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Teknologi og Udvikling

The Danish Committees on Scientific Dishonesty

Guidelines for Good Scientific Practice

with special focus on

health science
natural science
technical science

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Preface

The Danish Committees on Scientific Dishonesty (DCSD) hereby issue a revised and updated set of guidelines covering a wide area of the DCSD's conception of good scientific practice.

The DCSD's scope according to act on scientific advice, etc. is limited to the processing of cases relating to scientific dishonesty raised by report. Scientific dishonesty is defined in the act revised in 2008 as "falsification, fabrication, plagiarism and other serious violation of good scientific practice committed wilfully or grossly negligent by planning, performing or reporting of research results." The DCSD's scope has been changed and now – opposite to previous – relates directly to serious violation of good scientific practice which has made the existing updated version of the guidelines topical. Over the years, the DCSD has gained quite some experience in what gives rise to conflicts among scientists and even sometimes causes suspicion and accusations about scientific dishonesty. It is clear to the DCSD that many scientists and groups of scientists would have avoided conflicts, had they been more aware of the contents of the DCSD's guidelines.

However, these guidelines are no answer book. Please note that the DCSD does not find insufficient observance of the recommendations of the guidelines in any event as being criticisable, nor that this would represent potential for scientific dishonesty. As such, an actual reasoned deviation from the presentation of good research practice of the guidelines would in certain events be acceptable. Reversely, it should also be assumed that actual situations may arise which have not been described in the guidelines, but which will be considered as scientific dishonesty.

The guidelines do not pretend, either, to constitute an exhaustive review of good scientific practice. Parallel to the

DCSD's guidelines are various other sets of rules, policies and directions of good scientific practice. References to such other sets of rules have to some extent been included in the individual chapters, but it should be specified that the DCSD's guidelines have not been fully coordinated with all other sets of rules.

Finally, it should be emphasised that the guidelines are precisely "guidelines" which do not have effect of law. As appears from law, it is not the DCSD's assignment as such to ensure prevention of scientific dishonesty, nor is it the DCSD's assignment to define, issue rules or teach good scientific practice The duties of prevention and teaching rest with the research institutions, but hopefully, the contents of the guidelines will be included, among others, in the formalised Ph.D. teaching – i.e. in the education of scientists.

The first guidelines were issued in 1993, and the most recent update was made in May 1998. To the now updated guidelines, the following is added: Guidelines on research in the field of mathematics – including statistics, and The Act on Processing of Personal Data and scientific projects.

The chapters have been designed so as to be read independently, and therefore there are some overlaps between them.

As the previous guidelines also the 2009 guidelines have been made subject to hearing among a wide spectrum of Danish research institutions. There was general acceptance of the principles of the guidelines, and there were proposals of adaptations and clarifications which, to a wide extent, have been observed in the existing version.

Please note that the guidelines do not include all scientific disciplines, but that, to a considerable extent, they are based on issues within health science, natural science and technical science. This is neither an expression of the DCSD downgrading other scientific areas nor an expression of insufficient – or at least unwritten – standards for good scientific practice within all areas. In a next phase, the DCSD will be open to contribute to prepare guidelines also for other research areas – for instance, the humanities and the social sciences. However, it is estimated that the 2009 guidelines are

of such general nature that they will be applicable to a broad range of research areas.

Hopefully, Danish scientists will consider the guidelines as supportive to their work and supportive to introducing younger scientists to good scientific practice for the overall purpose of raising the scientific quality of the research process.

It is recommended that managers and project supervisors in all research institutions', including research departments in hospitals, will make all scientists aware of the guidelines, or produce local guidelines based on similar principles.

The 2009 update of Guidelines on Good Scientific Practice has been performed by: Chief Consultant Physician, DMSc Nils H. Axelsen, General Counsel, LLM. Charlotte Elverdam, Professor, DPhil Vagn Lundsgaard Hansen, Head of Institute, Associate Professor, Ph.D., MPM Kirsten Ohm Kyvik, Professor, DMSc. Ebba Nexø, Research Associate Professor, Consultant Physician, DMSc Ole Haagen Nielsen, Professor, DMSc et DSc, Jens F. Rehfeld, and Professor, DMSc Thorkild I.A. Sørensen. Furthermore the secretariat of DCSD has contributed to the update.

Ole Haagen Nielsen
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Chapter 1

Guidelines for research protocols and reports, data documentation and data storage in basic health research

All persons participating in a project shall be able to see and understand the original trial results, their processing and interpretation. The research results ought to be available in the longer term so as to be reassessed or applied for further research. An appropriate design and storage of research protocols (i.e. description of the project with background and purpose, methods incl. statistical methods and any sample-size calculations, statement of authors, premises for examination and time horizon) and research reports (i.e. description of already performed sub-elements/examinations as described in the trial protocol), data documentation data storage are accordingly crucial. See Chapter 7 if personal data is included.

The overall section of research protocols should be written before the research is carried out. The research report should be written as soon as possible after termination of the research and should include details about calculations and their assumptions to the extent necessary to the comprehension of the results.

Below, a number of requirements to research protocols and data collection are stated.

Trial protocols and data may exist electronically or in hardcopy.

If electronic research protocols are applied, you should:

a) by completion of a research protocol, save a read-only version on a central server,
b) introduce a system so as to ensure order of different versions.

c) ensure that technically endurable media are applied which are placed physically so as to be protected with respect to confidentiality as well as protected from events which may destroy the original materials (i.e. back-up of trial protocols and data).

If hardcopy version is applied, you should:

a) use hard-back books
b) refer to appendices filed electronically or in other manner
c) refer to a copy being filed at another location.

Research protocols shall be kept with statement of date and identification of the person responsible for exercising the research. Index is to be updated regularly. It is the author's responsibility that protocols, reports and appendices (also from not published research) are filed responsibly in a form which is immediately accessible to all participants.

Research protocols/reports shall be clear and unambiguous to all parties involved, not only to the ones planning and performing the trials, but also to those who perhaps subsequently want to assess the results. Accordingly, choose language in due respect thereof. To the extent possible, apply a standardised format of title, purpose, materials, methods (incl. recording methods), timelines, raw data and calculations as outline for each research protocol/report.

Research protocols/reports shall be designed to make it possible to reproduce the research even several years later or in other laboratories. Accordingly, it may be necessary to describe new research objects, appliances, chemicals, etc. when applied for the first time.

Research protocols/reports shall include sufficient information about potential errors and deviations from the planned procedures and the applied materials. This may become decisive to whether such data are to be excluded from a statement. Furthermore, such changes in the circumstances of the research may enlighten new aspects and be of scientific value.

Research protocols/reports shall include all corrections made, and the original text shall be visible.

Research protocols/reports shall make it simple to identify original observations included in the published data.

The research institutions may determine rules of storage of research protocols and research data, including rules about duration and access also to copies of data for the person responsible for the project in due respect of the guidelines of The Danish Data Protection Agency. The DCSD recommends that fixed rules be attempted set up for storage, for instance, for five years after the completion of the project. For drug trials, ICH-GCP rules apply (www.emea.europa.eu), which determine that data are to be filed for two years after a drug has been marketed or alternatively for two years after formal completion of clinical development. The person responsible for the project is allowed to bring a copy of data on expiry of the employment upon agreement with the persons responsible for data (i.e. regions, municipalities, research institutions, etc.).

Chapter 2

Guidelines for protocols, data documentation and filing of data within clinical and clinical/epidemiologic research

It is important for the performance of each project that all parties (i.e., scientists, supervisors and any other participants) have mutual information liability as to the original trial results, their processing and interpretation. An appropriate design and filing of research protocols, etc. is therefore decisive. This chapter should be read in connection with Chapter 7 about the Act on Processing of Personal Data.

