ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Regulatory and ethical requirements in medical devices studies

Portugal

SECTIONS

A.Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

SECTIONS

A.Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

A. Type of research

We have differentiated 8 types of research:

- Medical device alone with CE mark use within label
- Medical device alone with CE mark use outside label
- Medical device alone without CE mark
- Medical device combined with medicinal product with CE mark use within label
- Medical device combined with medicinal product with CE mark use outside label
- Medical device combined with medicinal product without CE mark
- Observational studies with medical device
- Registries

SECTIONS

A.Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

B. Definitions/Legal basis

Definitions in Portuguese law

- There is no Potuguese definition for the type of study previously cited.

B. Definitions/Legal basis

Conventions/guideline/laws to apply

- Declaration of Helsinki
- ISO 14155:2011
- Decree-Law 145/2009, 17 June (Transposition of Directives 93/42/CEE, 90/385/CEE and 2007/47/CE) ***(Except for medical device with CE mark use within label with or without medicinal product, observational study and registries)***
- Law 21/2014, of 16 April 2014

B. Definitions/Legal basis

Acts to apply

- Data protection act
- Medical device act ***(Except for medical device with CE mark use within label with or without medicinal product, observational study and registries)***

SECTIONS

A.Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

C. Insurance

• For all the type of studies in exception of observational studies and registries, an insurance must be contracted. It has to cover:

- Patients and/or healthy volunteers
- Investigators
- Sponsor

• It is not mandatory to have a compensation sum coverage per participant

SECTIONS

A.Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

D. Sponsor

- It is mandatory to have a sponsor for all study type
- Co-sponsorship is not allowed

SECTIONS

A.Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

E. Investigators

• As stated in ISO 14155:2011, in Portugal, the investigator must be qualified by education, training and experience.

SECTIONS

A.Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

F. Competent Authority

Portuguese Competent Authority:

Health Product Directorate INFARMED Autoritade Nacional do Medicamento e Produtos de Saude,
daps@infarmed.pt
Phone +351 21 798 7235
Fax: +351 21 798 7182
www.infarmed.pt

F. Competent Authority

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

	Approval	
	Yes	**No**
Medical device alone with CE mark use within label		X*
Medical device alone with CE mark use outside label	X	
Medical device alone without CE mark	X	
Medical device combined with medicinal product with CE mark use within label		X*
Medical device combined with medicinal product with CE mark use outside label	X	
Medical device combined with medicinal product without CE mark	X	
Observational studies with medical device		X

*** If it's a MD of class IIa, IIb or III an approval is required**

F. Competent Authority – Initial submission

• When a submission is required, the sponsor is responsible of it

• The submission to the Portuguese Competent Authority is national: you only have to submit one dossier to the national competent authority

• The submission have to be:

- by paper

- or electronic format (with specific signed documentation)

• English documents are accepted, except for documents intended for study subjects

• No submission fee

F. Competent Authority – Initial submission

- In general, 60 days maximum to obtain approval
- Approval after 60 days with ethic committee favourable opinion
- No deadlines for submission, you can submit anytime
- No need to have some kind of representative or a legal entity in Portugal to submit an application to the Competent Authority if you are from the EU

F. Competant Authority – Initial submission

Main documents required for submission (1/2):

- Submission letter
- Clinical Trial application form
- Clinical Investigation Plan/Protocol signed
- Clinical Investigation Plan/Protocol summary
- Informed consent form
- Subject information leaflet
- General practitioner information letter
- Investigator’s brochure or CE certificate
- Instruction for use/Technical manual
- Performance evaluation
- Pre-clinical evaluation

F. Competant Authority – Initial submission

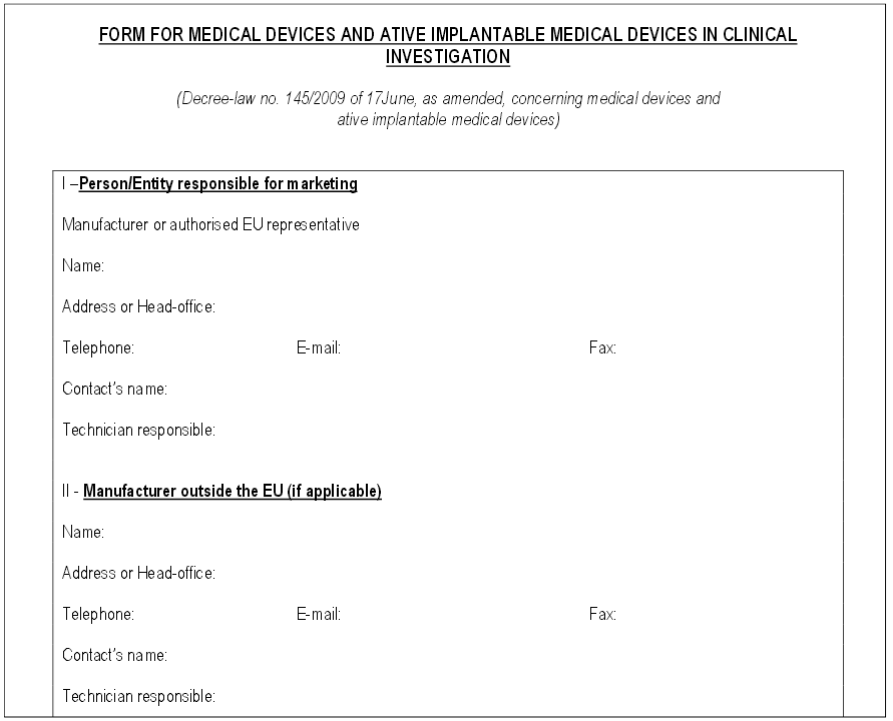
Main documents required for submission (2/2):

