Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (Text with EEA relevance)

CHAPTER 1

SUBJECT-MATTER

Article 1 (1) This Directive lays down the following provisions to be...

CHAPTER 2

GOOD CLINICAL PRACTICE FOR THE DESIGN, CONDUCT, RECORDING AND REPORTING OF CLINICAL TRIALS

SECTION 1

GOOD CLINICAL PRACTICE

Article 2 (1) The rights, safety and well being of the trial...
Article 3 The available non-clinical and clinical information on an investigational medicinal...
Article 4 The protocol referred to in point (h) of Article 2...
Article 5 All clinical trial information shall be recorded, handled, and stored...

SECTION 2

THE ETHICS COMMITTEE

Article 6 (1) Each Ethics Committee established under Article 6(1) of Directive...

SECTION 3

THE SPONSORS

Article 7 (1) A sponsor may delegate any or all of his...

SECTION 4

INVESTIGATOR’S BROCHURE

Article 8 (1) The information in the investigator’s brochure, referred to in...

CHAPTER 3

MANUFACTURING OR IMPORT AUTHORISATION

CHAPTER 4

THE TRIAL MASTER FILE AND ARCHIVING

CHAPTER 5

INSPECTORS

CHAPTER 6

INSPECTION PROCEDURES

CHAPTER 7

FINAL PROVISIONS

(**1**) OJ L 121, 1.5.2001, p. 34.

(**2**) OJ L 262, 14.10.2003, p. 22.

(**3**) OJ L 311, 28.11.2003, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).