1.

Research protocols, questionnaires, interview forms, case report forms and other documents shall be clear and unambiguous to all parties involved – not merely the ones planning and performing the research, but also to others who at a later stage might assess and make further use of the research. There must be a standardised format of title, purpose, materials, procedures, expected raw data and statistical calculations and any qualitative analyses of the project when the trial protocol or the project description is prepared. Finally, the protocols are to be dated so that you know which version is referred to on approval.

2.

For all projects comprising clinical examinations of patients or experimental subjects, participant information and consent forms as well as declaration of power of attorney for drug trials are always to be prepared in a comprehensible language. It is recommended that questionnaires, if any, have been validated before initiation of the project.

3.

All projects, registers, etc., in which personal sensitive data are included, are to be reported to The Danish Data Protection Agency (see The Danish Data Protection Agency's website for advice to this effect and Chapter 7). As permits from The Danish Data Protection Agency are time limited, it should be considered early in the process, how data is subsequently anonymized. Projects entailing human trials or trials on human biological materials are to be reported to The Danish National Committee on Biomedical Research Ethics system according to effective guidelines to this effect which are currently adjusted. All projects comprising studies of a pharmaceutical are to be reported to the Danish Medicines Agency (see www.laegemiddelstyrelsen.dk), see The Danish Medicines Agency's guidelines for application for permission to perform clinical trials with pharmaceuticals on human beings (section 88 subsections 2 and 3 of the Medicines Act, see executive order no. 744 of 29 June 2006 about good clinical practice (GCP) in connection with clinical trials with pharmaceuticals on human beings) (implements parts of Council directive 2001/20/EC of 4 April 2001, The Official Journal of the European Communities, L 121 and parts of Commission directive 2005/28/EC of 8 April 2005), and are to observe the 'Good Clinical Practice' rules (www.europa.eu). The Danish Medicines Agency will then decide whether it is an actual drug trial which is to observe the GCP rules. This is, for instance, done by contacting a GCP unit attached to the public health service. Projects comprising medicinal equipment are also to be reported to The Danish Medicines Agency, see The Ministry of the Interior and Health's executive orders on medicinal equipment no.s 1268 and 1269 which became effective on 1 January 2006 (may be downloaded from www.dgm-nb.dk/dokumentgrupper). Projects comprising use of irradiation are to observe the rules existing therefore, for instance, executive order no. 823 of 31.10.1997 about dosage limits for irradiation, executive order no. 975 of 16.12.1998 about medicinal x-ray systems for examination of patients, and executive order no. 954 of 23.10.2000 about the use of open radioactive sources in hospitals, laboratories, etc.

4.

There must be detailed description of inclusion and exclusion criteria in relation to the project in the appendices to the trial

protocol and study design description as well as random samples to be examined are to be sufficiently detailed so as to enable the specification of the representativity in relation to the population from which they stem. Whenever relevant, power calculations are required to ensure that the examined random sample is sufficiently large to examine the problem set up with a necessary statistical strength. In certain events, it will also be appropriate to state the recruitment strategy. There must additionally be a description of which circumstances of the study may lead to it being terminated prematurely, or to the individual participant being taken out of the protocol and how in such event you would inform the persons or patients participating in the trial.

5.

Personal data from clinical scientific surveys shall be unambiguously identifiable, and each case report form is to be dated and signed (perhaps electronically). Boxes not filled in are to be crossed out.

6.

Permissions obtained from The Danish National Committee on Biomedical Research Ethics system, The Danish Data Protection Agency, Radiation Protection Laboratory, The Danish Medicines Agency and any other instances involved as well as consent forms from all patients or experimental subjects included in the study are to be filed according to the provisions of effective law and in due consideration of any controlling examinations. This also applies to interviews, questionnaires and other personal documents. Electronic data may be filed in the Danish Data Archive which is a part of The Danish State Archives. Here, it is possible to file anonymized as well as personal materials, but it is to be considered archiving. The Danish Data Protection Agency equals archiving of personal data in the Danish Data Archive with anonymization, which enables subsequent repeated examination of the relevant persons. Permission from The Danish Data Protection Agency is necessary to extract personal materials from the Danish Data Archive (see http://www.sa.dk/dda).

7.

The final report of the project or the trial shall include all calculations and corrections performed as well as the assumptions therefore as necessary documentation and to ease the understanding of the published results towards all participating scientists in the project.

8.

Details about quality control of significant data including handling of data appearing as deviating observations (outliers) and their in-dating in databases or statistical programmes are to exist. Detailed descriptions of applied statistical methods and software shall be stated - as well any qualitative analyses and electronic analyses programmes.

9.

It must be possible based on case report forms and questionnaires to identify the observations included in the published tables and figures.

10.

Interviews, questionnaires, case report forms or similar personal data materials should not be filed in journals as such materials shall not be handed out, for instance, in connection with request from insurance companies or similar.

Chapter 3

Guidelines for agreements at the initiation of research projects

The following list comprises items which it might be advantageous to have discussed and formally agreed about at the initiation of research projects, especially when several centres or departments participate.

Such agreements may be based on a selection or all the items in the list. Smaller research groups may not need formal agreements, but the more complex the collaboration, the greater the need for agreements. The scope of the contract/agreements must depend on the research group's concrete evaluation. The list may serve as a *check-list* a list for *agreements* as well as for the many *activities* necessary during the course of the project.

Employees of a public research institution may obtain assistance from the institution in negotiation and preparation of the agreement. If the agreement comprises intellectual property rights, the agreement shall be signed by the management of the institution.

The recommendations shall ensure *an unequivocal project management* (item 4), an *up to date information* to all participants concerning the protocol/ research plan and the related tasks (items 5-7), and a precisely *formulated distribution of duties and rights* concerning the work and the resulting data (items 8-12).

It is also the aim that the recommendations clarify the individual participant's *realistic expectations* of personal gain in the form of thesis reports and authorships and about what they are liable to perform in this connection (items 13-16). All information relating to a project is openly distributed to all members of the project group.

Item 15 also includes *the preparation of an authorship declaration* concerning the individual participant's contribution to articles, which with the present international development

may be expected to be become a future editorial requirement from many scientific journals. It is in any case recommended to prepare such a declaration as documentation in relation to later applications and the submission of academic dissertations.

Finally, a few items (17-20) deal with *patenting, financing, external information and conflict resolution*.

Several other aspects of importance for the planning of research projects may be found in the previous guidelines on the presentation of research protocols etc. in basic health-scientific research and clinical-epidemiological research. Aspects concerning data storage may also be found in Chapter 4.

Participants in a project (the project group) are in the following defined as persons, who intellectually and work wise participate creatively in the project to such a degree that the requirements to co-authorship are expected to be fulfilled, cf. item 1 in Chapter 5. Also persons acting as supervisors or advisors to the participants in the project group are included although they may mot necessarily qualify as co-authors.

Basic elements of collaborative agreements

1. Title of the research project

2. Participants in the project

Statement of participating institutions, departments, institutes, etc. with specification of participants from the individual units. Any industrial participants are to be defined unambiguously in the agreement.

3. Objective and timeline

- Statement of objective.
- Statement of time plan for the activities assumed necessary to achieve the objective.

- Statement of any intermediary stages and separate research sub-objectives assumed to be realisable at these stages.

4. Project management

- Statement of procedure for appointment/election of project management team (project manager, steering committee if necessary, expert monitoring group, etc.) and statement of the appointed/elected persons.
- Statement of function and competence of the project manager, including the relation to any steering committee, expert monitoring group etc.

