

Medicinal Products for Human Use - SWITZERLAND

Competent authority

Contact Details

Contact Name 1

Swissmedic - Schweizerisches Heilmittelinstitut / Swiss Agency for Therapeutics products

Contact Name 2

Clinical Trials

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Country

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Web address

<http://www.swissmedic.ch/>

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Competent Authority/-ies (CA)
Ethics committee(s)

CA - Submission for authorisation mandatory for

Clinical trials on Medicinal Products of categories B and C

CA - Registration/ notification without approval required for

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CA - Submission required to

National CA

National trial registry - Registration mandatory

Yes

National trial registry

All clinical trials need to be registered in a national registry (Art. 64-67 KlinV/ClinO).

An official portal is expected to be available by the end of 2015; entries in www.clinicaltrials.gov will continue to remain acceptable in Switzerland.

More information is provided on the kofam website of FOPH.

Email: [kofam\(at\)bag.admin.ch](mailto:kofam(at)bag.admin.ch)

Applicable national legal framework/ Reference

Verordnung über klinische Versuche; KlinV (de)/ Clinical Trials Ordinance; ClinO (en)

Additional Information

Clinical trials of medicinal products are categorised into A, B or C (Art. 19 KlinV/OClin).

Category A trials are exempt from submission obligation (Art. 30 KlinV/ClinO).

NB! ! NB: Special submission requirements apply to clinical trials on:

(1) Gene therapy/ GMO clinical trials: Additional application documents for Category B and C clinical trials of gene therapy and of genetically modified or pathogenic organisms are required and provided in Annex 4(4) KlinV/ClinO. Further respective guidelines, checklists and standard forms are provided on the Swissmedics website in section: Licenses > Clinical trials > Clinical trials on transplant products / gene therapy / genetically modified organisms.

Enter Link: "Swissedic_Clinical trials on transplant products / gene therapy / GMOS"

<https://www.swissmedic.ch/bewilligungen/00155/00242/00328/index.html?lang=en>

(2) Radioactive substances, with regard to radiological protection for trial participants: The sponsor must submit the trial to the CA, the EC and, in addition, to the Radiological Protection Division of the Federal Office of Public Health (FOPH).

Link: "FOPH": <http://www.bag.admin.ch/themen/strahlung/index.html?lang=en>

Additional application documents for clinical trials of therapeutic products capable of emitting ionising radiation are required and provided in Annex 4(5) KlinV/ClinO.

(3) Combination trials on IMP(s) and transplant products (organs, tissues, cells) must also be additionally submitted to the BAG. Details for submission can be found on their website.

(Link: "BAG": <http://www.bag.admin.ch/>)

Submission of Application

Responsible for study submission

Sponsor

Legal representative domiciled in the EU/EEA

Entitled to study submission

—

Prerequisites for submission

—

Guidance on submission of application

"Clinical Trial Application dossier Guideline"

(available on Swissmedic website in section: Home > Licensing > Clinical trials > Clinical trials on medicinal products > Clinical Trial Application

Additional Information

NB! Combined trials (medical device & IMP) must be reviewed by Swissmedic as IMP/transplant product trials and also as MD trials. The requirements for both trials must be met and two separate dossiers (full documentation as well as the complete application form, including electronic copy) must be submitted to the corresponding department of the CA.

The explicit submission procedure depends on the licensing status of both the IMP and MD and is specified in the "Information Sheet FAQ" (Q&A related to clinical trials with medicinal products), published on the Swissmedic website in section: Home > Licensing > Clinical trials > Clinical trials on medicinal products > Q&A and important links (Link:

<https://www.swissmedic.ch/bewilligungen/00155/00242/00327/00347/index.html?lang=en>)

Submission Format	<p>Format option(s)</p> <p>One copy of each document (A4) in a ring binder (colour indicated on Swissmedic homepage) + one electronic copy on a CD-ROM.</p> <p>Preferred format</p> <p>—</p> <p>Standard application form</p> <p>“Clinical Trial Application Form (CTA Form)” for clinical trials with IMP and ATMP (transplant products, gene therapy products, genetically modified organisms/GMO)</p> <p>Standard application form - Additional information</p> <p>The required documentation described in the Clinical Trial Application Dossier Guideline must be accompanied by the completed and signed Standard application form. This standard form is available in ‘Forms and Checklists’ on the Swissmedic website in section: Home > Licensing > Clinical trials Clinical trials on medicinal products > Clinical Trial Application.</p> <p>Use of standard application form binding</p> <p>Yes</p> <p>Guidance on submission format</p> <p>“Clinical Trial Application Dossier Guideline”</p>
Language of Submission	<p>Language(s) of application</p> <p>French German Italian English</p> <p>Preferred language of application</p> <p>—</p> <p>English accepted</p> <p>Partly, not for all documents</p> <p>Documents mandatory to be in official national language</p> <p>—</p>
Submission Fees	<p>Fees for trial submission mandatory</p> <p>Yes</p> <p>Fees</p> <p>Evaluation of Clinical Trials: New Notification of clinical drug trial- new application: 1000.- CHF Additional work for evaluation of answers after first review: 200.- CHF/ hour. Notification of clinical trials with transplants: 1000.- CHF Approval of ATMP clinical trials: 5000.- CHF Approval of clinical trials on gene therapy with transplants containing GMOs: 2000.- CHF Evaluation of Amendments of Clinical trials with IMP, and other additional submissions: 200.- CHF/ hour ATMP: 1000.- CHF somatic gene therapy with transplants containing GMO: 5000.- transplants: 200.- CHF Response to extensive inquiries (not related to a submitted or approved study): 200.- CHF</p>

