Ministry of Social Affairs and Health, Finland

N.B. Unofficial translation. Legally binding only in Finnish and Swedish

No. 841/2010

Decree of the Ministry of Social Affairs and Health on Clinical Drug Trials

Issued in Helsinki on 30 September 2010

Section 1

Scope

This Decree lays down provisions on the format of the request for opinion addressed to an ethics committee and on delegating requests for opinion to a regional ethics committee.

Section 2

Delegating requests for opinion

(1) The National Committee on Medical Research Ethics may decide on delegating the handling of a clinical drug trial to a regional ethics committee even before the actual request for opinion is made. The decision on delegating is made by the National Committee or the subcommittee dealing with decisions on delegating the handling of clinical drugs trials set up by the National Committee. The decision must be unanimous. The decision can be made via a written procedure. If the National Committee or the subcommittee set up by it for handling the decisions on delegating is not unanimous as to whether the handling should be delegated to a regional ethics committee or not, the National Committee shall handle the matter.

(2) Before making the decision on delegating the handling of a clinical drug trial a prior notification shall be made to the National Committee on Medical Research Ethics on the form contained in Appendix 1 to this Decree *Prior notification of a clinical drug trial.* [1]

Section 3

Requests for opinion

(1) The request for opinion on a clinical drug trial shall be drawn up on the form contained in Appendix 2 to this Decree *Request for opinion on a clinical drug trial.*

[1] Appendices are not available in English.

(2) The matters delegated by the National Committee on Medical Research Ethics shall be handled by the regional ethics committee of the region where the person in charge of the trial is based or of the region where the trial is to be carried out principally and whom the party commissioning the trial asks for an opinion.

Section 4

Changes to the research plan

(1) Any changes to the research plan for a clinical drug trial shall be notified on the form contained in Appendix 3 to this Decree *Request for opinion on a significant change to the clinical drug trial*.

(2) Notification of a change to the plan for a clinical drug trial shall be addressed to the National Committee on Medical Research Ethics. When the application for opinion has been handled by the regional ethics committee referred to in section 3, the notification shall be addressed to the ethics committee that handled the application for opinion.

Section 5

Notification of termination of a trial

Notification of termination of a clinical drug trial shall be made on the form contained in Appendix 4 to this Decree *Notification of termination of a clinical drug trial* and addressed to the ethics committee referred to in section 4.

Section 6

Entry into force

This Decree enters into force on 1 October 2010.

This Decree repeals the Decree of the Ministry of Social Affairs and Health on Clinical Drug Trials (316/2005) of 1 June 2005.