5. Rules of procedure

- Determination of the frequency of ordinary plenary meetings and rules for convening non-scheduled meetings.
- Decision on the person responsible for convening meetings (project manager or an appointed co-worker).
- Decision on a standard agenda including any ad hoc items and minutes as well as the person responsible for preparation and distribution to the participants.
- Decision on the person responsible for keeping the list of participants up to date and distributing it to all participants.
- Decision on procedure for accepting new participants and for voluntary or forced resigning of participants. It should also be determined how to act in such cases with respect to items 9-14.
- Statement of procedure for any change in project management.
- For large studies: Location of and tasks for a centrally located scientific secretariat.

6. Research protocol/study plan

- Decision on the person responsible for:
  - preparation of final edition
  - distribution to all participants
  - obtaining response from all participants as to approval or comments

- Decision on the person obtaining any necessary permission from from:

- The regional science ethical committee (always the person responsible for the trial, i.e., the person holding a position recognised for performing research, e.g., by employment as scientist or Ph.D. student or in other manner employed in actual research, and who is responsible for the practical performance of the trial at a specific trial location).
- The Danish Medicines Agency
- The Danish Data Protection Agency
- International registers for clinical drug trials
- The Radiation Protection Laboratory.
- The Council for Animal Testing.

- Decision on the person responsible for storage of:
  - Electronic data in a common database, storage of other data, and e.g. biological samples, see also Chapter 4
  - Consent forms, research annexes, curricula

- Determination of procedure for adoption of potential subsequent protocol changes, including how they are processed at meetings and made known to all participants.

7. Internal information about project progress

Determination of frequency of and form of progress reports internally in the group and about meetings when agreed data collection has been completed.

8. Allocation of functions

Indication for each function of who is in charge of it, potentially who is to perform it and how it is perhaps allocated among several participants.

9. Access to equipment, assistance and other facilities

Indication for each employee of which equipment the individual has access to, at which interval and with which assistance.

10. Applications for research grants

- Decision as to who is primary applicant, co-applicant and in other manner are to be mentioned in the application,

and therefore responsible *vis-à-vis* the source of funding. However, it should be possible to change the role as primary or co-applicant as the individual members of the project group may have different possibilities of applying for funds.

- All persons mentioned by name in the application are to approve the final design of the application before it is submitted to, e.g., scientist councils, funds, etc.
- It should be indicated which financial and other resources are available at the workplace(s).
- It should be indicated which funding has already been achieved (fund name, perhaps amount).
- It should be indicated which other funds are applied for concurrently, and if more funds are subsequently applied for, each of the funds already applied for should be informed thereof.
- When partial funding is granted from one of the funds applied for, the remaining funds should immediately be informed thereof.
- In the event of full funding from one fund, the application is to be withdrawn immediately from the other funds.

11. Guidance

Determination of who is to be in charge of the day-to-day guidance of less experienced scientists in the group.

12. Distribution of right of disposal of data

- Specification of the participants who have free access to all information within the limits of the planned project. However, there may be studies for which it is not appropriate to provide current free access to all information. This accordingly applies to studies, where no unplanned interim analyses or local analyses should or shall be performed. In such events, it is necessary to limit the access to data in order to be able to efficiently prevent such analyses in multiple centre cooperation and thereby also prevent results of such analyses from being published before the total project has been completed and finally analysed. There may also be reasons for only being accessed to a certain set of the common data, if, in an application to a steering committee, you have

described what to study – and with which data. This may be necessary to ensure a balanced distribution of research possibilities and merits among the participants contributing to creating data. It is not fair if such applications are based on prior probing analyses of data. The temptation to ″look at″ data you are freely accessed to may be so strong that, in relevant connections, decisions should be made to efficiently protect all parties from such temptation by limiting the access.

- Indication for each type of data of who is expected to be allowed to apply for use of such data for publications.

- Statement of rules for
  - Which data each participant is allowed to have copies of.
  - Which data or, e.g., tissue samples or other biological materials each participant is permitted to bring for other purposes after the completion of the project.
  - Background or foreground knowledge and potential right to subsequent use of such knowledge – things not intended for the primary protocol, but which will be studied in future, perhaps partly with new scientists.
  - Which data or other materials the individual employees are permitted to bring on potential premature, voluntary or involuntary, disruption of the cooperation with the group, see also Chapter 4.

- In any event, the Act on Processing of Personal Data shall be observed, and permission from the Danish Data Protection Agency shall exist. It is crucial to be aware that such permission from The Danish Data Protection Agency is time limited. Personal data shall accordingly be anonymised or deleted on expiry of the permission.

- When cooperation has been established with an external source of financing, data shall be property of the research institution. In individual events, other requirements of ownership may occur via a cooperation agreement. This has been discussed, among others, among The Danish Association of the Pharmaceutical

Industry and the Danish Medical Association, which has given rise to rules to this effect.

13. Planned publications and academic theses

- Indication of a preliminary list of expected publications from the project.
- Indication of which participants apart from common publications may plan to use results from the project for Ph.D. or Doctoral dissertations outlining which data are expected used for such purposes.

14. Allocation of authorships (see also Chapter 5)

- Statement of who has the responsibility of preparing a preliminary list of the publications expected to result from the work.
- Statement of expected first and last authors and, to the extent possible, co-authors.
- Statement as to which supervisors and other contributors should be mentioned, for instance, in Acknowledgements.
- Statement about of authorship for participants resigning before the project has been completed.

15. Preparation of publications (see also Chapter 5)

Statement of who is responsible for:

- Preparation of the first manuscript draft (most often the first author).
- Preparation of the final manuscript.
- Who is the corresponding author, before publication with the editorial office, and after publication with interested readers.
- Submission of manuscript draft and final edition to all participants.
- Agreement about who submits the final manuscript to the journal.
- Preparation of a detailed authorship declaration prior to submission for publication with personal attestation of the individual participants' contribution. In multiple centre studies, the first author or the person responsible for correspondence may on behalf of all participants

declare that signatures will be collected, should the manuscript be accepted for publication.
- Obtaining approval from all participants prior to submission of a manuscript and co-author declarations for publication.
- Submission of referee comments to all participants.
- Preparation of changes as a result of referee comments and submission to all authors for *written* approval of the finally revised manuscript.

16. Adjustments

The preliminary nature of many of the decisions necessitates current adjustments which should regularly be taken up for consideration.
The decisions about changes from the preliminary decided allocations should be taken at meetings, and be described in the meeting minutes, the relevant protocols etc.

17. Patenting

Allocation of potential intellectual property rights should be taken into consideration at the beginning of the project. The agreement should ensure that the results will be published in scientific media, but it should also be agreed that publication shall not take place until after the patenting potential has been examined and a potential application has been submitted. A timeline should be made for this probing, and is usually about three months.

The Danish Act on Inventions at Public Research Institutions as well as the Danish Act on Employees' inventions includes provisions about employees' and employers' rights to inventions made during an employment. The basis is that the right to inventions is attributable to the employed scientist, but that the employer is able to claim conveyance of the right against a fee. Accordingly, referring to this act – the employee is liable to report any invention made to the institution, see also Chapter 4.

18. Financing

- Agreement as to who is responsible for the project financing and agreement about principle of resource

allocation among scientists, scientist groups and participating institutions.
- Description of already achieved financing.
- Plan for future financing with statement of who is responsible for applying, and how financing of the sub-objectives of the project is to be prioritised, see also item 3.
- Indication of other matters regarding the project financing, including also any income earned through the project.
- Agreement about allocation – after the end of the project – of ownership of potential equipment purchased with project funds.
- For human trials, significant parts of the financial contract are to be presented to the scientific ethics committee.

19. External information for non-scientific fora

Determination as to *who* may speak on behalf of the group before authorities and news media, as well as agreement as to *what* may be spoken externally especially before publishing in scientific journals and in case of potential submission of a patent application.

