Annex 3.2.6.4

This annex consists of the following two parts:

1. Overview of the Health ethics permits, issued by the Danish Research Ethics Committees, indicated in scientific papers co-authored by Milena Penkowa (p.1-2)
2. Information on the Danish Research Ethics Committees (De Videnskabsetiske Komiteer) and the Danish rules concerning experiments involving humans (p.2-26)

1. Health ethics permits, issued by the Danish Research Ethics Committees, indicated in scientific papers co-authored by Milena Penkowa

The table below is an overview of the health ethics permits that are indicated by ID number in scientific papers co-authored by Milena Penkowa.

Besides the four permits indicated by ID number in the papers co-authored by Milena Penkowa, two permits have been identified by the “Health Research Ethics Committees of the Capitol Region” by searching on “Penkowa. These two permits are indicated in the bottom of the overview. (PJ has attempted to identify papers for which these two permits may have been used.)

<table>
<thead>
<tr>
<th>Ethics permit</th>
<th>Title(s) of scientific paper(s), in which the permit is indicated, incl. bibliographic information</th>
<th>A.no</th>
<th>Laboratory of origin</th>
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2. Information on the Danish Research Ethics Committees (De Videnskabsetiske Komiteer) and rules concerning experiments involving humans  24.10.2011-PJ

According to Danish law, all research projects in Denmark involving human beings or any kind of human tissue, cells etc. need permission from a regional ethics committee.

The information below has been found on: http://www.cvk.sum.dk/CVK/Home/English.aspx

“Since 1980 Denmark has had a system of research ethics committees with 11 regional committees and a national committee: The Danish National Committee on Biomedical Research Ethics.

1. Concerning the system of research ethics committees

Slightly more than half of the committee members are lay men, appointed by the political system and the other half are medical professionals and active researchers. The system became regulated by law in 1992.
According to Danish law, all research projects in Denmark involving human beings or any kind of human tissue, cells etc. need permission from a regional ethics committee. In the case of medicinal and medicinal devices trial projects a permission from the Danish Medicines Agency is also required before the project can be initiated. In March 2006 the Parliament adopted an act amending the act on a biomedical research ethics committee system: Further access to making clinical trials involving medicinal products on incapacitated trial subjects etc.

See also the departmental circular on the amendment act.

The investigator – not the sponsor - of the research project must apply for permission from the regional research ethics committee for the area in which the investigator is operating. The application should conform with the “Guidelines about notification etc. of a biomedical research project to the committee system on biomedical research ethics”.

The investigator shall use an electronic application form: www.drvk.dk/anmeldelse and send the application on paper as well. Further information at the regional research ethical committees.

In the case of multi-center trials, the investigator shall only apply for permission from one regional committee, i.e. the regional committee in the area, where the principal investigator carries out the research project. However, in the case of multi-national trial projects, a permission from a Danish committee is always required.

The review of the application by the regional research ethics committee will take place when a complete and valid application has been submitted. A valid application must include the following elements:

- Application form
- The clinical trial protocol
- Subject information and the informed consent procedure

- all in Danish, including the clinical trial protocol.

Applicants whose project is rejected by the regional ethics committee can appeal the decision at The Danish National Committee on Biomedical Research Ethics.

Further information about the Danish committees can be found in the publication “The Scientific Ethical Committees – Yesterday, Today and Tomorrow”.

2. Concerning The Danish National Committee on Biomedical Research Ethics

Under the Committee Act, it is the responsibility of the committee system on biomedical research ethics to ensure that from a research ethical point of view, biomedical research projects are carried out in a responsible manner, and that the rights, safety and wellbeing of trial subjects participating
in such biomedical research projects are protected, while at the same time possibilities are being created for the development of new, valuable knowledge.

The National Committee consists of 26 members. 4 members, including the chairman, are appointed by the Minister for the Interior and Health, hereby 2 members on the recommendation of the Minister for Science, Technology and Innovation. Furthermore the committee consists of 22 members appointed by the Minister for the Interior and Health on the recommendation of the 11 regional committees - 2 from each regional committee.

Members of The Danish National Committee for Research Ethics:

By the Minister of the Interior and Health:
- Consultant doctor, DMSc Johs Gaub (chairman)
- Science writer, cand. scient., PhD Lone Frank

on the recommendation of the Minister of Science, Technology and Innovation:
- Director Peter Johan Mads Clausen
- Consultant Diana Ringgaard

Regional members:
- Doctor, PhD Simon Francis Thomsen, Capital Region
- Member of the Region Council Nina Berrig, Capital Region (vice chairman)
- Vice Director Inger Marie Bruun-Vierø, Capital Region
- Consultant doctor, associate professor Mikael Bitsch, Capital Region
- Member of the Region Council, MPA Ellen A. Thrane, Capital Region
- Consultant doctor, DMSc Jørgen E. Villumsen, Capital Region
- Member of the Region Council Birgit Tystrup, Capital Region
- Consultant doctor, PhD Inge Bernstein, Capital Region
- Consultant doctor, associate professor, DMSc Niels Vidiendal Olsen, Capital Region
- Technician Erik R. Gregersen, Capital Region
- Professor, Consultant doctor, DMSc Henrik Enghusen Poulsen, Capital Region
- Director Ebbe Saling, Capital Region
- Member of the Region Council Timo Jensen, Region Zealand
- Consultant doctor, DMSc Knud Rasmussen, Region Zealand
- Consultant doctor, MSc Birger Møller, Region Southern Denmark
- Member of the Region Council, Freddie H. Madsen, Region Southern Denmark
- Consultant doctor, PhD Marianne Kleis Møller, Region Central Jutland
- Natascha Joof, Region Central Jutland
- Consultant doctor, DMSc Jørgen Aagaard, Region Central Jutland
- Agronomist Jens Ove Keldsen, Region Central Jutland
- Consultant doctor, PhD Henrik Krarup, Region North Jutland
- Member of the Region Council, Project Manager Pernille Buhelt, Region North Jutland
The special tasks of the National Committee on Biomedical Research Ethics include:

- coordination of the work in the regional committees,
- laying down guidelines
- giving opinions on issues of a fundamental nature, if this is not related to the approval of a concrete research project,
- acting as a board of appeal in connection with findings in the regional committees and decide on matters where members of the regional committees disagree,
- monitoring the development of research within the health sector and promote the understanding of the ethical problems resulting from the development in relation to the health services and the biomedical research environments; and
- considering whether the National Committee on Biomedical Research Ethics is to make recommendations to the Minister for the Interior and Health under Sections 26 and 27 of the Committee Act. These provisions deal with specific, new fields of research.

