

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 projects¹⁾

(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:

1. In the footnote of the title of the act after »(the Official Journal of the European Communities 2001 No. L 121, pp. 0034-0044)«, add: », and provisions implementing part of the European Parliament and Council Directive 2005/28/EC of 8 April 2005 (the Official Journal of the European Communities, No. L 091 of 09/04/2005, pp. 0013-0019)«.

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

¹⁾ The Act includes provisions implementing part of the European Parliament and Council Directive 2005/28/EC of 8 April 2005 (the Official Journal of the European Communities, No. L 91 of 09/04/2005, pp. 13-19)

Links to EC directives, cf. note 1

[Directive 2005/28/EC\(EF\)](#) Celex no. 32005L0028 (Danish)