KAROLINSKA INSTITUTE
– a medical university –

Guidelines for planning, conducting and documenting experimental research

Scientists at Karolinska Institutet are required to adhere to current regulations governing human[1] and animal experimental research[2]. Recommendations for Good Laboratory Practice[3] should be respected. With respect to scientific reports and publications, authors are also accountable for the data underlying their conclusions, i.e. the original data and how these were handled in the project. It is therefore important to respect the following formal requirements for research.

1. An outline of the experiment, containing a description of the major sections of the research project, must be written by the project leader before experiments begin, in order that the work can be adequately planned, and also so that it can be satisfactorily presented to an outsider. Plans for the experiments must be clear and unambiguous for both co-workers and outsiders, and contain: the project title, specific aim/s, experimental material, procedures and measurements, data collection and calculations, and planned statistical analyses.

2. Necessary approval from The Local Ethics Committee on Animal Experiments or (for human experiments) the Ethics Committee – must be obtained before the start of the project.

3. Log books (journals) must be maintained, and entries made for all experiments, observations and/or measurements. Any alterations must be dated and signed, and entered in such a way that the original text is still legible.

4. Experimental records must be kept with dates and entries by the person responsible for the conduct of the experiments. The experimental record must be formulated in such a way that the experiments can be repeated, even after an interval of several years, and in another laboratory. This requires documentation of both the experimental material (animal, cells etc.) and equipment and measurement procedures, chemicals, isotopes etc., which are of importance to the results.

5. As soon as possible after completion, reports of the experiments must be compiled. The reports must contain or have as appendices information on calculations and statistical analyses, and a description and justification of any alterations, so that it is possible to reconstruct how the final results were arrived at. All research documents must be written in Swedish or in English, and be intelligible to an outsider.

6. Information about quality control of the accuracy of measurements, and the methods and computer programs used for analysis of results should also be available. It should be possible to assess experimental variation within and between experiments, reproducibility and possible errors of method.

7. As far as possible, the results should be stored in the form of raw data, in legible and easily identifiable form e.g. permanent print-outs of electronic data, print-outs from measuring instruments, lasting photographs of morphological data or molecular biological analyses (e.g. gels) which can be identified with certainty, print-outs of statistical calculations, etc. Even unpublished results should be kept. From the archives, it must be possible to identify the original observations on which published tables and figures were based (e.g. by referring to the protocol number of the relevant experiments).

8. The project leader must retain on file approval granted by the various authorities (e.g. from The Local Ethics Committee on Animal Experiments). As soon as possible after completion of the project, the original data, protocols, etc. must be prepared for archiving; if the data are to be used for subsequent projects, it must be stated clearly how and where they are being stored. The results must be archived for a reasonable time, retrievable for review or critical enquiry, i.e. at least 10 years after publication of the results. Where applicable, the need for confidentiality (e.g. where there are commercial interests) must be respected, both during conduct of the experiments, and with respect to archiving.

9. The Department (Head of Department) is responsible for the archives; scientists should have access to copies of data from their own projects. If the scientist in charge of the project leaves KI, an agreement with respect to access to the archived data base must be made with the responsible head of department.

Literature with more detailed descriptions and references to statutes, etc:

1 Riktlinjer för etisk värdering av medicinsk humanforskning – forskningsetisk policy och organisation i Sverige. MFR-rapport 2, 1996.

2 Swedish National Board for Laboratory Animals (CFN): Provisions And General Recommendations Relating To The Use Of Animals For Scientific Purposes, CFN Publications no. 25, 1994; Regulations and Recommendations for Research at KI Involving Animals, March 18, 1998, Lab Animal Unit, Karolinska Institutet.

3 The OECD Principles for Good Laboratory Practice. OECD/GD (92) 32 – Paris 1992. Läkemedelsverkets föreskrifter om verksamheten vid GLP-laboratorier. LVFS 1996:10.

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Svensk översättning ➡