- Insurance certificate
- Signed and dated CV of investigators
- Law training of investigator
- Product training of investigator
- Conflict of interest statement from the investigator
- Financial disclosure
- Study approval from administration department
- Agreement between sponsor and CRO specifying responsibilities
- Ethical committee's approval

F. Competent Authority – Initial submission

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

- Standard application form available on the Infarmed's website:



FORM FOR MEDICAL DEVICES AND ATIVE IMPLANTABLE MEDICAL DEVICES IN CLINICAL INVESTIGATION

(Decree-law no. 145/2009 of 17June, as amended, concerning medical devices and ative implantable medical devices)

I –**Person/Entity responsible for marketing**

Manufacturer or authorised EU representative

Name:

Address or Head-office:

Telephone: E-mail: Fax:

Contact's name:

Technician responsible:

II - **Manufacturer outside the EU (if applicable)**

Name:

Address or Head-office:

Telephone: E-mail: Fax:

Contact's name:

Technician responsible:

F. Competent Authority - Vigilance

• SAE definition:

Any untoward occurrence that may led to death or led to serious deterioration in the health of the subjects, according to Decree-Law 145/2009

SAE declaration by the sponsor:

- If life in danger: 2 days after awareness
- Other case: 7 days after awareness

• The sponsor has to declare events to the Competent Authorities in the specific countries

• The sponsor needs to provide to the Competent Authority an annual safety report

F. Competent Authority - Vigilance

A. Type of research
B. Definitions/Legal basis
C. Insurance
D. Sponsor
E. Investigators
F. Competent Authority
G. Ethics Committee
H. Data Ptotection
I. Healthy volunteers/Patients
J. Specific requirements

Events mandatory to declare to the Competent Authority:

	AE	ADE	SADE	SAE
Medical device alone with CE mark use within label			x	
Medical device alone with CE mark use outside label			x	x
Medical device alone without CE mark			x	x
Medical device combined with medicinal product with CE mark use within label			x	
Medical device combined with medicinal product with CE mark use outside label			x	x
Medical device combined with medicinal product without CE mark			x	x
Observational studies with medical device			x	

AE: Adverse Event (Non device related)
ADE: Adverse Device Effect (Device or procedure related)
SADE: Serious adverse Device Effect (Device or procedure related)
SAE: Serious Adverse Event (Non device related)

F. Competent Authority - Vigilance

A. Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Ptotection

I. Healthy volunteers/Patients

J. Specific requirements

- The sponsor is responsible for the declaration to the Competent Authority
- Special form for the declaration of SAE:

MEDDEV 2.7/3 SAE Report Table- V1												
EUDAMED - ID:												
Title of Clinical Investigation:												
CIP Number:												
Contact person (Name, Address, E-Mail, Telephone Number)									**Device type:**			
MS+NCA Reference Numbers for all participating Countries:									**Reference Member State:**			
No. of Patients enrolled to date (date of report):									**No. of Invest. Devices used to date**			
Date of Report:												
Status: a, m, u	Date Sponsor received Report of SAE	Country	Study Center	Patient ID Code	Date of Procedure/ First Use	Date of Event Onset	Event: Organ System	Description of event	action/ treatment/patient outcome	Assessment of Relationship to Procedure: Yes No Possibly	Assessment of Relationship to Investigational Device: Yes No Possibly	Unanticipa SADE yes/

F. Competent Authority - Notification

- It is not mandatory to notify the first patient enrolled to the Competent Authority

F. Competent Authority – Substantial amendment

- There is no specific procedure for submitting a substantial amendment to the Competent Authority
- Substantial amendments to the study plan shall be simultaneously notified to the competent EC and the national CA
- Standard Notification form to be used by the applicant for submission of substantial amendments is the same as used for IMP studies and is provided on the INFARMED website

SECTIONS

A.Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

G. Ethics Committee

National EC

CEIC - National Ethics Committee for Clinical Research/ Comissão de Ética para a Investigação Clínica
www.ceic.pt

Local ECs

Portugal ethic committees are local. You have to address the one of the hospital or clinical site. There are almost 100 institutional ECs (public and private, health and academic)

G. Ethics Committee

	Positive opinion required	
	Yes	**No**
Medical device alone with CE mark use within label	x	
Medical device alone with CE mark use outside label	x	
Medical device alone without CE mark	x	
Medical device combined with medicinal product with CE mark use within label	x	
Medical device combined with medicinal product with CE mark use outside label	x	
Medical device combined with medicinal product without CE mark	x	
Observational studies with medical device	x	
Registries	x	

G. Ethics Committee – Initial submission

- When a submission is required, the sponsor is responsible of it
- The submission to the Ethics Committee is local
- The submission have to be by paper
- The submission fee and the document language accepted depend on the ethic committee.