20. Conflict resolution

Determination as to how disagreement is to be handled and as to establishment of a potential arbitrator function or other forms of external assistance for resolution of potential greater conflicts. It could perhaps be determined that the institution of higher education's practice committee can appoint an arbitrator.

References

- Andersen MB. Act on employees' inventions with comments. Copenhagen: The Danish Confederation of Professional Associations, 1995

- Act no. 142 of 29 April 1955 about employees' inventions with subsequent amendments.

- Act no. 347 of 2 June 1999 about inventions at public research institutions with subsequent amendments.

Chapter 4

Guidelines relating to rights and duties concerning storage and use of research data

As a part of promoting good scientific practice and preventing conflicts between scientists or research institutions internally and among scientists or research institutions and other parties, it is recommended that the below guidelines on rights and duties of filing and on right and duty of use in connection with research data be observed.

The purpose of scientific work (research) is to provide reliable new knowledge, and is characterised by descriptive, hypothesis generating research and actual hypothesis testing, based on systematic collection and analysis of data, including qualitative observations, and critical assessment thereof,

Scientific work may be performed in university institutes and other public research institutes, in public non-scientific institutions or under private auspices, and the results may be published in scientific journals or in scientific reports and reviews.

It is recommended that identical rules be applied for scientific work whether performed from research institutions in the conventional sense or from other institutions. Also, it is recommended to apply equal rules in connection with publication of scientific data whether published in scientific journals or in other ways.

These guidelines do not mention ownership of scientific data, but merely the right and duty to use them in a responsible way and have them in custody. A reason for this is that the overall ambition for research is acquisition of new knowledge and spreading of the knowledge thereof, unprejudiced and with no other restriction than as follows from quality assessment. This is incompatible with "ownership" which usually means that the owner also may destruct or keep secret research results as he or she deems appropriate. It is also incompatible with the nature of conveyance of tissue and

blood samples, etc. which the Danish patients give for the Danish health scientists aimed at a particular purpose, but not to be owned by scientists or other persons.

It has been emphasised that the guidelines are in accordance with effective rules or law, including the Danish Copyright Act and the Danish Act on Processing of Personal Data. Please refer to the references at the end of this chapter.

The guidelines only aim at rights and duties in the mutual relationship between scientists and between scientists and research institutions. It is assumed that scientific data and biological materials have been collected and filed in accordance with law and provisions in effect from time to time with respect to patient information and consent as well as filing of personal data.

1. Filing and securing of data

1.1

It is recommended that the total amount of collected data and any biological materials entering a research project be located in a central information or bio-bank at the institution or department under an institution which is home of the research. If several institutions or departments cooperate, a central information bank should be appointed which holds all data included in the common project. By prior agreement, it should be determined where such central information bank is to be placed. However, it may be agreed that special raw data or biological materials are not to be located in the central bank but are to be filed in one or several of the institutions in which they have been produced or provided.

The individual institutions or departments may furthermore file the non-biological data or copies of the data they have produced themselves. By storage of the research materials, the Act on Processing of Personal Data is to be observed, i.e., data materials are to be destructed or anonymised as soon as the permission from The Danish Data Protection Agency expires. For especially valuable bio bank collections, it may be necessary to confer with central research authorities for potential destruction.

Also, if research under an institution is carried out in cooperation with, for instance, commercial sponsors with own database, the institution ought to have an information bank holding the data produced at the institution.

Upon completion of a project, the information bank may perhaps be transferred to Danish Data Archives (DDA), which in 2004 has created DDA Health and DDA Society. Transfer for storage in archive is regulated by the Danish Archives Act (see section 14 of the Act on Processing of Personal Data).

1.2

The participating scientists shall not erase data or remove biological materials from the central information bank, but shall have free access to the information within the framework of the planned project and may have at their disposal a copy of the data they have assisted in producing by their own creative efforts. They may bring copies when the project is completed or if they leave the research cooperation before completion, unless otherwise agreed. However, all data are to be destructed or anonymised when the permission of The Danish Data Protection Agency expires.

1.3

Disposal of copy of other data than the ones the scientist himself or herself has assisted in producing by own creative efforts requires approval from the remaining members of the group of scientists.

1.4

Upon publishing of the results from a project, the institution ought to make data available to any scientist with relevant interest in and assumptions for using them – conditional upon the approval of the authorities (e.g. The Danish Data Protection Agency).

Before the results of the original research project have been published, outsiders, however, are only accessed to data if all participants of a project agree to grant permission to such access. Accordingly, institutions cannot redistribute data

without the permission of the scientists. If publishing of data is delayed, possibility of knowledge-sharing with other scientists should be opened after a suitable span of years, e.g. five years (see Chapter 5.8 about duty to publish scientific data).

With respect to personal data and sensitive information, it is a basic responsibility to comply with section 41(3) (se Chapter 7.2) of the Act on Processing of Personal Data.

2. Publication

2.1

Scientists shall have right of use of analysis and publication of the data they have produced or assisted in producing by creative efforts. However, other scientists shall only apply such unpublished data in own publications upon prior agreement with the scientists who have produced them. The scientists shall aim at publishing the finished result of their research, including the trials in which a commercial sponsor is included, irrespective of the accordance of the result with the prior expectations. Only qualitative assessments should be made. Political, administrative and scientific managers or supervisors who are not directly involved in the research process may be co-responsible for the quality of the work and the resulting publications, but they should not prevent or delay the publication for the reason that the results are unexpected or unwanted.

2.2

Universities and similar institutions usually do not exercise influence on the publishing process, but usually assume that publishing is made in scientific journals or books. Certain branches of science also publish on recognised websites. Sector research institutions and public, non-scientific institutions may have a tradition for the publication not exclusively taking place in scientific journals but also or only in reports or reviews published by themselves.

The rights and responsibilities of scientists in relation to a publication which appears scientific should be considered independent of the manner of publication.

That a project is performed in cooperation with, e.g., a commercial sponsor shall not reduce the scientists' responsibilities for analysis and publication of data (i.e. that positive as well as negative trial results are published).

2.3

The individual scientists' right of use of data should be exercised within the framework of the cooperation with the other participants according to the agreements entered into, fully open and respecting the other members' duties and rights.

On use of data, the scientists in cooperation should seek to avoid unnecessary delays.

Requests from individual scientists as to use of data for academic theses or other separate publications which were not agreed on initiation of the project should, as soon as such request arises, be disclosed to the entire group whose acceptance should be obtained. Please also refer to the limitations of the Act on Processing of Personal Data as to use of data for other research projects, see Chapter 7.

2.4

With a view to distribution, communication or publication of research results via electronic channels, the scientists are to be aware of not unintendedly including underlying, hidden data with personal data, for instance, Excel object or PowerPoint presentations (see The IT and Telecom Agency's guidelines relating to hidden data in documents (http://www.itst.dk/it-sikkerhed/privacy/beskyttelse-af-privatlivssferen-2/Risici-ved-skjulte-data-i-office-filer)).

3. Patenting

3.1

If scientists predict that a possibility of patenting arises, the allocation of such potential intangible rights should be decided. The agreement ought to ensure that the results are published in scientific media, but that publication will not take place until

after the patenting potential has been examined and a potential application has been submitted. A deadline should be set for such probing, usually approximately three months.

3.2

If, during the course of a project, a patenting possibility arises, and no prior agreement to this effect exists, a subsequent voluntary agreement about publication and secrecy should be attempted concluded. If the project participants cannot agree to this effect, a publication right, which would be significantly influenced by a patent case, shall be first priority, as the cooperation is to be considered to have rested on this usually applying assumption.

