KAROLINSKA INSTITUTE
– a medical university –

Guidelines for planning, conducting and documenting clinical and epidemiological research

Scientists at Karolinska Institutet are required to adhere to current regulations for human research[1] and good clinical research practice[2]. 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. Protocols, questionnaires, Case Report Forms (CRF) and other project documents must be clear and unambiguous for both co-workers and outsiders. The documents, including submissions to the ethics committee, must contain the following: project title, specific aim/s, patient/volunteers studied, procedures and measurements, data collection and calculations, and planned statistical analyses.

2. Research project planning must take into account the time required for preliminary testing of questionnaires and procedures, and for obtaining the necessary approvals to conduct the project: approval for human research projects must always be obtained from the Ethics Committee. Approval may also be required from the Radiation Protection Committee, the Medical Products Agency, or the National Board of Health and Welfare. Scientists must also adhere to current regulations by the Data Inspection Board, governing the collection of personal data and compilation of registers with personal data. In collaborative projects, there must be unambiguous agreement about "ownership rights", and the right to use data and collected biological material in future research.

3. Research protocols and appendices must contain sufficient detail to allow scrutiny e.g. whether the selected sample of patients/subjects is representative of the original population from which they have been recruited. A clear description is required of both the selection criteria and the means by which subjects are to be enrolled in the study (e.g. if consecutive patients are to be recruited, or how it is intended to select and contact potential participants from the population). Management of drop-outs, should they occur, should also be described at this stage. All documentation must be written in Swedish or in English and should be intelligible to an outsider. Any alterations made to primary data must be dated and signed, and the original entries should still be legible.

4. 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.

5. In clinical/epidemiological projects, it must be possible to identify clearly primary data on individual subjects, and the information must be dated and signed. Missing information must be noted as such or indicated appropriately (not left "open"). Data on individual subjects must be filed securely, inaccessible to unauthorized persons.

6. As far as possible, the results must be documented in the form of original data, in readily accessible form, e.g. permanently stored electronic data, lasting print-outs from measuring equipment or an attached printer, lasting photographs of morphological data or molecular biological analyses (e.g. gels) which can be identified with certainty, print-outs of statistical calculations, etc. The results of interviews or questionnaires and information from or in patient case-notes must also be filed securely. It must be possible to identify from the archive material the original observations on which published tables or figures are based.

7. Information on quality control of the accuracy of measurements, and the methods and computer programs used for analysis of results must be available. Informed consent should be obtained from subjects beforehand, or alternatively according to procedures approved by the ethics committee – consent must be documented in a form appropriate for each individual subject participating in the project.

8. The final report must contain, or have appendices of the statistical analyses, and a description and justification of any alterations. It must be possible to reconstruct retrospectively how the results were obtained. Confidentiality of patient data must be respected, but where possible coded lists should be kept.

9. After completion of the project, the project leader must retain approvals granted from the various authorities (see above) and the original data from the project. Approval from the ethics committee and written consents must be kept. As soon as possible after completion of the project, the original data, protocol, 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 after publication, to allow for review or possible critical enquiry. For testing of pharmaceuticals, an archival time of at least 15 years is required, and for other research at least 10 years. Where applicable, National Archives instructions must also be followed.

10. 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 Riktlinjer för god klinisk forskning. MFR-rapport 3, 1996.

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