Waiver for academic (non-commercial) studies possible

No

Official guidance on required fees

Fees are provided on Swissmedic website in section: Home > Licensing Clinical trials > Clinical trials on medicinal products > Clinical Trial Application.

Applicable national legal framework/ Reference

Heilmittel-Gebührenverordnung, HGebV (Ordinance on Fees levied by the Swiss Agency for Therapeutic Products), Appendix 5, version dated 01.01.2013. The document and external website are only available in German, French or Italian.

Timelines
Authorisation

General timespan (max nr days)

30

Mode of approval (General)

—

ATMP/GMO trials (max nr days)

60

Mode of approval (ATMP/GMO trials)

—

External expert advice required (max nr days)

—

Xenogeneic cell therapy (max nr days)

—

Mode of approval (Xenogeneic cell therapy)

—

Clock-stop possible if complementary information requested

Yes

Timespan counted from

Confirmation of formal completeness

Applicable national legal framework/ Reference

Art. 33-36 KlinV/ClinO

Additional Information

Initial application: The CA shall notify the sponsor of receipt of application or of any formal deficiencies within 7 days.

If the therapeutic product is to be used in persons for the first time ("first-in-man") or manufactured using a new procedure: extension by a maximum of 30 days possible.

Trial applications with products capable of emitting ionising radiation or radiation sources: 60 calendar days (Art. 36(4) KlinV/ClinO)

Amendments/
Substantial
Amendments (SA)

Notification mandatory for

—

Authorisation mandatory for

All clinical trials requiring authorisation by CA

Responsible for submission of SA

Sponsor

Legal representative domiciled in the respective country

Timeline for approval of SA (max nr days)

30

Additional Information

The Agency informs the responsible EC and other competent cantonal authorities of its decision.

Other amendments must be declared to the CA, but do not require explicit approval by the CA.

Cave: Some of them require explicit approval by the EC according to Art. 29 KlinV/ClinO.

Safety Reporting

Responsible for AE reporting to CA

Sponsor

Legal representative domiciled in the respective country

Sponsor must declare reportable events to

—

Reportable AEs

Only SUSARs observed at Swiss trial centres

SUSAR being life-threatening or leading to death must be reported

Within 7 days for SUSARs resulting in death

All other SUSARs

Within a max of 15d upon first knowledge

SAE /SADE must be reported

—

National standard reporting form available

No, European standard SUSAR reporting form CIOMS-I recommended

Standard Reporting Form

CIOMS form, always together with the accompanying form for SUSARs

Reporting format - Options

—

Preferred format

In electronic form (not by fax!)

Provision of Annual safety report mandatory

Yes

Annual safety report shall be provided by sponsor to

National CA (for Cat B and C trials)

Guidance on AE reporting procedure

Further information, instruction and standard reporting forms available on the Swissmedic website in the section: Licenses > Clinical trials on medicinal products > Safety measures in clinical trials.

Applicable national legal framework/ Reference

Art. 40, 41 & 43 KlinV/ClinO

Additional Information

Address for SUSAR notification: SUSAR(at)swissmedic.ch

!NB: Specific AE reporting requirements apply to clinical trials with Transplant Products, Gene Therapy and GMO:
All fatal cases, SUSARs and SADRs from Switzerland and abroad must be reported to the CA by the sponsor. SUSARs being life-threatening or leading to death: within 7 days; SADRs and other events requiring notification: within 15 days.
Further details and standard reporting forms are provided on the Swissmedic website: Licenses > Clinical trials on gene therapy/GMO)

Investigator shall report SAE to

Sponsor

Reporting timeline

Immediately (without delay)

End of Trial

End of trial declaration mandatory for

All clinical investigations requiring authorisation by CA

Responsible for End of trial declaration

Sponsor

Legal representative domiciled in the respective country

Regular Termination - Declaration timespan (max nr days)

90

Timespan counted from

—

Early/premature Termination - Declaration timespan (max nr days)

15

Applicable national legal framework/ Reference

Art 37-38 KlinV/ClinO

Additional Information

Premature interruption of a Cat A trial for safety reasons must be reported to the EC within 7 days.