Moreover, the National Committee provides consultative statements on biomedical research projects planned by Danish researchers for implementation in developing countries.

The Danish National Committee on Biomedical Research publishes each year an annual report in Danish.

The committee can establish subcommittees. Furthermore the committee has established some standing committees with other authorities and organisations.

The committee has founded "The honorary prize of biomedical research ethics".

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3. EFGCP: "Procedure for the Ethical Review of Protocols for Clinical research Projects in the European Union" - Denmark


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Rules:

Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects

Senest opdateret: 11.02.2009
WE MARGRETHE THE SECOND, by the grace of God Queen of Denmark, hereby make known:

Folketinget has passed and We have by Our Consent confirmed the following Act:

**Part 1**

*The scope of the act – the committee system*

1.- (1) The purpose of this Act is to lay down the legal framework for the scientific ethical evaluation of biomedical research projects.

(2) A research ethics committee shall be independent and consist of members who are active within medical research and lay members without medical qualifications and with no current connection with the healthcare professions.

(3) It shall be the responsibility of the research ethics committee system to ensure that from a scientific ethical point of view biomedical research projects are carried out in a responsible manner, and that the rights, safety and wellbeing of trial subjects participating in a biomedical research project are protected, while at the same time creating the possibility of developing new, valuable knowledge.

2.- (1) The county councils shall set up regional research ethics committees. A county council may set up one or more committees within its geographical area. A committee may also be set up jointly by several county councils.

(2) County councils shall also include the local councils of Copenhagen and Frederiksberg and the regional council of Bornholm.

3.- (1) A regional committee shall consist of at least seven members of whom three shall be active within medical research.

(2) The members of the regional committees shall be associated with the region covered by the committee, and the members active within medical research shall be appointed upon the recommendation of relevant professional research forums.

(3) A committee may consist of nine, eleven, thirteen or fifteen members if a county council finds that this is justified by the interests of the activities of a regional committee, the number of projects or other considerations. In case of a membership of nine, eleven, thirteen or fifteen, the members active within medical research shall be four, five, six and seven, respectively.

(4) The regional committee shall elect its own chairperson and one deputy chairperson from amongst its appointed members. The chairmanship shall consist of one person representing medical research and one person representing the lay members.

(5) The regional committee shall prepare draft regulations to be approved by the National Committee.

(6) Committee members shall be appointed for a period of four years, corresponding to the election period of county councils. Members may be re-appointed once. Substitutes may be appointed for the members.

(7) A retiring committee shall continue its activities until new members have been appointed and the new committee has elected its chairmanship.

(8) The Minister for Science, Technology and Development may lay down rules on which forums shall be relevant professional research forums, cf. section 3(2) above.
4.- (1) The Minister for Science, Technology and Development shall set up the Danish National Committee for Biomedical Research Ethics and shall appoint the chairperson and one member. In addition, the Committee shall consist of two members appointed upon the recommendation of each of the regional committees and two members appointed upon the recommendation of the Minister for the Interior and Health.

(2) Of the members appointed on the recommendation of the regional committees one member shall be appointed from among the members who are active within medical research. The other member shall be elected from among the lay members of the committee.

(3) The chairperson shall represent official research interests and public information, general cultural or social interests of significance to the activities of the National Committee. The two members appointed by the Minister for the Interior and Health and the member appointed by the Minister for Science, Technology and Development shall represent public information, general cultural or social interests of significance to the activities of the National Committee. The chairperson and the members appointed by the Minister for the Interior and Health and the Minister for Science, Technology and Development shall not be members of the Folketing or local councils.

(4) The Committee shall elect its own deputy chairperson from among the appointed members.

(5) The Committee shall prepare draft regulations to be approved by the Minister for Science, Technology and Development.

(6) The Committee members shall be appointed for a period of four years, corresponding to the election period of county councils. Members may be re-appointed once. Substitutes may be appointed for the members.

(7) A retiring Committee shall continue its activities until new members have been appointed and the new Committee has elected its chairmanship.

5.- (1) Committees shall continually follow the development within biomedical and clinical research and shall within their fields promote the dissemination of knowledge of the ethical problems that may be involved.

(2) The National Committee shall cooperate with the Danish Council of Ethics, among other things through joint meetings. The Committee and the Council may jointly prepare current reports on fundamental ethical problems that have been discussed between them.

6. The regional committees and the National Committee shall each submit annual reports containing an account of the activities and practice of the committees during the past year. The annual reports shall describe significant scientific ethical problems discussed by the committees and state the background for the outcome of important issues. The reports shall include a list of all notified projects.

**Part 2**

*Definitions*

7. For the purposes of this act:

1) “Biomedical research projects” shall mean a project that involves trials on liveborn human individuals, human germ cells intended to be used in fertilization, human fertilized eggs, embryos and foetuses, tissue, cells and genetic material from humans, foetuses and the like or deceased individuals. In addition, such projects shall also include any trial intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects, identify any adverse reactions or study pharmacokinetics (absorption, distribution, metabolism and excretion) with the object of ascertaining the safety or efficacy of medicinal products.
2) "Multi-centre clinical trial" shall mean any trial carried out in accordance with one and the same trial protocol, but in different locations, with one investigator as co-ordinator or with different investigators. Trial sites may be located in an individual member state, in several member states or in member states and third countries.

3) “Sponsor” shall mean an individual or a corporate body assuming responsibility for the implementation, management or financing of a biomedical research project.

4) “Investigator” shall mean an individual who is engaged in a profession authorised to perform research, for instance through employment as a researcher or a PhD-student or otherwise through employment within actual research, and who is responsible for the practical implementation of the trial on a specific trial site.

5) “Research protocol” shall mean a document that describes the objective(s), design, methodology, planning, statistical considerations, scientific ethical considerations, financial circumstances, publication matters and the informing of the trial subjects in connection with a biomedical research project and shall include the research protocol, subsequent versions of the protocol, changes to the protocol, a lay-person protocol, written information to participants and material for the recruitment of participants.

6) “Trial subject” shall mean an individual who participates in a biomedical research project, either as a recipient of investigational medicinal products or as a participant in a control group.

