

ISO 14155-1:2003-02 (E)

Clinical investigation of medical devices for human subjects - Part 1: General requirements

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Justification for a clinical investigation	5
5	Ethical considerations	5
5.1	Declaration of Helsinki	5
5.2	Improper influence or inducement	5
5.3	Compensation and additional health care	5
5.4	Responsibilities	5
6	General requirements	5
6.1	Formal agreement(s)	5
6.2	Qualifications	5
6.3	Clinical investigation plan	6
6.4	Design of the clinical investigation	6
6.5	Confidentiality	6
6.6	Start of clinical investigation	6
6.7	Informed consent	6
6.8	Suspension or early termination of the clinical investigation	8
6.9	Document and data control	8
6.10	Accounting for subjects	9
6.11	Access to preclinical and clinical information	9
6.12	Auditing	9
7	Documentation	9
7.1	General	9
7.2	Clinical investigator's brochure	9
7.3	Other documents	10
8	Sponsor	10
8.1	General	10
8.2	Responsibilities of sponsor	10
9	Monitor	11
9.1	Responsibilities of monitor	11
10	Clinical investigator	12
10.1	General	12
10.2	Qualification of clinical investigator	12
10.3	Responsibilities of clinical investigator	12
11	Final report	14
11.1	Presentation of results	14

11.2	Contents of the final report	14
	Annex A (informative) Suggested procedure for literature review	15
	Annex B (informative) Information for the ethics committees	17
	Annex C (informative) Final reports of clinical investigations with medical devices	18
	Bibliography	21