A fundamental definition for the end of the trial should be explicitly mentioned in the trial protocol. It is usually the date of the final visit by the final trial participant: LPLV (last patient, last visit).

Additional Information
& Specifics

Additional Information

Useful information for sponsors, investigators or research institutions conducting clinical trials with medicinal products in Switzerland is available in German, French, Italian and English on the Swissmedic website in section: Licences > Clinical trials > Clinical trials on medicinal products (e.g. Information Sheet FAQ, etc.)

Contact Details	<p>Contact Name 1</p> <p>Swissethics- Schweizerische Ethikkommissionen für die Forschung am Menschen / Swiss Association of Ethics Committees for research on humans</p> <p>Contact Name 2</p> <p>Geschäftsstelle Swissethics/AGEK (Arbeitsgemeinschaft der Schweizer Ethikkommissionen)</p> <p>Phone</p> <p>041 440 26 67</p> <p>Address</p> <p>Haus der Akademien - Laupenstrasse 7</p> <p>ZIP/City</p> <p>3008 Bern</p> <p>Country</p> <p>Switzerland (CH)</p> <p>E-Mail</p> <p>info@swissethics.ch</p> <p>Web address</p> <p>http://www.swissethics.ch/</p> <p>Additional Information</p> <p>The Swiss Ethics Committees on research involving humans have formed a joint working group (swissethics). Swissethics is organised as an association, its members are all the recognised regional/cantonal ethics committees of Switzerland.</p>
Ethical Review – General	<p>Submission for Ethical review mandatory for</p> <p>—</p> <p>Submission to CA and EC to be performed in the following order</p> <p>—</p> <p>Additional Information</p> <p>A positive vote from the EC is mandatory for all clinical projects. Some of the recognized Cantonal ECs are competent for several cantons. The competent Cantonal EC can act as local EC in a single-centre trial or as lead EC in a multi-centre trial.</p> <p>Regulatory and ethics bodies involved in approval process</p> <p>Competent Authority/-ies (CA) Ethics committee(s)</p>
Single-Centre Studies - Ethical Review	<p>Ethical approval (favourable opinion) to be obtained from</p> <p>Cantonal EC being competent for the respective trial site</p> <p>Additional Information</p> <p>The study dossier shall be submitted to the responsible Cantonal EC according to Art. 24 KlinV/ClinO. The area of competence of the Cantonal ECs (EC can be competent for more than one Canton) are provided on the Swissethics website.</p>
Multi-Centre Studies - Ethical Review	<p>Ethical approval (favourable opinion) required from</p> <p>Lead EC (authorised to issue a single opinion)</p>

Submission of application required to

Lead EC + All concerned local ECs for site-specific assessment

Additional Information

In multi-centre studies, the coordinating investigator or the sponsor submits the study dossier to the lead ethics committee (responsible ethics committee of the canton at the site of activity of the project coordinator (HRA Art. 47)). The lead EC checks formal completeness and informs applicant. Applicant submits clinical trial dossier to all local Cantonal ECs responsible at other trial sites. The cantonal ECs evaluate local items only (e.g. adequate qualification of the investigator, infrastructural requirements, acceptance by the local community) and inform the lead EC on their decision.

The lead ECs review the complete documentation, issues its final reasoned opinion on the clinical trial application and communicates its decision to the applicant, the local ECs concerned and to the CA (in case of Cat B and C trials). The local ECs can accept or refuse this decision or eventually add locally determined minor supplements.

Additional trial sites must be submitted to the local EC(s). (Art. 27 KlinV/ClinO).

Submission of Application

Responsible for study submission

Sponsor

Entitled to study submission

Sponsor
Coordinating Investigator

Prerequisites for submission / approval

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Guidance on study submission

Further details on submission procedure and use of the web portal (BASEC) are provided under "Submission Format".

Additional Information

The applicant (Sponsor or Coordinator) will be the primary contact person for further communication.

!NB: Specific submission requirements apply to clinical trials involving radiation sources pursuant to Art. 28 KlinV/ClinO:

Additional documents as specified in Annex 3 (5) KlinV/ClinO have to be submitted to the EC by the investigator.

The FOPH shall deliver an opinion on compliance with radiological protection legislation and on the dose estimation which have to be considered by the EC granting authorisation.

