

# **Regulatory and ethical requirements in medical device studies**

## **DENMARK**

# **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**

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## **A. Type of research**

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### **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**

- A. Type of research
- B. Definitions/Legal basis**
- C. Insurance
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- F. Competent Authority
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- J. Specific requirements

### **Definitions in Danish law**

- The following are sources for the definition for clinical research in medical device studies in Denmark:
  - Danish Health Authority
  - Danish Medicines Agency
  - Danish Data Protection Agency

## ***B. Definitions/Legal basis***

- 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

### **Conventions/guideline/laws to apply**

- ICH Guideline of EMA
- European Directive 2011/20/EC

These apply for all medical device studies other than observational studies and registry studies.

## **B. Definitions/Legal basis**

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

### **Acts to apply**

- For device with CE mark used within label:
  - Data Protection Act
  - Ethics Law
- In addition, for medical device studies alone with CE mark use outside label, for medical device alone without CE mark and for medical devices with or without CE mark combined with medicinal product
  - Medical Device Act
  - Drug Act – For medical devices combined with medicinal product



# **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

- 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

- For all the type of medical device studies listed, it is not necessary to cover insurance for
  - Patients or healthy volunteers
  - Investigators
  - Sponsors
  - Manufacturers
- No mandatory compensation sum per participant or per trial is required.

# **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**

- 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

It is mandatory to have a sponsor in all the interventional studies listed below:

- 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

# **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***

- 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

- There are no specific requirements/regulations for GCP training of the investigators in Denmark for any of the study types.

# **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***

- 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

### **Danish Competent Authority:**

**!** As from 8 October 2015, Danish Health and Medicines Authority (DHMA) has been split into three agencies.

Until January 2016, the DHMA website will display information and guidance from the Danish Health Authority, the Danish Medicines Agency and parts of the Danish Patient Safety Authority

In January 2016, they will launch three new websites.



## 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 Protection
- I. Healthy volunteers/Patients
- J. Specific requirements

### **Danish Competent Authority:**

Danish Health and Medicines Authority

<http://www.sundhedsstyrelsen.dk/en/>

#### **Danish Health Authority**

Islands Brygge 67

2300 Copenhagen S

Denmark

[sst@sst.dk](mailto:sst@sst.dk)

Tel. +45 72 22 74 00

#### **Danish Medicines Agency**

Axel Heides Gade 1

2300 Copenhagen S

Denmark

[dkma@dkma.dk](mailto:dkma@dkma.dk)

Tel. +45 44 88 95 95

[Sundhedsstyrelsen.dk/en/](http://www.sundhedsstyrelsen.dk/en/)

## F. Competent Authority

- A. Type of research
- B. Definitions/Legal basis
- C. Insurance
- D. Sponsor
- E. Investigators
- F. Competent Authority**
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- 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	

## **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 Protection
- I. Healthy volunteers/Patients
- J. Specific requirements

- The sponsor is responsible for the submission.
- The submission to the Danish Competent Authority is national: you only have to submit one dossier to the national competent authority

- The submission has to be :

-online via

Eudralink/DKMAnet

or

<http://sundhedsstyrelsen.dk/en/medicines/regulation/clinical-trials/applications>

or

-by CD-ROM

- English documents are accepted
- Submission fee is 2,600 Euro to 3400 Euro

## **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 Protection
- I. Healthy volunteers/Patients
- J. Specific requirements

- There is a standard application form - see link below:

<http://Sundhedsstyrelsen.da.da/medicin/medicinsk-udstyr/klinisk-afproevning/ansoegning-om-klinisk-afproevning>

- 60 days maximum to obtain approval
- No need to have some kind of representative or a legal entity in Denmark to submit an application to the Competent Authority

## ***F. Competant 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 Protection
- I. Healthy volunteers/Patients
- J. Specific requirements

Main documents required for submission:

- Submission letter
- Clinical Trial application form
- Clinical Investigation Plan/Protocol
- Clinical Investigation Plan/ Protocol signed
- Clinical Investigation Plan/Protocol summary
- Investigator's brochure or CE certificate
- Instruction for use/Technical manual
- Financial disclosure

## **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 Protection
- I. Healthy volunteers/Patients
- J. Specific requirements

- It is mandatory to declare AEs, ADE, SADE and SAEs to the Danish Competent Authority.