7) “Permanently legally incompetent adult” shall mean an individual who is covered by the definition in section 5 of the Act on Guardianship where no guardianship has been established.

8) “Informed consent” shall mean a decision in writing, dated and signed, or in electronic form along with an electronic signature, cf. the Act on Electronic Signatures, to take part in a biomedical research project, such decision being taken freely following satisfactory information about the nature, significance, implications and risk of the project and receipt of suitable documentation by a person capable of giving consent.

9) “Surrogate consent” shall mean a decision in writing, dated and signed, or in electronic form along with an electronic signature, cf. the Act on Electronic Signatures, to take part in a biomedical research project, such decision being made by the closest relatives and the general practitioner, alternatively the medical officer of health or the holder of custody or the guardian following satisfactory information about the nature, significance, implications and risk of the project and receipt of suitable documentation.

10) “Research biobank” shall mean a structured collection of human biological material stored for the purpose of biomedical research, which is accessible under certain criteria and where information bound in the biological material may be traced back to individuals.

Part 3

Notification and authorisation

8.-{(1) The investigator shall report any biomedical research projects, cf. section 7, subparagraph 1) to the regional committee for the area in which the investigator is operating. The notification to the regional committee must be in writing or in electronic form with the use of an electronic signature, cf. the Act on Electronic Signatures.

(2) In case of multi-centre trials the investigator co-ordinating the project, or the various investigators, shall report the project to the regional committee for the area in which the investigator is operating. The committee shall notify the other committees of its authorisation. In case of cross-border multi-centre trials, however, notification shall always be made in Denmark.

(3) Questionnaire-based projects and register research projects shall only be notified to a regional
committee if the project also involves human biological material.
(4) Trials on cell lines or the like originating from a trial involving collection of cells or tissue for which the necessary authorisation has been obtained shall not be notified.
(5) The Minister for Science, Technology and Development may lay down detailed rules on the issues mentioned in subsection 4 above.
(6) Subsections 4 and 5 shall not apply to trials concerning the use of fertilized eggs, stem cells and stem cell lines from these, the purpose of which is to obtain new knowledge that may improve the treatment of human illnesses, cf. the Act on Artificial Fertilization in connection with medical treatment, diagnostics and research, etc.

9.-(1) Projects that are notifiable pursuant to section 8 above shall not be initiated until scientific ethical evaluations have been made and authorisations for the initiation have been granted by the regional committee. Furthermore, clinical trials involving medicinal products shall be conditional upon authorisation pursuant to the Act on Medicinal Products.
(2) The committee shall inform the Medicines Agency of its decision.
(3) If a regional committee is unable to reach agreement on the evaluation of a project, the project shall be submitted to the National Committee for decision, cf. section 24 below. In that case the project may not be initiated until the National Committee has approved the project.
(4) The committees shall take advice from experts in cases where they do not themselves have the necessary professional expertise to evaluate projects submitted to them. When processing an application for trials on minors, the committee shall take advice from an expert in paediatrics. When processing an application for trials on individuals comprised by section 5 of the Act on Guardianship regarding personal circumstances and permanently legally incompetent adults, the committee shall take advice from an expert with knowledge on the group of individuals concerned.

Time limits

10.-(1) The committee shall decide on the approval of a project within 60 days of receiving a valid application, however, cf. subsections (2) and (3) below.
(2) The time limit pursuant to subsection (1) above shall be extended by 30 days if the processing concerns an application for the approval of trials involving gene therapy or somatic cell therapy or medicinal products containing genetically modified organisms. The 90-day deadline shall be further extended by 90 days in case of consultation of public boards or commissions. No time limit shall apply to the authorisation period in connection with the processing of an application for the approval of xenogenic cell therapy.
(3) The committee may within the processing period of the application send one request for information supplementary to the information already supplied by the applicant. The time limit pursuant to subsections (1) and (2) above shall be suspended until receipt of such supplementary information.

Part 4

The tasks of the committee system

11.-(1) When processing an application for the approval of a biomedical research project, the committees may not grant authorisation until they have evaluated the circumstances mentioned in this Part and in Part 5. The committees shall not evaluate whether requirements pursuant to other legislation have been met, however, cf. section 14(1), subparagraphs 3), 5) and 6) and section 15(1),
subsection 1).

(2) The committee shall ensure documentation of the identification of the investigator.

12. (1) The committee may only grant authorisation if
1) any risks in connection with the implementation of the project are neither in themselves nor in relation to the expected benefits of the project of an unjustifiable extent;
2) the project may be justified by the expected therapeutic and public health benefits;
3) the scientific standard of the project meets the requirement that the project must contribute to the development of new, valuable knowledge, cf. section 1(3); and
4) there are sufficient grounds for implementing the project, and the conclusions of the project are justified.

(2) When processing an application for the approval of a biomedical research project, the committee shall weigh the expected risks and inconveniences against the benefits for the individual trial subject and for other present and future patients, especially with regard to pain, discomfort, fear and other foreseeable risks being minimised in relation to the illness and the developmental stage of the trial subject. This weighing shall be carried out with due regard to whether the trial subjects are themselves able to give their informed consent or whether consent must be obtained from the closest relatives and the general practitioner, alternatively the medical officer of health or the holder of custody or a guardian in case of guardianship comprising personal circumstances, including authorisation to consent to participation in a biomedical research project, cf. section 5 of the Danish Act on Guardianship.

(3) The Minister for Science, Technology and Development may lay down detailed rules on the issues mentioned in subsections (1) and (2) above.

13. -(1)When processing an application for the approval of a biomedical research project on trial subjects who are incapable of giving their informed consent, the committee shall in addition to complying with the provisions of section 12 ensure that
1) the project is essential to verify data collected through trials on individuals who are capable of giving their informed consent or through other trial methods;
2) the project concerns directly a clinical condition of that person; and
3) the project may be expected to be beneficial to the group of patients.

(2) A biomedical research project not involving trials with medicinal products may be approved even if the provisions of subsection (1) above have not been met if
1) the project cannot with similar benefit be conducted by including legally competent trial subjects of legal capacity and
2) the project is expected to be of direct benefit to the trial subject.

(3) Furthermore, a biomedical research project not involving trials with medical products may be approved even if the provisions of subsections (1) and (2) above have not been met if
1) the project can only be carried out by the inclusion of individuals comprised by the age group, illness or condition concerned;
2) the project is expected to be of considerable benefit to the group of patients comprised by the same age group, illness or condition as the trial subject ; and
3) the project entails minimal risk and discomfort for the trial subject.

