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The European Parliament and the Council of the European Union issued Directive 2001/20/EC of 4th April 2001 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 of medicinal products for human use (GCP directive).

The directive is based on the principles of ICH-GCP. With regard to the Danish committee system on health research ethics the main part of the directive has been implemented in Danish law through Act no. 593 of 14th June 2011, the Act on Research Ethics Review of Health Research Projects. The Act applies to the processing of applications for authorization of Health Research Projects submitted after 1st January 2012.

The committee system on health research ethics does not fully comply with the GCP-directive, but only the section implemented in the above mentioned Committee Act.

Kind regards,

The Committees on Health Research Ethics for Central Denmark Region