- The sponsor is responsible for declaring Adverse Events to the Competent Authorities in the specific countries

- Danish Competent authority has a standard form for SAE reporting. See link below:

[Sundhedsstyrelsen.dk/en/medicines/medical-devices/incident-reporting-system](https://sundhedsstyrelsen.dk/en/medicines/medical-devices/incident-reporting-system)

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

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
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- SAE definition = standard ICH-GCP definition, including near incident.

SAE declaration by the sponsor

- all serious adverse events, including near-incidents- immediately and no later than **7 days**

-a serious adverse event which indicates an imminent risk of death, serious injury, or serious illness and which requires prompt remedial action for other patients/subjects, users or other persons must be reported no later than **2 days**

- AEs are reported in a final report



## F. Competent Authority - Vigilance

- A. Type of research
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- E. Investigators
- F. Competent Authority**
- G. Ethics Committee
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- The sponsor needs to provide an annual safety report to the Danish Competent Authority for studies involving:
  - 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

## ***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 Protection
- I. Healthy volunteers/Patients
- J. Specific requirements

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

## ***F. Competent Authority – Substantial amendment***

- 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

- There is a specific procedure for submitting a substantial amendment to the Danish Competent Authority

# **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

- 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

### 11 Local committees in 5 regional committees.

Contact should be made via the regional committees .

The National Committee on Health Research Ethics, Holbergsgade 6, 1057 København K, Tlf: +45 72 26 93 70, <http://www.cvk.sum.dk/>, E-mail: [DKetik@DKetik.dk](mailto:DKetik@DKetik.dk)

1. Regional ethics committee for the Capital Region: Kongens Vænge 2, 3400 Hillerød, Tlf. +45 38 66 63 95, [www.regionh.dk/vek](http://www.regionh.dk/vek), E-mail: [vek@regionh.dk](mailto:vek@regionh.dk)
2. Regional ethics committee for the Region Zealand: Alléen 15, 4180 Sorø, Tlf. +45 24 52 59 52, [www.regionsjaelland.dk/videnskabsetisk-komite](http://www.regionsjaelland.dk/videnskabsetisk-komite), E-mail: [RH-komite@regionsjaelland.dk](mailto:RH-komite@regionsjaelland.dk)
3. Regional ethics committee for the South of Denmark: Regionshuset, Damhaven 12, 7100 Vejle, Tlf. +45 20 59 89 30, +45 29 20 22 51, +45 29 20 22 52 og +45 29 20 12 03, [www.regionsyddanmark.dk/komite](http://www.regionsyddanmark.dk/komite), E-mail: [komite@rsyd.dk](mailto:komite@rsyd.dk)
4. Regional ethics committee for the Central Region of Denmark: Regionssekretariatet, Juridisk Kontor, Skottenborg 26, 8800 Viborg, Tlf. +45 78 41 01 83, +45 79 41 01 85, +45 78 41 01 81, +45 78 41 01 82, [www.komite.rm.dk](http://www.komite.rm.dk), E-mail: [komite@rm.dk](mailto:komite@rm.dk)
5. Regional ethics committee for the Region North of Denmark: Regionssekretariatet, Niels Bohrs Vej 30, 9220 Aalborg Ø, Tlf. +45 97 64 84 40, [www.vek.rn.dk](http://www.vek.rn.dk), E-mail: [vek@rn.dk](mailto:vek@rn.dk)

