Regulatory and ethical requirements in medical device studies

Sweden
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
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B. Definitions/Legal basis

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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
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B. Definitions/Legal basis

Definitions in Swedish law

- Definitions exist for studies in Clinical research of:
  - Medical device without CE Mark - alone or combined with medicinal product
  - Medical device with CE mark use outside label - alone or combined with medicinal product
- The following are sources for the definition for clinical research in medical device studies in Sweden:
  - LVFS 2003:11 (93/42/EEC) Annex XV paragraph 2.1
B. Definitions/Legal basis

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Conventions/guideline/laws to apply

• Declaration of Helsinki

These apply for all medical device studies other than observational and registry studies.
**B. Definitions/Legal basis**

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<td>J. Specific requirements</td>
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### Acts to apply

- For all Medical Device studies:
  - Medical device act SFS 1993:584
  - Medical devices ordinance SFS 1993:876
  - Medicinal products act SFS 1992:859

In addition LVFS 2003:11 or LVFS 2001:5 apply for the following types of studies:

- Medical Device with CE mark use outside label – alone or combined with medicinal product,
- Medical device without CE mark – alone or combined with medicinal product
B. Definitions/Legal basis

Acts to apply

- Code of Statutes LVFS are detailed regulations issued by MPA:
  - LVFS 2003: 11 for Medical devices (93/42/EEC)
  - LVFS 2001:5 for Active Implantable Medical Devices (90/385/EEC)
B. Definitions/Legal basis

Acts to apply

- Swedish Radiation Protection Act SFS 1988:220 – only if radiation is involved
- Act on public access to information and secrecy act: SFS 2009: 400
- SOFS 2008:1 Reporting of accidents and near accidents with Medical devices.
- Personal Data Act : SFS 1998:1191
- Personal Data Ordinance: SFS 2008: 355
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**Acts to apply - Re Ethical Review**

- SFS 2003:615 Ethical review act
- SFS 2008:192 changes to the ethical review act
- SFS 2003:615 covers regulations in connection with the ethical review act
- SFS 2007:1069 Instructions for regional ethical review boards.
- SFS 2007: 1068 re central ethical review board.
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• For all the type of medical device studies listed the CI or PI has to hold a patient injury insurance policy. See Patient Injury Act (SFS 1996:799) to cover both patients and healthy volunteers.

• No mandatory compensation sum per participant or per trial is required.
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J. Specific requirements
It is mandatory to have a sponsor in studies where the Medical device has no CE mark or where the Medical device has a CE mark but is being used outside label:

i.e

• 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 outside label
• Medical device combined with medicinal product without CE mark
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J. Specific requirements
• There are no specific requirements/regulations for GCP training of the investigators in Sweden for any of the study types.
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Swedish Competent Authority:

Lakemedelsverket
(In English = Medical Products Agency (MPA) )
Dag Hammarskjolds vag 42 /
P.O Box 26  SE-751 03 Uppsala
Sweden

Website: [www.lakemedelsverket.se](http://www.lakemedelsverket.se)
Email: [registrator@mpa.se](mailto:registrator@mpa.se)
Phone: +46 (0)18174600
Fax: +46 (0) 18548566
**F. Competent Authority**

<table>
<thead>
<tr>
<th>A. Type of research</th>
<th>Approval</th>
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<tbody>
<tr>
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<td>Yes</td>
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<td>C. Insurance</td>
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<tr>
<td>Observational studies with medical device</td>
<td>x</td>
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<tr>
<td>Registries</td>
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</tbody>
</table>
### F. Competent Authority – Initial submission

<table>
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<th>A. Type of research</th>
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</table>

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

- The submission may be done in several ways:
  - Electronically by use of e-service: medical device – e-service for notification of clinical investigation
  - By email (registrator@mpa.se)
  - By DVD/CD or USB
  - By paper.
**F. Competent Authority – Initial submission**

| A. Type of research          | • English documents are accepted, but patient information leaflet has to be in Swedish. |
| B. Definitions/Legal basis  | • Submission fee is 20 000 SEK (approx equivalent to 2157 Euro in Nov 2015) |
| C. Insurance                | • There is a standard application form - see link below: |
| E. Investigators            | |
| F. Competent Authority      | |
| G. Ethics Committee         | |
| H. Data Protection          | |
| I. Healthy volunteers/Patients | |
| J. Specific requirements    | |
F. Competent Authority – Initial submission