(4) The Minister for Science, Technology and Development may lay down detailed rules on the issues mentioned in subsections (1) – (3) above.

14.-(1) The committee may only grant authorisation if
1) the written or electronic information clearly states the financial support that the investigator
receives from private companies, funds etc. for the implementation of the research project concerned, and whether the investigator has any financial connection with private companies, funds etc. with an interest in the research project concerned;
2) any remuneration or other payment for participation in a biomedical research project will not influence the giving of consent;
3) the right of the trial subject to physical and mental integrity and the right to privacy are respected, and if information regarding the trial subject is protected pursuant to the Act on the Handling of Personal Information;
4) the investigator has ensured that the trial subject has access to further information about the project;
5) projects involving the export of biological material and information to third countries are carried out in accordance with the provisions of the Act on the Handling of Personal Information; and
6) both negative and positive trial results are published as soon as possible and as soon as it is professionally justifiable. Publication shall be carried out in accordance with the Act on the Handling of Personal Information.

(2) The Minister for Science, Technology and Development may lay down detailed rules on the issues mentioned in subsection (1) above.

Part 5

Informed consent
Biomedical research projects involving legally competent individuals

16.- (1) The committee may only grant authorisation to initiate and continue a biomedical research project if the legally competent trial subject has given his or her informed consent.
(2) The committee may only grant authorisation to initiate and continue a biomedical research project if the trial subjects involved in the project will receive written and verbal information about the content, foreseeable risks and benefits of the project, and if informed consents will be obtained and given.
(3) If a register research project that is notifiable pursuant to section 8(3) does not involve any health risks for the individual trial subject and will not in any other way according to circumstances cause harm to that person, the committee may decide that the project is not comprised by subsections (1) and (2) or section 17, subsections (1) and (2). Furthermore the committee may
decide that a notifiable register research project is not comprised by subsections (1) and (2) or section 17, subsections (1) and (2) if it is impossible or disproportionately difficult to obtain informed consent.

(4) The committee may only grant authorisation if the information clearly states that trial subjects may at any time withdraw their consent pursuant to subsection (1) above.

(5) The committee may only grant authorisation if the trial subject gives his or her informed consent when, in connection with a specific research project, the subject’s tissue is removed with the intention of storing it in a research biobank.

(6) The Minister for Science, Technology and Development may lay down detailed rules on the issues mentioned in subsections (1) – (5) above.

**Biomedical research projects involving minors, individuals under personal guardianship and permanently legally incompetent adults**

17.- (1) The committee may only grant authorisation to initiate and continue a biomedical research project involving minors if surrogate consent has been obtained from the holder of custody. The surrogate consent shall express the interest of the minor. The committee may only grant authorisation if the minor will receive information from a person with knowledge of the project area and also with educational qualifications to communicate the contents to the age group comprised by the project.

(2) The committee may only grant authorisation to initiate and continue a biomedical research project involving individuals under guardianship and comprising personal circumstances including authorisation to consent to participation in biomedical research projects, cf. section 5 of the Act on Guardianship, if surrogate consent has been obtained from the guardian. The committee may only grant authorisation to initiate and continue a biomedical research project involving permanently legally incompetent adults if surrogate consent has been obtained from the closest relative and the general practitioner, alternatively the medical officer of health. The surrogate consent shall express the interest of the trial subject. The committee may only grant authorisation if the trial subject will receive information adjusted to his/her capacity of understanding.

(3) The committee may only grant authorisation if the information clearly states that the surrogate consent pursuant to subsection (1) above, respectively subsection (2) above, may at any time be withdrawn without this being detrimental to the trial subject. Importance shall be attached to the indications of the trial subject in so far as these are relevant.

(4) The committee may only grant authorisation if the research protocol for projects involving individuals comprised by subsections (1) or (2) is evaluated by an expert with paediatric expertise or expertise in the condition of the group concerned.

(5) The committee may only grant authorisation if surrogate consent is obtained if, in connection with a specific research project, the tissue of the minor, the trial subject under guardianship or the permanently legally incompetent adult is removed with the intention of storing it in a research biobank.

(6) The Minister for Science, Technology and Development may lay down detailed rules on the issues mentioned in subsection 1-5.

**Biomedical research projects involving deceased individuals**

18.- (1) The rules on consent laid down in this Act shall not apply to the processing of applications for the approval of a biomedical research project involving deceased individuals comprised by the Act on Coroner’s Inquests, Post-Mortem Examinations, Transplantation Etc.
(2) Surrogate consent shall be obtained from the closest relative in connection with the processing of applications for the approval of a biomedical research project involving deceased individuals who are not comprised by the Act on Coronor’s Inquests, Post-Mortem Examinations, Transplantation Etc.

Exemptions from the requirement for surrogate consent regarding 15 – 17 year olds

19.-1(1) The committee may grant exemptions from the requirement for consent from the holder of custody, cf. section 17(1), if the trial subject has attained the age of 15 and is not legally competent and if the subject in question gives his/her informed consent. The exemption shall be given with due regard to the nature, risk and harmfulness of the project.
(2) If the 15 – 17 year old minor gives his/her informed consent pursuant to subsection (1), the holder of custody shall receive the same information and shall be involved in the decision of the 15 – 17 year old.

Research in emergency situations

20.-1(1) If the nature of the project means that it can only be implemented in emergency situations where the trial subject is unable to give his/her informed consent and it is impossible to obtain surrogate consent, the project may be implemented if it may in the long term improve the health of the subject.
(2) The investigator shall as soon as possible thereafter attempt to obtain informed consent or surrogate consent.
(3) However, subsections (1) and (2) above shall not apply to clinical research with medicinal products.

Consent in other situations

21. As regards the processing of an application for the approval of a biomedical research project that is notifiable pursuant to section 8 above but not comprised by sections 16 – 20 above, the Minister for Science, Technology and Development shall lay down detailed rules on the obtaining of informed consent or surrogate consent if the requirement for consent is not prescribed by other legislation.

