ICH-GCP statement

The Finnish Ethics Committees obey the current Finnish law. The Medical Research Act No. 488/1999 takes into consideration statutory regulations and directives (Mostly Directives 2001/20/EC and 2005/28/EC) within EC area.

The Ethics Committees of the Helsinki and Uusimaa Hospital District are organized and operate according to the principles of good clinical research practice (ICH-GCP-E6) and all clinical trials on medicinal products shall be planned, conducted and reported on observing the principles of good clinical research practice, and in accordance with the international obligations concerning the status of research subjects and the rules and guidelines that govern research (Medical Research Act 488/1999, chapter 2 a (23.4.2004/295), section 5 and 10a).

Human subjects research conducted or supported by Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services (HHS) is guided by Ethical Principles as stated in the terms of the Federalwide Assurance (FWA) for the protection of human subjects in international (non-U.S.) institutions. The Coordinating Ethics Committee of the Helsinki and Uusimaa Hospital District is registered with the HHS and follows ICH-GCP-E6 in reviewing all research in the Helsinki and Uusimaa Hospital District involving human subjects. (http://www.hhs.gov/ohrp/assurances/assurances_index.html)