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Clinical investigation of medical devices for human subjects —

Part 1: General requirements

Investigation clinique des dispositifs médicaux pour sujets humains —

Partie 1: Exigences générales



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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

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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**

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14155-1 was prepared by Technical Committee ISO/TC 194, *Biological evaluation of medical devices*.

This first edition of ISO 14155-1, together with ISO 14155-2, cancels and replace ISO 14155:1996, which has been technically revised.

ISO 14155 consists of the following parts, under the general title *Clinical investigation of medical devices for human subjects:*

— *Part 1: General requirements*

— *Part 2: Clinical investigation plans*

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Introduction

This part of ISO 14155 is intended to be applied worldwide to clinical investigations of medical devices in order to fulfil the technical aspects of the various national, regional and international regulatory requirements. As the legal regulatory requirements presently differ throughout the world, regulatory specifics have been excluded from the scope of this part of ISO 14155. They are part of national or regional legislative texts and can be referenced in the national or regional forewords, as appropriate.

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Clinical investigation of medical devices for human subjects —

Part 1:
General requirements

1 Scope

This part of ISO 14155 defines procedures for the conduct and performance of clinical investigations of medical devices. It specifies general requirements intended to

— protect human subjects,

— ensure the scientific conduct of the clinical investigation,

— assist sponsors, monitors, investigators, ethics committees, regulatory authorities and bodies involved in the conformity assessment of medical devices.

This part of ISO 14155

a) specifies requirements for the conduct of a clinical investigation such that it establishes the performance of the medical device during the clinical investigation intended to mimic normal clinical use, reveals adverse events under normal conditions of use, and permits assessment of the acceptable risks having regard to the intended performance of the medical device,

b) specifies requirements for the organization, conduct, monitoring, data collection and documentation of the clinical investigation of a medical device,

c) is applicable to all clinical investigation(s) of medical devices whose clinical performance and safety is being assessed in human subjects.

This part of ISO 14155 is not applicable to *in vitro* diagnostic medical devices.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

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