Part 6

Implementation and control of biomedical research projects

22.-1(1) The regional committee shall monitor that the biomedical research project is carried out in accordance with the authorisation given, cf. section 9.
(2) A committee may follow the course of a project and request that the final research report or publication be sent to the committee. The committee may request a reasoned statement from the investigator or the sponsor in cases where the project is not completed.
(3) The investigator shall immediately inform the scientific ethical committee if serious adverse reactions or serious events are encountered during the project. When reporting serious events caused by the project such as deaths, the investigator shall submit the information requested by the committee.
(4) Once every year during the entire research period the sponsor or the investigator shall to the
committee submit a list of all serious adverse reactions and all serious events encountered during the period and shall provide information about the safety of the trial subjects.

(5) Subsections (1) and (3) above shall not apply to clinical research with medicinal products.

Amendments to an approved biomedical research project

23. During the implementation of an approved biomedical research project, cf. section 9, amendments may only be made according to the following rules:
1) Substantial amendments to the research protocol may only be made following approval by the committee system. The sponsor or the investigator shall, according to the circumstances, take the appropriate urgent safety measures to protect the subjects.
2) The committee shall make a statement within a time limit of 35 days after receipt of the valid application for amendment. Amendments to the research protocol may only be initiated when the committee’s approval is available. The committee’s decision may be brought before the National Committee.
3) 90 days after the completion of a biomedical research project the investigator shall inform the committee that the project has been completed. If a project is terminated earlier than planned, the time limit for informing the committee shall be 15 days from the time when the decision to terminate the project is made. The grounds for the premature termination shall be given.

Part 7

The Danish National Committee for Biomedical Research Ethics

24. It shall be the responsibility of the National Committee
1) to coordinate the work of the regional committees, lay down guidelines and make statements regarding issues of a principle nature if these are not included in the approval of a specific research project;
2) to monitor the development of research within the health care sector and further the understanding of the ethical problems resulting from the development in relation to the public, the authorities etc.; and
3) to process research projects presented to the Committee pursuant to section 9(3) and act as an appeals body for the decisions of the regional committees.

25.(1) An investigator whose application for the approval of a biomedical research project has been refused may bring the decision before the National Committee no later than 30 days after receipt of the decision of the regional committee. Individuals who are parties to the case in the meaning of the Danish Public Administration Act may also bring a project before the National Committee no later than 30 days after the decision of the regional committee. The National Committee shall make a decision within the time limit stated in section 10 and section 23(1), subparagraph 2). Complaints to the National Committee shall be in writing or in electronic form with the use of an electronic signature, cf. the Act on Electronic Signatures.
(2) If the National Committee is unable to reach agreement on the evaluation of a project, the Committee may make its decision by simple majority, provided that the majority comprises a majority among both the members active within medical research and the lay members appointed to the Danish National Committee for Biomedical Research Ethics, cf. section 4(2). In connection with a vote, the chairperson of the National Committee shall be regarded as a member who is active within medical research. The other three members appointed by the Minister shall in connection
with a vote be regarded as lay members.

(3) Decisions by the National Committee may not be brought before another administrative authority.

26. The Minister for Science, Technology and Development may upon the recommendation of the Danish National Committee for Biomedical Research Ethics lay down rules to the effect that the processing of projects within specific, new research areas not involving clinical research with medicinal products may be suspended for a specified period until general ethical or scientific ethical clarification has taken place.

27. The Minister for Science, Technology and Development may upon recommendation from the Danish National Committee for Biomedical Research Ethics lay down rules for the regional committees on the scientific ethical evaluation of research projects within specific, new research areas. The Minister may in this connection decide that section 8(4) and (5) shall not apply to such a specific, new research area.

Part 8

Funding

28.-(1) The costs of the regional committees shall be paid by the county councils. The Copenhagen Hospital Corporation shall pay a proportional part of the costs of the regional committee serving the institutions of the Corporation. Research institutions etc. and private companies and hospitals shall as part payment of the costs pay a fee per project to the relevant county council. The county councils shall decide the size of the fee, which shall not exceed an amount corresponding to the project’s expected share of the relevant committee’s total annual expenditure.

(2) The expenditure of the National Committee shall be paid by the Minister for Science, Technology and Development. The Minister shall provide the Committee with the necessary secretarial assistance.

(3) Members of the regional committees and their substitutes, if any, shall be reimbursed for their expenses according to the rules in section 16(10) of the Danish Local Government Act. The county council may decide that the members and their substitutes, if any, shall also be paid attendance fees and compensation for documented loss of earnings pursuant to the provisions of section 16 a of the Local Government Act. Furthermore, county councils may decide that membership of a regional committee shall be remunerated at DKK 10,000 per year, that the job as chairperson of a regional committee shall be remunerated at DKK 35,000 per year and that the job of deputy chairperson shall be remunerated at DKK 30,000 per year. A chairperson or deputy chairperson receiving remuneration shall not at the same time receive attendance fees or compensation for documented loss of earnings.

(4) Members of the National Committee and their substitutes, if any, shall, apart from the chairperson and the deputy chairperson and the three members appointed by the Minister, receive attendance fees, compensation for documented loss of earnings and reimbursement of expenses pursuant to the provisions of section 16 a of the Local Government Act.

(5) The relevant county council shall pay the costs involved in remunerating members of the regional committees and the members of the National Committee who are also members of a regional committee. The same shall apply to costs in relation to any substitutes. The cost of fixed remuneration to the chairperson, the deputy chairperson and the three members of the National Committee appointed by the Minister shall be paid by the Minister for Science, Technology and Development.
(6) The Minister for Science, Technology and Development may lay down detailed rules on the issues mentioned in subsection (1) above.

Part 9

Penal provisions

29.-(1) Any person who initiates a project contrary to sections 8, 9 and 23 or initiates a project contrary to the terms of the authorisation, cf. Parts 4 – 6 may be punishable by fine or imprisonment up to four months.
(2) Regulations issued pursuant to the Act may determine penalties in the form of fines for violation of the provisions of the regulations.
(3) Companies etc. (corporate bodies) may be held criminally liable pursuant to the provisions of Part 5 of the Danish Criminal Code.

Compensation

30.-(1) The sponsor or, if Danish courts do not have jurisdiction over the sponsor, the investigator shall pay compensation of DKK 1,000 to any person who participates in a project initiated contrary to sections 8, 9 and 23 or who has not given their informed consent, cf. sections 16 and 19, or where surrogate consent has not been obtained, cf. section 17, unless the investigator or the sponsor is able to document that this is not due to an error on the part of the investigator or the sponsor.
(2) The provisions of subsection (1) do not affect a person’s right to compensation pursuant to the general rules of Danish law.