- 60 days to obtain approval, counted from date the dossier is complete and valid
- The MPA has 3 working days to validate the dossier after submission
- No deadlines for submission
- The clinical investigator acts as the representative or legal entity in Sweden to submit an application to the Competent Authority
Main documents required for submission:

- Clinical Trial application form
- Clinical Investigation Plan/Protocol
- Informed consent
- Subject Information Leaflet
- Copy of Insurance coverage/ information on insurance protection for subjects
- Copy of ethical review board’s statement and details of aspects looked at (if available)

OR if not yet available:

- a copy of application to ethical review board.
- List of Swedish investigation sites and PIs
- Evidence of competence of CI and Site Pis
- Declaration of conformity with essential requirements.
F. Competent Authority – Initial submission

A. Type of research
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C. Insurance
D. Sponsor
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Documents regularly requested by MPA:
• Intended labelling of Device
• User manual for staff and or test subjects

MPA may ask for various other documents, if applicable, including but not limited to:
• Results of risk assessments
• Design drawings
• CRF
• It is mandatory to declare SADE to the Swedish Competent Authority, for all study types.

• It is mandatory to declare SAEs to the Swedish Competent Authority for
  
  • Medical device with CE mark use outside label- device alone or combined with medicinal product

  • Medical device without CE mark – alone or combined with medicinal product
### F. Competent Authority - Vigilance

Events mandatory to declare to the Competent Authority:

<table>
<thead>
<tr>
<th>Event Description</th>
<th>AE</th>
<th>ADE</th>
<th>SADE</th>
<th>SAE</th>
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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**

- **SAE definition**: definition used in ISO 14155: 2011 (E).
- **Sponsor** is responsible for declaration of AEs to the Competent Authority.
- **No special templates/forms** for declaration of AEs. MEDDEV 2.7/3 form may be used.
- **SAEs must be reported immediately.**
- **The sponsor is responsible** for declaring AEs to the Competent Authorities in the specific countries.
### F. Competent Authority - Vigilance

<table>
<thead>
<tr>
<th>A. Type of research</th>
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<th>J. Specific requirements</th>
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- The sponsor needs to provide an annual safety report to the Swedish Competent Authority for studies involving:
  - Medical device with CE mark use outside label - device alone or combined with medicinal product
  - Medical device without CE mark – alone or combined with medicinal product
F. Competent Authority - Notification

- There is no specific requirement to notify the Competent Authority of first patient enrolled.
There is a specific procedure for submitting a substantial amendment to the Swedish Competent Authority.

The submission of the amendment may be done in several ways (similar to the initial submission):

- Electronically by use of e-service: medical device – e-service for notification of clinical investigation
- By email (registrator@mpa.se)
- By DVD/CD or USB
- By paper.
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Central Ethical Review Board
Centrala Etiksprovningsnamden EPN, c/o Vetenskapsrådet, Box 1035, 10138 Stockholm, Sweden Phone: +46 (0) 8546 77610; Fax: +46 (0) 8 54644 180; email: kansli@cepn.se

6 Independent Regional Ethics Committees:

1. Regionala Etikprövningsnämnden i Göteborg, Box 100, 405 30 Göteborg

2. Regionala etikprövningsnämnden i Linköping, c/o Hälsouniversitetets kansli, Sandbäcksgatan 7, 581 83 Linköping

3. Regionala etikprövningsnämnden i Lund, Box 133, 221 00 LUND

4. Regionala etikprövningsnämnden i Stockholm, FE 289, Karolinska Institutet, 171 77 STOCKHOLM

5. Regionala etikprövningsnämnden i Umeå, Samverkanshuset, Universitetsområdet, 901 87 Umeå

6. Regionala etikprövningsnämnden i Uppsala, Box 1964, 751 49 UPPSALA
### G. Ethics Committee

<table>
<thead>
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<th>Positive opinion required</th>
<th>Yes</th>
<th>No</th>
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G. Ethics Committee – Initial submission

A. Type of research  
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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 the relevant regional Ethics Committee  
- Appeals against regional EC decisions may be submitted to the central EC  
- The submission can be submitted using paper  
- Documents must be in Swedish but the annex for professional experts may be written in English  
- Fee for Initial Submission fee 16000 SEK (approx 1600 Euro). See application form for detailed fees (Annex 2 of 2003: 615)  
- Submission fee for an amendment is 5000 SEK (approx 500 Euro)
In general, 60 days to obtain approval

No deadlines for submissions- can submit any time.