3.3

It is recommended that an agreement be entered into on start-up of projects as to whether patenting or publishing shall have first priority in the event of unexpected patenting potential.

3.4

Act on inventions at public research institutions and act on employees' inventions include provisions about employees' and employers' rights to inventions made in an employment. The basis is that the right to inventions is attributable to the employed scientist, but that the employer may claim transfer of such right against payment. Referring to this act, the employee is accordingly liable to report an invention made to the institution.

4. Conflict resolution

4.1

Conflicts ought to be prevented by prior agreement about allocation of work efforts and about expected allocation of rights of use and related authorships. Procedures for current adjustments of plans and for dispositions on resignation or acceptance of employees during the course of the project

should be agreed. See also Chapter 3, Guidelines on contracting on initiation of research projects.

4.2

Conflicts must not prevent the publishing of achieved results or result in deterioration in terms of quality. The right of use to data may be deprived from a scientist in breach of agreements to such degree that the remaining scientists', institutions' or funds' interests are disregarded considerably. By publishing, the scientist who is excluded may be mentioned in an acknowledgement, if he/she has contributed with data entering in the publication, and the matter shall be disclosed to the editor or the journal to which the manuscript is submitted.

4.3

If conflicts prove difficult to solve, settlement should be attempted at an early point in time with assistance from an external umpire, perhaps by mediation.

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Chapter 5

Guidelines on publication matters

These guidelines based on standards developed within the area of health science are perhaps also applicable – fully or partially – to other areas.

The guidelines focus on some of the problems arising in connection with the completion of a scientific article:

a) who should have an author status?
b) how are potential conflicts of interest handled?
c) what is to happen with negative results/serious side effects?

1. Right to authorship

When scientific work is published, it either appears as the work of one person or as the work of a group of authors – of which one has main author status, while the others are co-authors. If it is not a situation of single authorship, unclearness and disputes may arise about who is entitled to an authorship.
However, it is internationally acceptable that right to authorship is acquired by creative efforts and only thereby. Volume and nature thereof have been described in the Vancouver rules (www.icmje.org), which are updated at years' interval. The most important principles have been incorporated in these guidelines.

In order to obtain the right to become author, the following three requirements must be met:

a) An author must have contributed significantly to the creative process, usually within more than one of the following elements: Idea, planning, experimental work, collection of clinical and epidemiological data, data analysis and interpretation.
b) An author must have contributed to preparation of the final article by participation in preparation of draft manuscript and/or through critical revision signifying the appearance of the article.

c) An author must have approved the final version of the manuscript in writing.

Prior to submission of the manuscript, a common authorship declaration ought to be prepared, which precisely indicates the nature and volume of each author's contribution without use of stereotypes. The authorship declaration should be signed by all authors so as for it to be enclosed to journals which require such declaration and used for applications and documentation, if any, for scientific efforts on submitting academic theses. For multiple centre studies, the group should appoint one or several authors who would accept to assume full responsibility for the integrity of the study from project start-up to publication, and the scientific editorial offices should in such cases (for instance, pharmaceuticals trials) ask for detailed indications of conflicts of interests (see subsequently).

In all other respects, an author shall be able to indicate in detail his or her own contribution and must have participated to such degree in the entirety of the work that the relevant party is able to indicate the full contents of the manuscript and be able to discuss fundamental aspects of the remaining contributions. Furthermore, all authors of an article – within the limits of what is possible and fair – are co-responsible for it being based on honest research so as for the risk of fraud to be minimised. If irregularities or dishonesty are proven in the research, it will be difficult for the co-authors of such work to disclaim co-responsibility. Especially in international cooperation, however, it may be impossible to be co-responsible for, e.g., a laboratory result produced in another country. In a couple of large international dishonesty cases, co-authors have been acquitted for co-responsibility upon thorough investigation of the circumstances of each case. In other cases, recipients of gift authorships have claimed innocence by reason of non-participation in the work. As starting point, authorship also entails a co-responsibility, but the problem does not become smaller in the strongly increasing international research cooperation which often takes place in fierce competition based on large research grants.

As predominantly creative efforts give access to authorship, individual instances in the form of, e.g. the head of institute's provision of framework conditions, specialist departments'

services of routine data or mere help in collection of data, should not be rewarded by authorship, but such institutions/persons should be acknowledged in a special section for providers of non-authorship-entitling contributions, usually named acknowledgements. The contributors who do not comply with the authorship criteria, and who are mentioned in such section, should concurrently acknowledge the mentioning by their signature on a copy of the text.

The guidelines may give rise to problems for supervisors accustomed to gift-authorships. However, the right to authorship must follow the usual rules, also in this relation, and accordingly, only supervisor(s), who meet the above three requirements should be co-author(s).

Obtaining right to authorship is not related to specific positions, professions or training and does not depend on whether the efforts of the relevant person are salaried or unsalaried. If the creative efforts meet the above three conditions, they entitle to authorship, also for instance, medical laboratory technicians or other employees who usually merely provide technical assistance. This also applies to employees of consultancy firms and employees from the pharmaceuticals industry that assists in planning, management and performance of research projects. Some journals request that individual authors appear as ″guarantors″ for the entire process, i.e. from project start-up to the final publication, including data processing.

For review articles, it also applies that the authors are to have performed the work on collecting, reading and critically assessing the referred literature. Accordingly, it does not entitle to authorship to merely having reviewed a manuscript prepared by others nor if corrections are proposed in this connection.

2. Order of authors

The order of authors is added different significance in the international scientific sphere, and the Vancouver group has unsuccessfully tried to create consensus to this effect. The generally applied practice, which however is not subject to international unanimity, is that the participant contributing the most significant work efforts and preparing the first

manuscript is indicated as first author, while the often senior participant who is overall responsible for the project, but who meets the previously stated criteria for co-authorship, is indicated as final author. The remaining authors are ranked according to their estimated share of the work. The order, however, is also sometimes sorted according to other fundamental principles and may for instance be alphabetical.

It is a great advantage if the order of authors is agreed on project planning, including how adjustments may be performed, when subsequently the participants' actual efforts are known. If a different approach is taken than the agreed one, for instance, where a journal has a limit to the number of scientists in multiple centre surveys, this should be indicated in a footnote.

Among younger authors there have been inquiries as to the possibility of sharing first authorship. However, this is not technically possible as the literature databases (for instance, PubMed and EMBASE) have the first author as main author, but an authorship declaration should be prepared so as for the actual work efforts to appear clearly and, by equal work efforts, second authors may in such case be in charge of the correspondence with the editorial office and subsequently the readers. The presently applied approaches, however, do not provide sufficient details about the efforts of each author. Accordingly, an arrangement is still being worked at by which these efforts are also mentioned in the authorship declaration in addition to the article and which is in accordance with the formerly said authorship statements.

3. Authorship and publishing by other means than journal articles

Sometimes, scientific work is published by other means than in scientific journals, for instance, in reports or reviews. Such reports or reviews may be published from non-scientific institutions. Conditions for authorship such as the above stated for journals are of such general wording that they should also apply as basis of such publications.

In certain connections, it is requested that scientific reports and similar works are published without names of authors. In such events, the participants, who in all other respects meet

the said three requirements of authorship, may be mentioned differently, for instance, by contributor descriptions. It should be intended that the highlighting of creative efforts generally takes place according to the same principles, irrespective of how the results are published.

There should be consistency in the principle applied so as for the persons complying with the conditions for authorship to either all be stated as authors or be mentioned in a contributor description.

4. Duty of authorship

The right to authorship is attached to the duty of entering this right as it is important for the list of authors to present the authors of a publication in a true and fair manner.

