Guidelines for research at KI

Version 2

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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 to: Parts regarding research documentation and data management have been moved to the new Guidelines for research documentation and data management. Reference has also been added to the new Guidelines for the examination of suspected deviations from good research practice.			

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 Aim

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.

3 Quality-assured 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. In the event of deviations from good research practice, KI's Guidelines for examining suspected deviations from good research practice apply.

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.

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 respresenative 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 may also be needed before the research can be performed, for example cooperation and assignment agreements, consortium agreements (usually in international collaborations), personal data or assistant agreements (when handling personal data) and Material Transfer Agreements (when samples are sent outside KI or received of external part).

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 Research documentation and data

All research at KI must be documented, either in Swedish or English. Employees and outsiders with specialist knowledge must be able to follow and review the research. It is important that the entire research process, from idea and planning to results and conclusions, is described in a way and at a sufficiently detailed level for the research to be traceable, interpretable and reproducible.

Research documentation at KI must be done electronically in approved systems, which is why KI provides a central ELN system (electronic notebook).

It is important that data is clearly described, traceable, handled securely and that it is easy to connect, for example, publications to the underlying data. In many cases, data management plans, where the actual management of research data is described, are required.

KI's Guidelines for research documentation and data management describe this in more detail.

Research documentation and original data from the implementation of the research project must be kept for at least 10 years, in most cases longer than 10 years, after publication or completion of the project. Samples should be saved for the same period of time if possible. This so that the researcher knows what the basis for results and conclusions is.

For detailed information on what should be preserved and what can be discarded (destroyed), see the document management plan for KI and information on archiving research. Contact the Archive for questions, arkiv@ki.se.

7 Making research available

Research should be as open as possible as part of the overall aim of open science, the FAIR principles and KIs Policy for open access to publications. 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.

8 References and links

Current references and links are available on the KI website.