

ICH/GCP

CENTRALA ETIKPRÖVNINGSNÄMNDEN
Central Ethical Review Board 2004-06-28

Re the Swedish research ethics review of clinical trials and ICH/GCP

Since January 2004 the Swedish research ethics review system is regulated by law, lagen (2003:460) om etikprövning av forskning som avser människor. This legislation takes into account both the European convention on human rights and biomedicine and the directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

The review is undertaken within six separate Regional ethical review boards involving at least two separate units for review. Each unit includes ten experienced scientists and five lay persons and is chaired by an experienced judge all elected by the government. The Central Ethical Review Board is responsible for supervision of the law except the supervision provided by the Medicinal Products Agency and the National Board of Health and Welfare and the Swedish Data Inspection Board. Appeals on decisions taken by a Regional ethical review board can be made to the Central Ethical Review Board.