

Guidelines for Publication Ethics at the Karolinska Institute

The goal of medical research is to increase scientific knowledge, with the aim of improving health and health care in society. Publication of findings is an important element of the research process. Scientists have a moral obligation to make their findings known to other scientists, and to professionals who may apply the findings in health care. When it is appropriate, and at an appropriate time, scientific results should also be communicated to the general public. Scientific results should be truthfully communicated so as to contribute to the growth of knowledge and generate appropriate consequences for the scientific community and for others in society.

The Karolinska Institute should maintain its reputation as a renowned Medical University. Reports regarding scientific findings presented by scientists who are affiliated with the Institute must be communicated in a responsible manner, and the reporting of research findings must conform to generally accepted ethical principles. Such reports should not mislead scientists, professionals or the general public.

The present guidelines on publication ethics for the Karolinska Institute are based on generally accepted principles and practices. Relevant background information can be sought in the following declarations and statements:

- * Uniform requirements for manuscripts submitted to biomedical journals [1]
- * The Helsinki Declaration [2]
- * Guidelines from the Swedish Science Council (Vetenskapsrådet) on Good Scientific Practice [3] and Ethics in Human Research [4]
- * KI statements on accountability, etc. [5, 6]

Publication ethics

Scientific work should be performed in accordance with generally accepted ethical rules and regulations. Whenever appropriate, publications should state that ethical approval was obtained for the human or animal research reported. In human research the integrity of research subjects should be respected. Published information should not identify individual subjects of the research unless they have specifically consented to this. Publications should state that informed consent was obtained from the research subjects or, if that was not the case, that the Ethics Committee has waived the requirement for informed consent from the participants in the study.

Scientific reports should accurately reflect the scientific work performed, and interpretations of results should be justifiable. Thus, authors have a responsibility to collect and document their data, and to report the methods used in such a way that the results can be reproduced by others. Authors should analyze and interpret data according to scientifically accepted standards, and report results in an unbiased and truthful manner. It is not acceptable to manipulate or withhold results from research projects, since this may distort the research process.

The right and obligation to publish

The design of research projects should be made publicly available, and scientists have a moral obligation to publish or otherwise disclose their results [2]. This means that results that have been obtained should not be suppressed if they do not suit vested interests (i.e. publication bias). Thus, researchers at the Karolinska Institute should reserve the right to publish results from research projects which are sponsored by commercial organizations. The sponsor should have the right to comment on the findings and interpretations, but should not have the right to impede publication. If there are specific reasons to delay publication of results (e.g. due to patent procedures, in the early development phase of a commercial project, etc.) this should be specifically stated in the research agreement. The scientist may thus delay publication after mutual agreement, but findings should be made available in due course.

Redundant or duplicate publication

Journals have Copyrights regarding the scientific manuscripts that they publish, and duplicate publications are generally not acceptable to the scientific community. Therefore, it is important to identify possible conflicts between Journals that may publish similar - or the same - material from a study. If findings are re-published in another Journal (e.g., in another language, or in a condensed format for educational purposes) it is important to cite the original paper. If extensions of a previous publication are made, it is also appropriate to cite the first publication in which results from the study were presented so that editors and readers can ascertain what is new in the follow-up publications. When several Journals are involved in the publication of similar study results, it is necessary to have approval from all editors involved [1].

Citation ethics

Scientific reports should put new work into context by fair acknowledgement (i.e. citation) of previously published work and scientific hypotheses. It is not acceptable to claim "intellectual ownership" of a theory if it may be disputed who actually contributed what to the theory.

Plagiarism or misrepresentation of contributions made by other scientists are not acceptable.

Accountability

Research at the Karolinska Institute should conform to generally accepted principles of Good Clinical Practice (GCP). Rules regarding documentation of study procedures, permissions, and results, as well as rules for archiving have been issued [5, 6]. These rules should be followed, so that the conflicts arising from unsuccessful attempts to duplicate the findings or general distrust can be solved. Investigators must respect the need for full accountability with regard to their published findings.

Authorship

All persons designated as authors should qualify for authorship, and all those who qualify should be listed [1]. Each author should have participated sufficiently in the work to take public responsibility for appropriate parts of the content. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article. Reports emanating from the Karolinska Institute should have at least one (co-)author who is clearly affiliated with the Institute.

To qualify for authorship one must have contributed significantly to the conception and design of the study, to the acquisition of data, and/or to the analysis and interpretation of data. The author should also have contributed to the drafting or critical revision of the article in the writing process. Each author must also approve the final version of the manuscript.

