN).
- Raw (primary) data must be stored in an un-editable read-only form as soon as it is generated and must be backed-up.
- Processed (secondary) data must be clearly labeled as such and should contain a reference to raw data.

Review and Reporting - [link](#)

- Reported research outcomes should be complete, accurate and findable.
- Experimental records should be reviewed by a member of the CF for completeness and accuracy and it is advised to document this review. Users should give CF staff the possibility to review data for analysis and reporting.
- Report should always provide summaries of all related data, processes, and conclusions, and include justification for excluding any relevant experimental records or individual data points from the summary analyses.
- Any external presentation/publication whether oral or in writing should give credit to the CF where the work was performed.
- Any external presentation/publication whether oral or in writing should include a statement of conflict of interest.

3. Glossary

**Must** Indicates actions that EQIPD considers as imperative and mandatory expectations.

**Should** Indicates a strong recommendation; however, EQIPD recognizes that individual circumstances might justify an alternative strategy; a rationale for not following this strong recommendation should be presented.

**Experiment** An operation or procedure carried out under controlled conditions in order to discover an unknown effect, law, characteristic of an object, subject or substance, to test or establish a hypothesis, or to illustrate a known law (based on definition in the Merriam-Webster’s dictionary).

**Study** One or more experiments, which may also be referred to as tests or trials, that are described in one study protocol, address the same research question(s) or objective(s), share key resources, and are part of one experimental record.

**Study protocol** To refer to a description of the design of a study. Design of individual studies is described in separate study protocols.

**Experimental procedure** To refer to descriptions of specific procedures, operations, or methods.

**Experimental Record** A research diary entry for an experiment recording all data and pertinent details of an experiment such that a peer could repeat the experiment. Each experimental record should include: [link](#)

**Raw data** All original records and documentation which are the result of the observations and activities in a study, such as: [link](#)

**Processed data** Raw data that has been processed in a manner that allows scientists and managers to draw conclusions and determine the need for/direction of further experiments and/or analysis.