G. Ethics Committee – Initial submission

- When both Competent Authority approval and Ethics Committee positive opinion are required, the Ethics Committee opinion have to be obtained first.

- No need to have some kind of representative or a legal entity in Portugal to submit an application to the Competent Authority or Ethics Committee if you are from the EU

G. Ethics Committee – Initial submission

- For the following type of study the documents required for the submission depend on the Ethic Committee.
  - Medical device alone with CE mark use within label
  - Medical device combined with medicinal product with CE mark use within label
  - Observational study

G. Ethics Committee – Initial submission

Main documents required for other type of study submission (1/2):

- Submission letter
- Clinical Investigation Plan/Protocol signed
- Clinical Investigation Plan/Protocol summary
- Informed consent form
- Subject information leaflet
- General practitioner information letter
- Investigator’s brochure or CE certificate
- Instruction for use/Technical manual
- Performance evaluation
- Pre-clinical evaluation

G. Ethics Committee – Initial submission

Main documents required for other type of study submission(2/2):

- Insurance certificate
- Signed and dated CV of investigators
- GCP training of investigator
- Law training of investigator
- Product training of investigator
- Qualification certificate of investigators
- Conflict of interest statement from the investigator
- Financial disclosure
- Study approval from administration department
- Agreement between sponsor and CRO specifying responsibilities

G. Ethics committee – Initial submission

- The use and the type of a standard application form depends on the Ethical Committee.

G. Ethics Committee - Vigilance

- SAE declaration by the sponsor:
  - If life in danger: 7 days
  - Other case: 15 days

- The sponsor doesn’t have to declare events to the Ethics Committee in the specific countries

G. Ethics Committee - Vigilance

Events mandatory to declare to the competent authority:

	AE	ADE	SADE	SAE
Medical device alone with CE mark use within label			x	
Medical device alone with CE mark use outside label			x	x
Medical device alone without CE mark			x	x
Medical device combined with medicinal product with CE mark use within label			x	
Medical device combined with medicinal product with CE mark use outside label			x	x
Medical device combined with medicinal product without CE mark			x	x
Observational studies with medical device			x	

AE: Adverse Event (Non device related)
ADE: Adverse Device Effect (Device or procedure related)
SADE: Serious adverse Device Effect (Device or procedure related)
SAE: Serious Adverse Event (Non device related)

G. Ethics Committee - Vigilance

- The sponsor is responsible for the declaration to the Ethics Committee
- It depends on the Ethic Committee but it’s unlikely there is a special form for the declaration of SAE

G. Ethics Committee - Notification

- There is no specific regulation for the notification of the first patient enrolled to the Ethics Committee

G. Ethics Committee – Substantial amendment

- There is no specific procedure for submitting a substantial amendment to the Ethics Committee
- Substantial amendments to the study plan shall be simultaneously notified to the competent EC and the national CA
- Standard Notification form to be used by the applicant for submission of substantial amendments is the same as used for IMP studies and is provided on the INFARMED website

SECTIONS

A.Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

H. Data Protection

Portuguese Data Protection:

CNPD
(Comissão Nacional de Protecção de Dados)
Rua de São Bento n.º 148-3º 1200-821 Lisboa
Tel: +351 213928400 - Fax: +351 213976832
e-mail: geral@cnpd.pt
http://www.cnpd.pt

H. Data Protection

	Notification required	
	Yes	No
Medical device alone with CE mark use within label	x	
Medical device alone with CE mark use outside label	x	
Medical device alone without CE mark	x	
Medical device combined with medicinal product with CE mark use within label	x	
Medical device combined with medicinal product with CE mark use outside label	x	
Medical device combined with medicinal product without CE mark	x	
Observational studies with medical device	x	
Registries	x	

H. Data Protection

- Submission in english accepted
- 150€ submission fee
- Online submission

SECTIONS

A.Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

I. Healthy volunteers/Patients

• In Portugal, there are specific requirements/regulations for specific population (Decree-Law 145/2009):

- Children
- Pregnant women
- Lactating women
- Adults protected by the law

I. Healthy volunteers/Patients

• Subject remuneration is regulated by Decree-Law 145/2009

• There is no National healthy volunteers registry

• There is no obligation to inform the healthy volunteers/patients on the outcomes of the study

SECTIONS

A.Type of research

B. Definitions/Legal basis

C. Insurance

D. Sponsor

E. Investigators

F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

J. Specific requirements

• No specific requirements to publish both positive and negative results of clinical studies in scientific journals

• Specific requirements/regulations to provide devices without CE mark or used outside the intended use for free

• Specific requirements/regulations regarding devices emitting radiation

• No specific requirements/regulations regarding the ICF

• Specific requirements/regulations regarding archiving of documentation: **see Decree-Law 145/2009**

J. Specific requirements

- No specific requirements for data management

- No specific strategies for monitoring

- Mandatory to register clinical studies which include medicinal product in a registry