When both Competent Authority approval and Ethics Committee positive opinion are required, it is possible to request the 2 in parallel.

Standard Application form used.

http://www.epn.se/sv/start/ansoekan/
### G. Ethics Committee – Initial submission

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<tr>
<th>A. Type of research</th>
<th>Main documents required for submission:</th>
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<tbody>
<tr>
<td>B. Definitions/Legal basis</td>
<td>• Application Form</td>
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<td>C. Insurance</td>
<td>• Certificate indicating that there are adequate resources available for the study at the trial site, signed by the manager of the clinic.</td>
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<td>D. Sponsor</td>
<td>• No other formal requirements but the application dossier should include:</td>
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<td>E. Investigators</td>
<td>• Proof of payment</td>
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<td>F. Competent Authority</td>
<td>• The protocol</td>
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<td><strong>G. Ethics Committee</strong></td>
<td>• Patient information leaflet</td>
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<td>G. Ethics Committee - Vigilance</td>
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- No obligation to report AEs to the Ethics Committee
- Not mandatory to submit an annual safety report to the relevant EC.
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- No specific procedure for submitting a substantial amendment to the Ethics Committee
- A letter including the content and the reason for the amendment is sufficient.
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**H. Data Protection**

A. Type of research  
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G. Ethics Committee  

**I. Healthy volunteers/Patients**

**J. Specific requirements**

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**Datainspektionen /Swedish Data Protection Board**

Postal Address: Box 8114104 20 Stockholm, Sweden  
http://www.datainspektionen.se/in-english  
Email: datainspektionen@datainspektionen.se  
Tel: + 46 8 6576100  
Fax: +46 8 652 86 52
| A. Type of research | • Processing and treatment of integrity-sensitive personal data (e.g. a genetic study where genetic predisposition is being studied) should be notified to the Swedish Data Inspection board in advance. |
| B. Definitions/Legal basis |
| C. Insurance |
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| G. Ethics Committee |
| **H. Data Protection** |
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### I. Healthy volunteers/Patients

<table>
<thead>
<tr>
<th>A. Type of research</th>
<th>• In Sweden there are specific requirements/regulations for the following specific populations:</th>
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<tbody>
<tr>
<td>B. Definitions/Legal basis</td>
<td>- Children (less than 18 years of age) - LVFS 2003:6 chapter 3 (2) and section 18 2003:460</td>
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<tr>
<td>C. Insurance</td>
<td>- Incapacitated adults –LVFS2003:6 Chapter 3 (2-3) and Section 20-22 2003:460</td>
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<tr>
<td>D. Sponsor</td>
<td>- Emergency situations - LVFS2003:6 Chapter 3 (2-3) and Section 20-22 2003:460</td>
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<tr>
<td>E. Investigators</td>
<td>No specific requirements for pregnant or lactating women</td>
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<td>F. Competent Authority</td>
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I. Healthy volunteers/Patients

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G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

• No mandatory compensation sum defined.

• Healthy volunteers and patients are covered under the Patient Injury Act SFD 1996: 799
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J. Specific requirements
J. Specific requirements

- No Specific requirements to publish both positive and negative results of clinical studies in scientific journals.

- No specific requirements to provide devices without CE mark, or used outside intended use for free.

- Specific requirements regarding devices emitting radiation. Additional approval needs to be granted by the local radiation protection committees – these are based at university hospitals.
J. Specific requirements

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J. Specific requirements

• Specific requirements re Informed Consent: It needs to be voluntary, explicit and specific to the particular research and documented, even if not given in writing. (see Section 16, 17, 19 2003:460)

• Specific requirements/regulations regarding archiving of documentation.
  
  o LVFS 2003:11 (93/42/EEC) - 5 to 15 years
  o LVFS 2001:5 (90/385/EEC), Annex 6 - 15 years
J. Specific requirements

A. Type of research

B. Definitions/Legal basis

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F. Competent Authority

G. Ethics Committee

H. Data Protection

I. Healthy volunteers/Patients

J. Specific requirements

• It is mandatory to register clinical studies in a registry, namely Eudamed

• There is no official national register for clinical studies in Sweden.

• There is no accreditation process for research centres in Sweden.