It follows that funding of work or providing working facilities for scientists at the Karolinska Institute does not qualify for authorship. Contributions of patients or the provision of animals or other resources (e.g. personnel, equipment, facilities, reagents, antibodies, etc.) to the study are not regarded as sufficient reason for co-authorship if this is the sole contribution (see below). An author should be actively involved in the scientific process that results in the article, and should take responsibility for the ensuing publication. Gift authorship (i.e. the inclusion of a co-author, such as the Head of the Department or a well known senior scientist, who did not contribute significantly to the study and its publication) is not appropriate. Contributions that facilitated the scientific work should, however, be properly acknowledged.

The order of authorship should be agreed between co-authors, and the order should reflect the distribution of work and responsibilities within the project. It should be possible to identify the contribution of every co-author of a scientific article. Every co-author should take responsibility for his/her part(s) of the article, and at least one author should assume responsibility for the entire article. Senior scientists and supervisors should be aware of, and protect the rights of younger scientists to publish their work.

Medical Journals increasingly require statements regarding the contributions and responsibilities of each individual author. Such statements should be agreed upon between the authors, and should be made available to editors upon submission of scientific manuscripts. The statements may or may not be published, depending on Journal policy. The Karolinska Institute encourages the policy to clearly identify contributions and responsibilities in collaborative research, regardless of Journal requirements.

Acknowledgements

Persons who have contributed to the scientific work in a fashion which is not compatible with the rules for authorship (see above) should be acknowledged, after approval by the person(s) in question.

When several centers have contributed patients and/or information to a study it may be appropriate to acknowledge all local participants with a list of investigators, and their affiliations, as an Appendix to the publication.

Conflict of interest

Research sponsors should be identified, and potential conflicts of interest (funding, expert assignments, personal financial interests, etc.) should be appropriately disclosed when results are reported. If the sponsor has taken an active part in the design, analysis, interpretation, or reporting of study results this should be stated in the publication. It is fully acceptable to have vested interests, and to collaborate with commercial sponsors in various ways, provided that this is openly declared.

Peer review of manuscripts, applications for funding, etc.

Peer review is an essential part of the scientific process, and involves the evaluation of manuscripts, grant applications, job applications, etc.. Those who perform such peer review duties must respect that ownership of results and ideas presented in the material under review

belongs to the author/applicant, and that the material is confidentially released to the reviewer. Thus, it is not acceptable to use such privileged information without prior agreement with the author or applicant. It is also unacceptable to participate in a peer review process if potential conflicts of interest are at hand.

Prepublication

New findings regarding diagnostic, preventive or therapeutic strategies, new discoveries regarding health hazards, as well as new knowledge in basic science may be suitable for communication to the general public. Researchers have a responsibility to give correct and balanced information when releasing such information to the media. For clinical research the timing of the release of information is important, as premature release of information may cause problems in the communication between patients and their physicians. The physicians should have the possibility to inform themselves on the issue, and evaluate the information before discussing it with their patients. Thus, "press releases" should be synchronized with publication dates for clinical studies.

Premature release of information (other than in Abstract form at scientific meetings) may complicate the publishing process, since Journals wish to publish new findings, not information that is already widespread. When releasing information before publication it is advisable to have an agreement with the Journal.

Communication with the media

When communicating with the media researchers at the Karolinska Institute should provide balanced information on the significance and applicability of the study. If results have been obtained in the test tube or in animal models, one should emphasize the need for confirmation in clinical studies. In clinical research on, e.g., the value of a new treatment, not only relative benefits, but also absolute benefits (i.e. how many patients might benefit, and to what extent) should be estimated so that the general public can understand the magnitude of the benefit. When risks are described it is similarly prudent to state how many individuals may be at risk and how much the risk increases in absolute terms upon exposure to a certain situation or treatment. When a scientific field is still in its early exploratory phase it is not appropriate to state that it is only a matter of a short time before the problem is solved. Scientists should not create unfounded expectations or fear among laymen via the media.

References

1. International Committee of Medical Journal Editors: Uniform Requirements for Manuscripts Submitted to Biomedical Journals (updated October 2001). www.icmje.org
2. World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects (6th revision, Edinburgh, Scotland, October 2000). www.wma.net/e/policy/17-ce.html
3. Vetenskapsrådet: Riktlinjer för god medicinsk forskning. 2001.
4. The Swedish Medical Research Council: Guidelines for ethical evaluation of medical research involving human subjects – the policy and organization of research ethics in Sweden. MRC report 2, 1996; english translation 1999. The Swedish version, MFR-rapport 2, has been updated twice by Vetenskapsrådet, most recently in 2002.

5. Karolinska Institutet: Guidelines for planning, conducting and documenting clinical and epidemiological research. 1998.
6. Karolinska Institutet: Guidelines for planning, conducting and documenting experimental research. 1998.