Guidelines for research at KI

Version 1

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NOTE: This is a translation of the Swedish version (Riktlinjer för forskning på KI). In the event of any discrepancy between the versions, the Swedish version constitutes the official decision and the Swedish wording will prevail.

Karolinska Institutet

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Revision with respect of: Replaces the existing guidelines for planning, conducting and documenting research, as well as adding a new connection to the quality system at KI.			

1 Introduction

Research is surrounded by regulations and recommendations in order to protect laboratory animals, study participants, co-workers and not least the integrity of research. Several government agencies give permissions (approvals) and are responsible for oversight and supervision. This document is directed towards all researchers and doctoral students at Karolinska Institutet (KI), who should have knowledge on regulations and need to follow those that apply to their own research.

This document covers the whole research process, from the initial thoughts and ideas, through collection and analysis, to the results and dissemination of the research, and includes how research data should be managed, documented and archived correctly.

2 Purpose

These guidelines for research at KI summarise how research should be planned, conducted and documented in a way that facilitates compliance with legislation and other regulations for researchers and doctoral students. Furthermore, the more important aspects of research data documentation and management is described more in detail.

3 Quality assurance of research

The Higher Education Act (*högskolelagen* SFS 1992:1434) and the Higher Education Ordinance (*högskoleförordningen* SFS 1993:100) stipulate specific requirements that form the basis for quality assurance of research at higher education institutions (HEI). In addition, several national and international frameworks and guidelines for research play an important part in the quality assurance work at KI. Of particular relevance are the *European Charter for Researchers and Code of Conduct for the recruitment of researchers* and the Association of Swedish Higher Education Institutions (Sveriges universitets- och högskoleförbund, SUHF) National framework*, Joint framework for HEIs' research quality assurance and enhancement systems.* At KI, as specified in the internal guidelines, *Sammanhållet kvalitetssystem vid KI, riktlinjer*, quality assurance is defined as "in a systematic and methodological way and with the help of documented routines assure and maintain high quality".

A lot of research gets quality audited through peer-review, many times in conjunction with other internal and/or external audits.

4 Good research conduct, responsibility and ethics

All research at KI shall follow good research conduct and the founding principles as described in the European code of conduct for research integrity ALLEA 2017: reliability, honesty, respect and accountability. Furthermore, the Vancouver guidelines for authorship shall apply for publications. More on good research conduct can be found at the Swedish Research Council's CODEX website.

Each individual researcher at KI is responsible for following the regulations that exist. If any other organisation or person is assigned to perform whole or part of the work, the responsible researcher needs to make sure that the right competence for performing the work is in place. When needed, potential bias and conflict(s) of interest need to be addressed.

One of the fundamental research ethical principles is to organise one's research through documentation and is central for describing the research process according to good research conduct and good data management.

The head of each department has the ultimate responsibility to ensure that all research at the department, including documentation, data management, storage and archiving is done according to relevant guidelines and regulations.

4.1 Scientific representative for guidance

There is a Scientific representative appointed at KI for researchers and doctoral students. The Scientific representative can help with informal, guiding discussions concerning research and research ethics questions.

5 Approvals and agreements for research

Any approvals needed from the animal ethical committee, the human ethical authority or any other approving agency should be in place before the start of the project and should be updated continuously when needed.

Different types of agreements, for example collaborative agreements or commissioned work, consortium agreements (common in international collaborations), data processing agreements (when sending or receiving personal data) and Material Transfer Agreement (when samples are sent or received), may also be needed before the project starts.

Approvals and agreements should be registered in the KI registration system (diariet) according to the KI document management plan and should be easy to trace back to the relevant parts of the performed research.

For guidance regarding agreements, please contact the KI legal unit at avtal@ki.se.

5.1 Personal data

Personal data is data that can be traced to a living person. Sensitive personal data (special categories) is data consisting of racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, biometric data, data concerning health or data concerning a natural person's sex life or sexual orientation.

Processing of personal data should be reported at KI through a web form.

When processing personal data in research, the data must be protected according to data protection regulations, as well as KI guidelines for information security and IT-security.