# G. Ethics Committee

- 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

	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	

## G. Ethics Committee – Initial submission

- 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

- The sponsor is responsible for submission.
- The submission to the Ethics Committee is local: you only have to submit one dossier **to one of the regional Ethics Committee**
- The submission has to be:
  - Online via email, using a digital signatureOr
  - Via the online portal DKMAnet
- English documents are accepted
- Submission fee is 650 to 950 Euro

## **G. Ethics Committee – Initial submission**

- 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

- In general, 60 days to obtain approval
- No implicit approval
- Deadlines for submissions
- When both Competent Authority approval and Ethics Committee positive opinion are required, it is possible to request the 2 in parallel.
- No need to have some kind of representative or a legal entity in Denmark to submit an application to the Competent Authority or Ethics Committee.



## **G. Ethics Committee – Initial submission**

- 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

Main documents required for submission:

- Submission letter
- Clinical Trial application form
- Clinical Investigation Plan/Protocol
- Clinical Investigation Plan/Protocol summary
- Inform Consent Form and subject Information leaflet
- General Practitioner information letter
- Copy of advertisement materials for research participant
- Financial disclosure

## **G. Ethics committee – Initial submission**

- 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

- Standard application form
- Standard application form available on the DNVK website:
  - [www.fnvk.dk/englis.h/notification%20of%20%clinical%20trial.aspx](http://www.fnvk.dk/englis.h/notification%20of%20%clinical%20trial.aspx):

## **G. Ethics Committee - Vigilance**

- 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

- Sponsor is responsible for SAE declaration to Ethics Committee :

Timeline: 7 days in device trial not involving a medicinal product.

- The sponsor also has to declare events to the Ethics Committee in the specific countries
- Annual safety report must be provided to the Ethics Committee

## G. Ethics Committee - Vigilance

- 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

Events mandatory to declare to the competent authority in Denmark:

	AE	ADE	SADE	SAE
Medical device alone with CE mark use within label			x	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	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				

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**

- 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

- The sponsor is responsible for the declaration to the Ethics Committee
  
- A Special form is used for the declaration of AE to the Ethics Committee.

## **G. Ethics Committee – Substantial amendment**

- 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

- There is a specific procedure for submitting a substantial amendment to the Ethics Committee

# **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

- 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

**Danish Data Protection Agency:**

[www.datatilsynet.dk/english/](http://www.datatilsynet.dk/english/)



# H. Data Protection

- 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

	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	

## H. Data Protection

- 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

- Submission in English is accepted by the Danish data protection agency
- No submission fee

# **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

- 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

• In Denmark there are specific requirements/regulations for the following specific populations:

- Children – Ethics Law + written consent from parts or legal guardians

- Pregnant and lactating women – Ethics law

[www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500002877.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002877.pdf)

- Incapacitated adults –written consent from legal guardian or nearest relatives

- Emergency situations: written consent post incident.

# I. Healthy volunteers/Patients

- 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

- No specific requirements in Denmark re compensation fees for subjects participating in clinical research
  
- No national healthy volunteers registry in Denmark

# **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

- 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**

- Specific requirements to publish both positive, negative and inconclusive results of clinical studies in journals or in registries such as ClinicalTrials.gov or EurdraCT.
- No specific requirements to provide devices without CE mark, or used outside intended use for free.
- Specific requirements regarding devices emitting radiation. Approval needs to be granted by the National Institute of Radiation.
- Specific requirements re ICF – but not detailed here.

## J. Specific requirements

- A. Type of research
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- D. Sponsor
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- F. Competent Authority
- G. Ethics Committee
- H. Data Protection
- I. Healthy volunteers/Patients
- J. Specific requirements**

- No specific requirements/regulations regarding archiving of documentation
- Specific requirements regarding blood/tissue samples: Blood banks and centres must be authorised by the Danish Patient Safety Authority.
- No specific requirements for data management of clinical investigations.
- Specific strategies for monitoring of medical device studies are :  
labelling and instructions



## ***J. Specific requirements***

- 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**

- It is not mandatory to register clinical studies in a registry.
- There is no official national register for clinical studies in Denmark.