Part 10

Commencement etc.

31.-(1) This Act shall come into force on 1 June 2003.
(2) The Act shall apply to the processing of applications for the approval of biomedical research projects notified after 1 May 2004.
(3) Act on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects, cf. Consolidated Act No. 69 of 8 January 1999, shall be repealed on 1 May 2004, cf. subsection (2).
(4) Regulations issued pursuant to the Act, cf. subsection (3), shall remain in force until they are repealed or replaced by new regulations.
(5) Members of present committees shall continue their activities until the end of their appointment period with the possibility of re-appointment if they could have been re-appointed pursuant to the previous act.
(6) The Minister for Science, Technology and Development shall lay down detailed rules on the transitional provisions regarding the processing of applications for the approval of biomedical research projects notified before 1 May 2004.

32. This Act shall not extend to the Faroe Islands or Greenland, but may by Royal decree be extended to these parts of the realm with the variations dictated by the special conditions in the Faeroe Islands or Greenland.
Act amending the act on a biomedical research ethics committee system and treatment of biomedical research projects

UNAUTHORISED TRANSLATION

Act amending the act on a biomedical research ethics committee system and treatment of biomedical research projects.

(Further access to making clinical trials involving medicinal products on incapacitated trial subjects, etc.)

ACT No. 272 of 01/04/2006 (Current) Subsequent amendments to the regulation

Full wording of the regulation:

Act amending the act on a biomedical research ethics committee system and treatment of biomedical research projects

(Further access to making clinical trials involving medicinal products on incapacitated trial subjects, etc.)

WE MARGRETHE THE SECOND, by the Grace of God Queen of Denmark, hereby make known:

Folketinget has passed and We have by Our Consent confirmed the following Act:

1.- In Act No. 402 of 28 May 2003 on a biomedical research ethics committee system and treatment of biomedical research projects, as amended by S.13 of Act No. 440 of 9 June 2004 and S.12 of Act No. 545 of 24 June 2005, the following amendments shall be made:


2. S.1(3) reading », and that the rights, safety and wellbeing of trial subjects participating in a biomedical research project be protected, while at the same time possibilities are being created for the development of new, valuable knowledge« shall be amended to read: ». In relation to creating possibilities for development of new, valuable knowledge, the regard for the rights, safety and wellbeing of the trial subjects shall prevail over the interests of research and society.«

3. In S.7, No.1, insert as (para.3):

»Finally, clinical testing of medicinal devices shall be included, see also subsection 2.«

4. In S.7, No.7, S.9(4)(para.3), the heading of S.17, S.17(2)(para.2), and S.17(5), delete the word »permanently«.

5. In S.7 after No. 7 insert as a new No.:

» 8) Legal representative: an entity of two physicians who in emergency situations, ref. S.20(a), can give surrogate consent on behalf of the incapacitated trial subject. The legal representative shall attend to the interests of the trial subject and shall be independent of the trial subject’s interests and of any interests in the research project in general.«

Nos. 8-10 will now be numbered 9-11.

6. In S.7, No. 9, which is now No. 10, amend »closest relatives and the general practitioner, alternatively the medical officer of health or the holder of custody or the guardian« to read: »the
guardian, the holder of custody or the legal representative or from the closest relatives and the general practitioner – alternatively the medical officer of health«.

7. In S.7 insert as subsection (2):

»-( 2) The Minister for the Interior and Health may lay down rules for demarcation of what medicinal devices are covered by subsection (1) No. 1, (para.3).«

8. In S.9(1)(para.2), insert after »trials involving medicinal products‹: »or clinical testing of medicinal devices«.

9. In S.9(1)(para.2), after »Act on Medicinal Products« insert: »the Act on Medicinal Devices, respectively«.

10. In S.9 insert as subsection (5):

»-( 5) Subsection (4) shall not apply to non-intervention trials relating to minors.«

11. In S.12(2)(para.1), after »developmental stage« insert: », ref. S.1(3)«.

12. In S.12(2)(para.2), change »alternatively the medical officer of health« to read: » – alternatively the medical officer of health – or from the legal representative«.

13. In S.15(1)(para.1), after »Act on Medicinal Products« insert: »or clinical testing of medicinal devices covered by the Act on Medicinal Devices, see also S.7(2)«.

14. In S.17 after subsection 5 insert as a new subsection:

»-( 6) Subsection (4) shall not apply to non-intervention trials relating to minors.«

Subsection (6) will now be subsection (7).

15. Insert after Section 20:

»20(a). If a biomedical research project involves clinical trials involving medicinal products, and if the nature of the trial means that it can be implemented only in emergency situations where the trial subject is incapable of giving informed consent, and it is not possible to obtain a surrogate consent from the guardian, the holder of custody or from the closest relatives and the general practitioner – alternatively the medical officer of health – the project may be implemented if surrogate consent has been obtained from the legal representative.

-( 2) As early as possible after this, the investigator shall seek to obtain informed consent or surrogate consent from the guardian, the holder of custody, or from the closest relatives and the general practitioner - alternatively the medical officer of health.«

16. In S.22 after subsection (4) insert as a new subsection:

»-( 5) Not later than 90 days after the completion of a biomedical research project the investigator shall inform the committee that the project has been completed. If a project is discontinued earlier than planned, the time limit for informing the committee shall be a maximum of 15 days from the time when the decision to discontinue the project was made. The grounds for the premature termination shall be given.«

Subsection (5) will now be subsection (6).

17. S.23, No. 3, is repealed.

2-( 1) This Act shall come into force on 01 Apr 2006.

-( 2) The Act shall apply to all biomedical research projects notified to a committee on research ethics as from 01 April 2006.

Given at Jagthuset, Trendskov, 1st April 2006

Under Our Royal Hand and Seal
Margrethe R.

/Lars Løkke Rasmussen Official notes

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Ministerial Order No 806 of 12 July 2004 on Information and Consent at Inclusion of Trial Subjects in Biomedical Research Projects

Pursuant to S.16(6), S.17(6), and S.29(2) of Act No. 402 of 28 May 2003 on a Biomedical Research Ethics Committee System and the Processing of Biomedical Research Projects the Order provides as follows:

Part 1

Objective, applicability, definitions etc.

1. The objects of the Ministerial Order are to lay down stipulations on providing information to and obtaining consent from trial subjects in connection with their participation in biomedical research projects.

2. Trial subjects shall mean healthy as well as sick individuals participating in research as part of biomedical research projects.