5. Deviations for correct performance and duty of authorship

a) Gift authorships occur when a person receives an offer for and accepts to appear as author of a publication, even though the conditions therefore have not been met. Examples thereof may be heads of institutions or supervisors who have not contributed to the work forming the basis of the publication. Authorship may not be used as an act of friendship, return service, commercial products or compensation for irrelevant services.

b) Planted authorship: This is an equivalent of a gift authorship which is granted without the knowledge or acceptance of the relevant person. It is, for instance, applied to give a work a false quality guarantee by including a recognised scientist.

c) Renounced authorship: A person with right to authorship has not complied with the duty to enter this right, but has let other be sole authors. An example of this may be employees from the pharmaceuticals industry, who contribute to clinical pharmaceutical studies, but let the participating doctors stand alone as authors. Thereby, misguiding information is given as to who has performed the work and entirely legitimate matters of interest are covered up.

d) Ghost writing: A person with a right to authorship has not complied with the duty to enter such right, and has had another person receive gift authorship instead of the said person. In this way, the manuscript may unjustly appear as being performed by an independent expert.

The above phenomena may give rise to considerable distortion of the external environment's perception of who has performed the work, and thereby been responsible for the contents of scientific articles. At the same time, in relation to co-author status, it should be possible for persons having contributed significantly to the creative process (see right to authorship) to be entitled to approve the final manuscript – and thereby obtaining the right to authorship.

6. Duty to disclose conflicts of interest

The reliability of published articles depends on, among other things, how conflicts of interest have been handled during the production of the manuscript, during the evaluation process and during the editorial processing. Conflicts of interest arise when authors or their institutions, referees or editors have financial or personal interests that inappropriately influence the judgement of the relevant person, i.e. give rise to bias.

Potential conflicts of interest may exist whether an individual himself or herself believes to influence the handling of the manuscript or not. Financial relations in the form of employment in the board of directors of a company, "advisory board", shareholdings and/or paid expert statements are relatively easily cleared whereas personal relations, academic competition and passionate perception of a scientific area which cannot necessarily be shared by others are far harder to identify. On this basis, all of the above three players (authors, referees and editors) may openly state matters which may form the basis of potential conflicts of interest – and more and more journals, also in each article, state whether especially the authors have declared conflicts of interest, and many journals have a policy of the referees routinely being asked about potential conflicts of interest. For editors, the rule applies that they shall not handle their own manuscripts or manuscripts from their own organisation, nor should they be in a dependency of private enterprises that have interests on the area. Statement of potential conflicts of interests is not only

important in connection with original works. This also applies to review articles and editorials, where bias may be far harder to identify. By a potential conflict of interest, it is important that the readers be made aware of such conflicts and be able to decide themselves whether the research results may be unreliable.

It is also to be informed in the publication if financial support or other significant assistance has been obtained for the project. Parallel therewith, by human trials, it is a requirement of the act on The Danish National Committee on Biomedical Research Ethics system that the patient information includes information to this effect and that the contract be presented to the committee system. This also applies to sponsoring of non-revised supplement to journals, in which original articles or review articles are published, for instance, sponsored by a pharmaceuticals company where there is possibility of bias, among others, by the selection of references. The Danish National Committee on Biomedical Research Ethics system not only ensures openness about the direct sponsoring, but that it has been informed whether a scientist in all other respects has financial affiliation (including, for instance, own enterprise) with private enterprises, funds, etc., with interests in the relevant project. Otherwise, covering up potential dependencies may occur which does not exist in the ordinary, consultant (peer-review) assessed editions of the journal.

On this basis, authors should accordingly always explicitly declare whether there are potential conflicts of interest or not. Journal editorial offices should apply the stated conflicts of interest as basis in the editorial decision-making process. In general, it is not the intention to exclude authors who in connection with a current project for instance have received external support, but merely to create complete transparency – not least to the reader. Sponsors and the parties (i.e. authors, editors or other persons), which the sponsoring has been agreed with, have mutual responsibility for this being disclosed.

7. Collegial considerations for preparation of publications

Preparation of manuscripts for publications should take place within the framework of the cooperation in the group of

scientists, fully open and in accordance with agreements entered into (see Chapter 3, Guidelines for agreements at the initiation of research projects). Members of a group of scientists should accordingly not prepare publications, without the other members of the group being briefed to this effect and having accepted such fact. Furthermore, by reason of, among others, a Norwegian scandal, it is recommended that all co-authors receive confirmation e-mail from the editorial office when a manuscript has been submitted – and several journals observing the Vancouver rules have already introduced such system. Thereby, deception becomes more difficult, but so does co-authors subsequent claim of not knowing about the publication.

Use of results from a project for special forms of publication, such as for instance academic theses, which were not forecasted on project start-up, assumes prior details to this effect for the entire group of scientists, the acceptance of which should also be attempted achieved.

8. Duty to publish all research results

Completed research projects are to be published, also in cases when the result is not in accordance with prior expectations or requests. The responsibility resting upon the scientists of the fact that quality considerations above all determine how the publication is to take place is not reduced by a research project being sponsored, for instance, by the pharmaceuticals industry. This corresponds to the science ethical requirement maintained in many countries, including Denmark, of completed surveys being available either via publication in a journal or as a published report (for instance, on the website of an institution) and considered an open document.

All parties in the performance of research, including professional, political and administrative managements with approval powers, should recognise that, as mentioned above, only the overall quality of the work determines whether it can be published in a scientific journal. For instance, the international Cochrane cooperation which forms the basis of evidence-based medicine may be interested in publishing such negative data. Also, it should be mentioned that negative results may be just as important as positive results and that the Vancouver group generally recommends that publishing of

negative results be favoured, if the research work is of the necessary quality. Positive as well as negative findings thereby become publicly accessible. Deviations from this lead to distortion of the research mediation, for instance, publication of an individual study showing that a pharmaceutical has a beneficial effect on a given disease where subsequent studies – which the pharmaceuticals company does not want published – shows no effect of the pharmaceutical separating it from placebo – or perhaps even shows damaging side effects. This phenomenon called selective reporting is to be considered scientific dishonesty which has formed the basis of the Vancouver group claiming mandatory, public registration of clinical trials.

As defined by the Vancouver group, it is required that the registers relating to clinical trials be owned and operated by non profit organisations; that they comprise a certain minimum of data, and that they are accessible to electronic search free of charge. For this purpose, among others, the American database (www.clinicaltrials.gov) as well as the English database (www.controlled-trials.com/isrctn) exists. Several other European and Japanese registers have appeared, and WHO intends to develop a common website, so as to only log into one place to be briefed about whether a project is registered in one of these databases. Concurrently, the purpose of the databases is to ensure that a given drug trial is not subsequently published with other ″end points″ than as primarily planned. Finally, in several places, it is a requirement for drug trials to be presented in accordance with the CONSORT standard (so that readers quickly obtain clarity of the primary size and number of defections for various reasons (www.consort-statement.org)).

9. Several publications of the same results

Concealed double publication, i.e. identical or almost identical publications perhaps in translation, as stated in the Vancouver rules, must not take place, but secondary publication, for instance in two languages (English and a ″minor language″ such as for instance Danish) or for different fora within the same linguistic area may take place when done openly before the editorial offices and according to rules determined to this effect. Use of identical data or subsets thereof in different connections and in different presentations is not necessarily

double publication, provided that the data coherence between ″new″ work and prior work be disclosed to editorial offices as well as to readers. In this connection, it should be emphasised that a potential new publication (a so-called ″salami″ publication) should include significant new information – more than 50% is recommended. Thereby, quoting of own former results and new and original manner of processing raw data are distinguished. However, there is yet no international consensus about rules within this area. It should be specified that the National Library of Medicine only includes secondary publications for primary work which are already registered in MEDLINE, if it is clearly stated in the title that the matter is a secondary publication.