For guidance on processing of personal data, contact the legal unit at dataskyddsombud@ki.se.

5.2 Secrecy

The need for secrecy should be considered, for example when processing personal data, patentable inventions and for specific business interests, both during the project and after archiving.

5.3 Human samples

Specific regulations apply to handling of human samples. Help and guidance can be provided by KI Biobank (biobank@ki.se).

6 Planning and documentation

All research at KI should be documented, either in Swedish or English. Co-workers and, within the field, knowledgeable persons should be able to follow and review the research. It is important to describe the whole research process, from idea and planning to the results and conclusions in a way that is detailed enough to be able to trace, interpret and reproduce the research.

Several reasons exist to document your research well:

- *Traceability and the possibility to reproduce analyses and studies.* Documentation is essential in order to review and troubleshoot collected data and analyses, as well as for reproducing studies. Documentation of data (metadata) is necessary in order to verify results and to investigate potentially falsified results.
- *Reusability.* In order to be able to continue to use the data in new research, data must be documented and described. New approvals or agreements may be needed.
- *Copyright and patents.* Documentation of intellectual work is a prerequisite in order to follow principles for immaterial legislative protection and joint ownership, as well as patent application processes.
- *Collaboration.* Documentation is important to avoid unnecessary double-work and to improve collaboration amongst co-workers. It is also important in order to maintain written collaborative agreements.

Research documentation at KI should be done in approved electronic systems, and this is why electronic notebooks (KI ELN) are provided centrally.

6.1 What should be documented?

The research documentation should cover both intellectual and practical aspects of the research, as well as refer to administrative documents, like agreements and approvals, that pertain to the research. Much of the information can be given as part of a project description and associated data management plan and is continuously built upon by active documentation of the research process where the methods and data management are described and any changes are documented. This also includes information on any delays, changes or early termination of the project for any reason.

On the project level, the information should cover:

- Project description/plan (possible to for example refer to an application)
- Financial support
- Approvals, for example ethical approvals, and any amendments or changes
- Agreements, and any amendments or changes
- Data management plan
- Any correspondence relevant to the research
- Reports and publications
- Minutes from meetings and/or collaborations

The daily research documentation should cover:

- Background and aim
- Material
- Data
- Method
- Processing and analysis of material and/or data
- Results
- Conclusion(s)
- Decision(s)

7 Data management

It is important to describe data in a clear way, make sure that data is traceable, is managed in a secure way and that it is easy to connect publications and results to the underlying data. If data is not collected in a standard format, it may have to be migrated before long-term storage and archiving.

As mentioned earlier, in many cases a data management plan that describes how data is managed in the project is needed. It is the responsible researcher who is responsible for drafting and continuously updating the data management plan when needed. A data management plan usually consists of:

- Description of the data
- Documentation and data quality
- Storage and backups
- Legal and ethical aspects
- Accessibility and long-term storage
- Responsibility and resources

8 Store and archive

Research documentation and original data from the research project should be stored for at least 10 years, in many cases even longer, after publication or close-out of the project. If possible, samples should be stored for the same time period. This is for the researcher to know and be able to prove the basis for the results and conclusions.

It is important to make sure that the formats used for the documentation and data can be accessed and read during the long-term storage period. If needed, migration to more persistent archiving formats may have to be done before long-term storage.

In addition to long-term storage after publication or project close-out, decisions are needed with regards to archiving – that is when that data and/or documentation should be stored for all eternity. For detailed information on what to keep and what can be discarded, see the KI document management plan and information for archiving of research. For guidance, contact the KI Archive, arkiv@ki.se.

9 Making research accessible

Research should be as open as possible as part of the overall aim of open science and the FAIR principles. This means that publications should be made available through open access as soon as possible, and data, if possible, should be open. Open science facilitates reproduction of the research and new research.

If the data contains personal data that directly or indirectly can be traced to a living individual, then the data cannot be made completely open. If there is still a need to share these data, access will have to be regulated.

Contact the Research Data Office (RDO), rdo@ki.se, for support.

10 References and links

Current references and links are available on the KI website.