3. A biomedical research project shall mean an activity planned according to research methods which aims at producing new, valuable knowledge about human biological and psychological processes, either in relation to healthy persons or for the purpose of prevention, recognition, relief, treatment or cure of disease, symptoms and pain, including affecting bodily functions.

   - (2) A biomedical research project may include clinical research involving medicinal products or medical equipment.

   - (3) In certain cases, the Committee may direct that register research projects, which also include human biological material, cf. S.8(3) of the Act, shall not be covered by the stipulations on providing information and obtaining consent, cf. S.16(3) of the Act.

Part 2

Informed consent

General Issues

4. No biomedical research projects shall be initiated or continued without the informed consent of the trial subject who is of legal capacity and of age, cf. S.16 of the Act.

   - (2) For the purpose of this Ministerial Order, informed consent shall mean a decision made voluntarily, following satisfactory information, by a person capable of giving consent. The consent shall be given on the background of both the written and the oral information, cf. SS. 7-10 and S.12, cf. also S.6.

   - (3) The consent shall be given as soon as possible after the information is received. Although the trial subject shall be allowed time of reflection.

   - (4) In connection with the trial subject's provision of consent, at the latest, the investigator shall certify that the written information has been handed to the trial subject and that provision of oral information has taken place. The trial subject is entitled to receive a copy of the certified declaration of consent.

   - (5) An informed consent pursuant to this subsection must be in writing, dated and signed or submitted by electronic signature. The consent shall be given to the investigator or a person authorised by him/her who has direct connection with the research project.

   - (6) The trial subject may at any time withdraw his/her consent under subsection 1.
5. It is the task of the Committee to ensure that in connection with approval of the biomedical research project a form shall be provided for the use of the trial subject's provision of informed consent.

6. The Danish National Committee on Biomedical Research Ethics can lay down specific guidelines for situations in which the regional committees may authorise and subsequently evaluate information given in a form different from the rules in Part 2.

**Requirements concerning written and oral information**

**General Issues**

7. The trial subject shall receive information on the biomedical research project in which the individual contemplates to participate.

   -(2) The information shall be provided by the investigator, cf. S.7(1)(6) of the Act, or by a person authorised to do so who has the professional qualifications to communicate the contents of the research project and who is directly associated with the research project. The person submitting the information shall be responsible for the trial subject's proper understanding of the information prior to initiation of the trial.

   -(3) The information shall include an understandable presentation of the research project without the use of technical or value-laden terms and expressions. Information shall be given in a considerate way and be suited to the individual trial subject's circumstances such as age, maturity, experience, etc. The information shall contain details on any predictable risks, adverse reactions, complications and drawbacks and that participation in a biomedical research project may involve unpredictable risk and harm.

   -(4) In case of patients being involved in biomedical research projects aimed at results of research as well as treatment, the information shall be supplemented by both oral and any written information on other possible treatment methods, cf. Act on the legal status of patients.

   -(5) Where the trial subject is otherwise found not to be aware of matters of significance to the trial subject's consideration, the information shall include such matters.

8. It is the task of the Committee to ensure that in connection with approval of the biomedical research project, written information shall be provided as well as procedures described for providing oral information to the trial subject or his/her surrogate.

   -(2) Oral information must be based on the written information.

   -(3) The written information must be submitted in paper form or electronically. However, the trial subject may always request to receive the information in paper form.

   -(4) The written information shall as a minimum include the details mentioned in SS. 9, 10, and 12.

**Requirements concerning the contents of the written information**

9. The written information shall state that this concerns a request to participate in a biomedical research project and it must contain the following information:-

1) aim and method and the importance, nature and scope of the research project, including the practical arrangement of the project and any clinical trials,

2) the use of and the names of approved and non-approved medicinal products, the dosage and use of randomization, blind preparations and treatment-free periods including any known interaction with other medicinal products,

3) any predictable risks, side effects, including known long-term side effects, complications and inconveniences by participating in the research project, and that participation in a biomedical research project may involve unpredictable risk and harm,
4) the possible benefits of the research project. A distinction must be drawn between benefits accruing to the individual trial subject, to others and to research ethical progress,
5) circumstances which may result in the involuntary exclusion of the trial subject concerned from the research project, as well as circumstances under which the project as a whole may be discontinued.
In the event of a discontinuation of the project, the trial subject shall be informed about the reason for this, and
6) name, address, e-mail address and phone number of a contact person connected with the research project.

10. In addition to this, the written information shall state:-
1) that participation in the research project is voluntary and that participation can only occur after both written and oral information has been provided and written consent to participation has been given by the trial subject,
2) that the trial subject may at any time withdraw consent to participate in and discontinue participation in the project orally, in writing or in any other clearly expressed way without this affecting access to existing or future treatment or other rights which the trial subject might have,
3) that the trial subject has a right to time for reflection before giving consent, just as the trial subject shall be entitled to be accompanied by a friend or relative when receiving the oral information,
4) that data about the patient's health, other purely private matters and other confidential information about the trial subject which is given or is obtained during participation in the research project shall be covered by the rules on professional secrecy,
5) that storing of data identifiable with the subject concerned, including tissue, blood samples, etc, shall be done in pursuance of Act on the Handling of Personal Information and Act on the legal status of patients,
6) that it is possible to gain access to documents in the research protocol in accordance with the act on free access to public records, and
7) the complaints procedure as well as the possibility of obtaining damages in accordance with the act on patients' insurance, or the act on compensation for medicinal injuries and other compensation for injuries resulting from the research project.

11. Information to the trial subject on his/her general rights, as stated above in S.10, may be attached as a separate appendix to the information on the individual biomedical research project.

12. Under S. 14(1)(1) of the Act, the written information shall also clearly state the financial support that the investigator receives from private undertakings, foundations etc. for the implementation of the biomedical research project concerned. Information shall be presented in a way to provide the trial subject with an opportunity to decide whether he/she wishes to participate in the research project.
-(2) Information on financial support shall include details on
1) who initiated the biomedical research project,
2) names of commercial as well as non-commercial sponsors,
3) sponsored amounts for each sponsor and the way in which the sponsorship is involved in the research project, including whether the sponsorship is paid as a fixed sum or as a remuneration per trial subject, and whether the sponsorship is paid directly to the chief investigator, to his/her division/ward/institute, to a common research fund or otherwise, and
4) whether the chief investigator is otherwise financially attached to private enterprises, foundations, etc., who may have interests in the research project concerned.