10. Reference to the work of others

Reference to published works within the processed area of subjects has the purpose of partly connecting the current work with the other research on the area, partly to give other scientists the recognition due to them. These purposes are closely connected, and careful handling of them is significant to the quality of work.

No reference should be made to own work or the work of colleagues apart from what the compliance of the said purposes requires, and references should not be applied for artificial increase in the frequency of quotes or the work of others or for systematic omission of the references of others. Similarly, especially for preparation of review articles, there should be no possibility of bias in the selection of references, which has resulted in an increasing number of editorial offices now requesting a ″method section″ that clearly states search criteria (database, search terms, time span) as well as inclusion and exclusion criteria for references included in review articles.

11. Summary and abstract

It is important that results and conclusions are repeated in the same manner and with the same strength or reservation in a summary or abstract as in the specific article as summary/abstract is often published directly in MEDLINE. In the event of discrepancies, the scientific message may be distorted by summary reading and disclosure merely of the

contents of the summary. It is assumed that you have always read the articles you quote in your scientific publication.

12. Premature publication of scientific data

Scientific results, for instance, within health science and other similar research should primarily be presented in scientific organisations/societies, at congresses or in scientific journals/reports with full documentation. Primary publication or publication of not yet performed research work in non-scientific news media are very rarely factually justified and does not give the recipients of the message any chance of evaluating the work which at this point has not yet been through the critical review process. If a significant interest in society or persons in exceptional cases would necessitate deviation from this rule, it should be done according to prior agreement, if possible, with colleagues of the scientific forum as well as with the editorial office of the journal to which the results have been submitted or are planned submitted to. Certain leading journals reject manuscripts if the message has already been presented, for instance, in the mass media.

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Chapter 6

Guidelines on research in the field of mathematics – including statistics

The mathematical subjects take up an important role in the research of natural sciences and the technical sciences as supplier of appropriate formations of concepts and methods for modelling phenomena in the physical and biological surrounding world and for efficient analysis of technological constructions and processes.

Examples of scientific misconduct in natural scientific and technological spheres are often attributable to inappropriate use of mathematical and statistical methods. Also, the theoretical (abstract) mathematical sciences create some special issues in relation to good scientific practice which would perhaps have lesser significance in practical (concrete) sciences, where they will in principle identify themselves more rapidly. Such special issues will briefly be mentioned here.

1. Plagiarism

In connection with theoretical sciences where the matter is communication of ideas, the concept of plagiarism has extended significance. Conscious presentation of another person's scientific discovery – as one's own – is a serious breach of good scientific practice irrespective of whether the discovery has been communicated orally, by personal contact or in a lecture, or in writing in a manuscript, published or not.

2. Reference to the work of others

Concealed plagiarism in the form of rewriting of a text without changes of the substance of the contents has great implications in theoretical sciences as an original argumentation is more difficult to identify and document than an original trial setup. In the mathematical sciences, this matter is further complicated by the proof of a mathematical result often being just as important as the result itself. Decisive new evidence of an important, known mathematical result, for instance by using other mathematical methods,

contributes to ensuring the logical connection and consistency in mathematics and is therefore added great scientific value. As such, it is a matter of scientific misconduct if you do not give satisfactory references to all relevant, related work.

3. Authorship

In the mathematical subjects, there are usually very few authors of an article (most frequently one or two authors), and scientists of these subjects have significantly less scientific publications than scientists in natural sciences and technological sciences. On evaluation of the scientific qualifications of a scientist in the mathematical subjects, it is greatly emphasised that there are scientific contributions which quite unambiguously are attributable to the scientist. Accordingly, authorship should be taken extra seriously in the mathematical subjects. For instance, it is not sufficient for an authorship to have proposed a subject for a scientific publication, or to have been supervisor or project manager for the research of others. In the mathematical subjects, it takes more substantial contributions to the research performed to become co-author of a scientific publication, and anyone stated as author must be able to take responsibility for the full scientific publication, and be able to present it in scientific fora. It is considered scientific misconduct if a scientist exploits his position and influence to claim co-authorship of a scientific publication, the production of which is due to another person.

4. Requirements of correctness

As for other spheres, unsolved problems are a material driving force in the evolution of mathematics. The one solving a mathematical problem which over time has proven a difficult problem and which by being solved opens new paths in mathematics will achieve a high status in the mathematical world. As such, it is scientific misconduct to announce the solution of a mathematical problem if you are not sure of the correctness and do not immediately withdraw the announcement if you discover material error or within reasonable time provides the full details of the result. By knowingly withholding the lacking details, including also information about fallacies in proofs, you will be delaying the scientists working with the same problem, and you will

perhaps later be attributed a part of the honour for a result which is rightfully someone else's.

5. Scientific qualifications

Scientists in the mathematical subjects have a special responsibility in connection with advice as to matters entailing the use of mathematical, including statistical, models, if the advice is made with reference to scientific qualifications and scientific position. The special responsibility is hidden in the mathematical subjects being difficult for laypersons who must therefore to a wide extent accept the advice. It is poor scientific custom for a scientist to provide advice about a subject requiring scientific insight without drawing attention to weaknesses in his or her competence within the area and/or potential weaknesses and uncertainties in connection with the advice.

Reference

- American Mathematical Society Ethical Guidelines, http://www.ams.org/secretary/ethics.html

Chapter 7

The act on processing of personal data and research projects

In this chapter, firstly the Act on Processing of Personal Data is briefly examined; then specific rules relating to research and statistical projects are in focus. Finally, attention is drawn to the general rules of good data processing practice which applies to all projects. The state of law is in rapid development, and accordingly, it is always recommended to obtain further, updated information from The Danish Data Protection Agency (www.datatilsynet.dk) which is responsible for the Act on Processing of Personal Data.

Act no. 429 of 31 May 2000 about processing of personal data with subsequent amendments, hereinafter referred to as ″the Act on Processing of Personal Data″ is the main act as to when and how personal data may be processed. The act ratifies an EU directive from 1995 about ″protection of natural persons with regard to the processing of personal data and on about the free movement of such data″. It is implicit herein that the purpose of the act partly is to ensure natural persons′ interest in personal data not being collected and/or processed at random, partly to ensure the legitimate interest which public authorities, private enterprises as well as natural persons may have in personal data being exchanged in a free and transparent manner.

The Act on Processing of Personal Data replaces any previous acts on private and public registers.

1. Briefly about The Act on Processing of Personal Data

1.1 Scope

The Act on Processing of Personal Data applies to private enterprises, associations and organisations as well as to all public authorities.

Some central concepts have been more closely defined in section 3 of the Act, including the following:

Personal data: Any kind of information relating to an identified or identifiable natural person (the person registered).

Processing: Any operation or set of operations – performed with or without the use of electronic data processing to which information is made subject.

Register of personal data (register): Any structured set of personal data which are accessible according to specific criteria, whether centralized, decentralised or dispersed on a functional or geographical basis.

The person responsible for data: The natural or legal person, public authority, institution or any other body, which alone or jointly with others determines the purposes and means of the processing of the personal data.

The Act on Processing of Personal Data generally applies to all electronic processing of personal data. Furthermore, the act applies to manual processing of personal data included in a register.

In the private sector, the Act on Processing of Personal Data furthermore applies to systematic processing of personal data even though it is not performed electronically (for instance case files, binders, etc.).

1.2 Types of information

The Act on Processing of Personal Data divides personal data into three types: Sensitive data (s. 7), data about other purely private matters (s. 8) and ordinary non-sensitive data.

The division is reasoned by the fact that different conditions and procedures apply to the processing of personal data depending on the sensitivity of data.