13. The trial subject shall be informed, if during the implementation of a biomedical research project significant information becomes available on the trial subject's health condition, unless the trial subject has expressly stated that he or she does not want this.
14. If, during the course of a biomedical research project, new facts turn up about the effects, risks, side effects, complications or drawbacks of the trial, or if the trial design of the research project is considerably changed in relation to the safety of the trial subject, the trial subject is to be informed accordingly. In such situations, the trial subject shall provide renewed consent, cf. S.4.

- (2) If it is feasible and the trial subject so wishes, the chief investigator or an authorised person when reporting the research project shall inform the trial subject of the results achieved and of any consequences for the individual trial subject.

*Increased requirements of information and consent when including trial subjects exposed to particular pressure or compulsion*

15. Where, because of placement in an institution, incarceration, circumstances of employment or in similar circumstances, the trial subject is particularly exposed to pressure regarding participation in a biomedical research project, but where the subject is otherwise capable of making decisions, the committee may after concrete assessment decide that the consent of the trial subject to participate in the research project shall be given to a person authorised by the committee. The committee may also decide that in such cases the information shall be supplemented by a statement that the course of the research project shall be observed by an independent professional.

- (2) Persons subject to compulsion cf. S. 23(1) of the act on incarceration and other compulsion in psychiatry may not participate as trial subjects in biomedical research projects.

Part 3

*Surrogate consent*

*General Issues*

16. The committee may only grant authorisation to initiate and continue a biomedical research project that involves trial subjects who because of age or reduced physical or mental functional capacity as a consequence of a mental condition, age, mental handicap or similar conditions are incapable of giving informed consent to participation in trials, if a surrogate consent is obtained, cf. also S. 21(1). The committee shall verify that a form is available to be used for making a surrogate consent under the rules in Part 2 as well as Part 3.

- (2) At the evaluation of research projects implemented on the basis of surrogate consent, the committee shall ensure prior to the approval that the project cannot with similar benefit be conducted by including legally competent trial subjects of legal capacity whose voluntary participation cannot be disputed. The committee shall also ensure that surrogate consent is in the interest of the trial subject and that the criteria concerning adverse events in S.13 of the Act have been observed.

17. A trial subject who is incapable of giving informed consent shall be informed about and included in the discussions about the biomedical research project to the extent that the subject concerned understands the trial situation, unless this may harm the trial subject. Importance shall be attached to the indications of the trial subject in so far as these are relevant.

- (2) A biomedical research project shall not be initiated or continued on the background of a surrogate consent if the trial subject objects to it.

18. The person giving surrogate consent may at any time withdraw the surrogate consent orally, in writing or in any other clearly expressed way without this affecting access to existing or future treatment or other rights which he/she or the trial subject might have.
19. If a trial subject gains or regains legal competence during the course of the biomedical research project, informed consent is to be obtained from the trial subject prior to the continuation of the research project under the rules in Part 2.

Special issues on biomedical research projects involving minors

20. The committee may only grant authorisation to initiate and continue a biomedical research project involving legally incompetent persons under the age of 18 if in connection with the surrogate consent the minor has been given oral information on the research project, its risks and benefits, cf. also S. 21(1). This information shall be provided by a person who has knowledge of the area concerning the research project and also with educational qualifications to communicate the contents to the age group comprised by the project.
   - (2) A trial subject in the 15-17 age group, who is not legally competent, must, if he or she so wishes, and to the extent the information may contribute towards clarifying the content of the research project, also receive written information on the research project.
   - (3) The oral as well as the written information to the legally incompetent 15-17-year-old trial subject must be adapted to this age group.
   - (4) The Danish National Committee on Biomedical Research Ethics may issue detailed guidelines for the contents of the information to 15-17-year-old trial subjects.

Exemptions from the requirement for surrogate consent regarding 15 – 17-year-olds

21. A legally incompetent 15-17-year-old trial subject may independently provide informed consent under the rules in Part 2 to participate in a research project where the research project does not involve or only to a limited extent involves clinical intervention, and where the research project is believed to present no risk or harm for the trial subject.
   - (2) If the 15 – 17-year-old minor gives his/her informed consent pursuant to subsection (1), the holder of custody shall receive the same information and shall be involved in the decision of the 15 – 17-year-old.

Special issues on individuals under personal guardianship and permanently legally incompetent adults

22. The committee may only grant authorisation to initiate and continue a biomedical research project involving permanently legally incompetent adults if surrogate consent has been obtained from the closest relative and the trial subject's general practitioner.
   - (2) The surrogate consent from the general practitioner shall be given on the background of the doctor's knowledge of the trial subject or on the doctor's ability to familiarize himself with the trial subject or to the doctor's ability to familiarize himself with the health condition of the trial subject in relation to the doctor's assessment of the content of the biomedical research project.
   - (3) In the trial subject's general practitioner's absence, or if the trial subject is not affiliated with a permanent general practitioner, the surrogate consent must be obtained from the closest relative and the medical officer of health.

Special issues on biomedical research projects involving deceased persons

23. A biomedical research project involving deceased individuals, can be implemented only in accordance with the rules under the Act on Coroner’s Inquests, Post-Mortem Examinations, Transplantation, etc., which, among other things, states that consent to medico-legal post-mortem examination is required, cf. also subsection (2).
   - (2) Minor interventions made in connection with a biomedical research project which affect deceased individuals and which are mentioned in S. 17(2) of the Act on Coroner’s Inquests, Post-Mortem
Examinations, Transplantation, etc., may be made with a surrogate consent from the closest relative, cf. S.16.

**Part 4**

*Penal Provisions*

24. Unless more severe punishment is determined in other legislation, any person who initiates and implements a research project contrary to S.4, S.7(2), SS.9 and 10, SSS.12-14(1), S.15, S.17, S.19 and S.23 of this Order shall be punishable by fine.

**Commencement, etc.**

25. The Ministerial Order shall come into force on 1st August 2004 in relation to research projects notified to a committee on biomedical research ethics as from this date.

-(2) At the same time Ministerial Order No. 935 of 12 October 2000 on Information and Consent at Inclusion of Trial Subjects in Biomedical Research Projects shall be repealed.

*The Danish Ministry of Interior and Health, 12 July 2004*

Lars Løkke Rasmussen

/Steen Loiborg