1.3 Rules of processing

The Act on Processing of Personal Data includes some general rules of processing which are always to be met. For instance, there must be a legitimate purpose for any processing of personal data.

The Act on Processing of Personal Data furthermore includes different conditions for processing of sensitive and non-sensitive data. Processing may take place when more closely determined conditions have been met.

Scientific projects, registers, etc. that include sensitive personal data are to be reported to The Danish Data Protection Agency.

1.4 Rights of registered persons

The Act on Processing of Personal Data gives the registered person a number of rights, including:

- Right to insight in the information processed about the person registered.
- Right of information about data being collected about the registered person.
- Right of having incorrect data erased or corrected.

2. Research and statistical projects

The rules of The Act on Processing of Personal Data also apply to processing of personal data performed for a scientific or statistical purpose.

When processing of sensitive data and data about purely private matters is requested, special rules apply:

If the processing, see section 10 of the Act on Processing of Personal Data, ″ takes place for the sole purpose of carrying out statistical or scientific studies of significant public importance and where such processing is necessary in order to carry out these studies″ processing may take place without obtaining prior consent from the registered person. Such data shall ″not subsequently be processed for other than statistical or scientific purposes. The same shall apply to processing of other data carried out solely for statistical or scientific purposes″. The data shall ″only be disclosed to a third party with prior authorization from the supervisory authority″ (The Danish Data Protection Agency).

If the processing of sensitive information, etc. has other purposes, the processing would have to be assessed according to the general provisions of the Act on Processing of Personal Data, i.e. the consent of the registered person for the processing must generally be obtained in advance.

2.1 Notifiable projects

If personal data of a purely private nature are processed (sensitive data) in a research or statistical project, the project is to be reported to the Danish Data Protection Agency.

According to sections 7 and 8 of the Act on Processing of Personal Data, sensitive data are about:

- Racial or ethnical origin.
- Political opinions, religious or philosophical beliefs.
- Trade union membership.
- Data concerning health, sexual and criminal matters.
- Data about significant social problems.
- Other similar private life data.

The expression ″health matters″ includes data about:

- The former, present and future physical or mental condition of a person.
- Use of pharmaceuticals and addiction to narcotics, alcohol and similar substances.

The concept of sensitive data also includes personal human biological materials (blood and tissue samples, etc.).

Projects that solely include non-sensitive data about participants are not to be reported to the Danish Data Protection Agency or require permission. The Danish Data Protection Agency does not set up any concrete conditions for the project, but the general rules of processing are to be observed, and the processing of data shall be in accordance with good data processing custom, see below for further details.

2.2 Procedure for reporting

The procedure for reporting depends upon whether the reporting party (the person responsible for data) is a private or public enterprise. Below, the rules are gone over in general terms. The more specific rules are included in chapters 12 and 13 of the Act on Processing of Personal Data.

- For private research projects, the procedure is the following:

The project must be reported and have permission from the Danish Data Protection Agency before collection and processing of personal data is initiated. The reporting may be done electronically on the website of The Danish Data Protection Agency.

Upon review of the reporting, the Danish Data Protection Agency will be issuing a permit with the conditions of the project. The conditions are determined for protection of the private lives of the participants and are to ensure that the personal data be processed in accordance with the law. The permission of the Danish Data Protection Agency is time limited.

Changes in the project are to be announced to the The Danish Data Protection Agency. Certain changes will require the prior permission of the Danish Data Protection Agency, while changes of lesser significance are merely to be reported.

- For public research projects, the procedure is the following:

If a public authority processes sensitive personal data for statistical or scientific purposes, this is to be reported by such authority to the Danish Data Protection Agency, and the permission of the Danish Data Protection Agency is to be obtained before processing is initiated.

In most cases, this will also apply if the project only includes details that are confidential, but not sensitive, for instance, financial data about individuals.

Public research and statistical projects are also to be reported electronically via the website of the Danish Data Protection Agency.

- For public research projects in hospitals, the procedure is the following:

Public research projects in hospitals are to be reported via the regions. The regions will ensure reporting to the Danish Data Protection Agency. Accordingly, the hospitals are not to submit report to The Danish Data Protection Agency.

- For Ph.D. projects in hospitals, the procedure is the following:

A number of Ph.D. projects are carried out in hospital departments of the regions which often involve patients of the department as well as supervision by the consultant physicians of the department. These projects may be reported as private, i.e. with the Ph.D. student as person responsible for data unless the region has decided otherwise.

Research projects performed by other state institutions are to be reported by the relevant authority.

For further details about who is to report a project, please refer to the website www.datatilsynet.dk

3. Good data processing practice

Section 5 of The Act on Processing of Personal Data sets up some general principles of the processing of personal data by the person responsible for data, including rules of collection, updating, filing, etc. The requirement of good data processing practice includes that processing is to be fair and legal. Registered persons are to be aware of the existence of processing, and on collection of data, the persons registered are to be given accurate and satisfactory information about the more specific circumstances of the collection.

3.1 Objects provision

Collection of data is to be performed for specified and explicit stated and legitimate purposes. Any subsequent processing of data shall not be incompatible with the original processing purpose. For instance, it is not legal to redistribute data obtained for research purposes for commercial purposes.

3.2 Expressly stated and legitimate purposes

The purpose of the collection must be specific and explicit, which is to say well-defined and well-limited in relation to creating openness and clarity about the processing. A consequence of the requirement is that the person responsible for data shall only collect details which are currently necessary.

3.3 Subsequent processing for other purposes

The data which the person responsible for data collects for a specific purpose shall not be reused or redistributed right away.
By any reuse or redistribution, an actual assessment of the purposes for which the data were originally collected is to be made by the person responsible for data.
The potential subsequent processing shall not be incompatible with the purposes for which the data were collected.

3.4 Relevant and adequate

Processing of data shall not be taken further than as required for compliance with the purposes which the person responsible for the data is entitled to pursue.

3.5 Data quality

The person responsible for data shall control such data. Data which turns out obsolete must generally be updated. The amount of control will depend upon the extent to which the data is to be applied as documentation for a professional result.

3.6 Duration of filing

Data shall not be filed in an identifiable form for longer periods than necessary in consideration of the purposes to which the data is collected or in connection with which the data are subsequently processed. There are no general time limits to filing which will accordingly be determined in the individual situation. The permissions of the Danish Data Protection Agency are always time limited. In practice, it is greatly emphasised whether continued filing of the data serves a legitimate purpose.

3.7 Data security

For private research projects, the Danish Data Protection Agency will set up conditions for filing in connection with the permission.

For public research projects, the executive order on security measures applies (see executive order no. 528 of 15 June

2000 about security measures for protection of personal data for the public administration).

It is hereby repeated that stricter requirements are made of the processing of sensitive personal data collected for the use in research projects, see section 3 above.

3.8 Sanctions

Violation of the rules of the Act on Processing of Personal Data is punished by fine or incarceration for up to four months, see section 70 of the Act.

References

- Website of The Danish Data Protection Agency: www.datatilsynet.dk with references.
- Kristian Korfits Nielsen and Henrik Waaben: Act on Processing of Personal Data with comments, 2nd edition, 2008, Jurist- og Økonomforbundets Forlag.
- Act no. 429 of 31 May 2000 about processing of personal data with subsequent amendments.

Forsknings- og
Innovationsstyrelsen
Ministeriet for Videnskab
Teknologi og Udvikling

The Danish Committees on Scientific Dishonesty may be contacted through the secretariat on the following address:

Danish Agency for Science, Technology and Innovation
Bredgade 40
1260 Copenhagen K
Tel.: + 45 3544 6200
Fax: +45 3544 6201

fi@fi.dk
www.fi.dk