Submission Format

Format option(s)

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Preferred format

BASEC (web portal): Mandatory from 1st of January 2016

Online portal

BASEC (Business Administration System for Ethics Committees):

Starting from November 2nd 2015 all new projects should be submitted through the web-portal. As of January 1st 2016 the online-submission is mandatory and replaces all former submission methods (paper, CD, other storage devices).

Please use these former submission methods for amendments and additions to old projects until December 31 2015; from January 1st 2016 the web-portal will also be compulsory for old projects.

NB: Registration is required to use the web portal. Explanations and links are provided to guide the applicant through the process. Required application documents is automatically determined by BASEC based on the information provided by applicant.

	<p>Standard application form available</p> <p>Yes</p> <p>Standard application form</p> <p>The standard form ("Basisformular") and checklist formerly used for submission to the competent EC(s) has been replaced by the BASEC "Research application form" (as of January 1st 2016).</p> <p>Use of standard application form binding</p> <p>Yes</p> <p>Guidance on submission format available</p> <p>Yes</p> <p>Guidance on submission format</p> <p>Guidance on use of the BASEC web portal (FAQ BASEC Introduction) is published on the Swissethics website.</p>
Language of Submission	<p>Language(s) of application</p> <p>Regional language(s) English</p> <p>Preferred language of application</p> <p>—</p> <p>English accepted</p> <p>Partly, not for all documents</p> <p>Documents mandatory to be in official national language</p> <p>—</p> <p>Additional Information</p> <p>Regional languages in Switzerland: German, French and Italian.</p>
Submission Fees	<p>Fees for Ethical review mandatory</p> <p>Yes</p> <p>Waiver for academic (non-commercial) studies possible</p> <p>Yes</p> <p>Fees for Ethical review</p> <p>The fees charged by the EC for trial evaluation depend on the Cantonal EC concerned and the study type: e.g. Lead EC review for industry sponsored projects: up to CHF 7,000 EC review for mono-centre, industry sponsored projects: up to CHF 6,000 Simplified procedure for Cat A trials: CHF 500, up to 5000 (for industry sponsored projects) Amendments: CHF 200-3000 Non-commercial projects that are only sponsored by the investigator or by non-profit organisations: reduction or waiver is possible.</p> <p>Additional Information</p> <p>Each Swiss Canton regulates financing of its competent EC and, therefore, determines its separate charging rates, resulting in wider variations (Art 54 (5) HRA). The particular fees can be found on the websites of the respective ECs.</p>
Timelines Ethical Review	<p>General timespan for single-centre studies (max nr days)</p> <p>30</p>

General timespan for multi-centre studies (max nr days)

45

ATMP/GMO trials (max nr days)

—

External expert advice required: Timespan (max nr days)

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Xenogeneic cell therapy: Timespan (max nr days)

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Clock-stop possible if complementary information requested

Yes

Timespan counted from

Confirmation of formal completeness

Additional Information

The lead EC / local EC shall acknowledge receipt of the application within 7 days and notify the applicant (the (coordinating) investigator or sponsor) of any formal deficiencies. 1. Single-centre studies: Local EC informs applicant on its final decision (plus the CA in case of Cat B and C clinical trials). 2. Multi-centre studies: the local ECs shall reach a decision on the trial sites within 15 days upon receipt of the application documents and communicate them to the lead EC. Lead EC informs applicant on its final decision (plus concerned local ECs in case of multi-centre trials as well as the CA in case of Cat B and C clinical trials). 3. Trials involving radiation sources: Local EC shall issue a reasoned opinion within 45 calendar days of acknowledgement of receipt of the formally correct application dossier; local EC shall inform the FOPH of its decision.

Amendments/
Substantial
Amendments (SA)

Ethical review mandatory for

Any substantial amendments

Responsible for notification of SA

Investigator

Standard notification form available

Yes

Standard notification form

Submission via the web portal BASEC

Timeline Ethical review of SA (max nr days)

30 (local EC) + 45 (lead EC)

Guidance on submission of SA

Detailed Guidance to the use of the new web portal BASEC is available on the website of Swissethics.

Please use these former submission methods for amendments and additions to old projects until December 31 2015; from January 1st 2016 the web-portal will also be compulsory for running projects (a submission form will be available inside the web-portal for these projects).

Applicable national legal framework/ Reference

Art. 29 KlinV/ClinO

Additional Information

CAVE: The definition of substantial amendments for ECs is different to the definition for CA!

Other changes must be notified to the EC in the annual safety report.

Safety Reporting

Reportable AEs

SAE + SUSAR occurring at a Swiss trial centre

Investigator shall report SAE to

Sponsor

Reporting timeline

Immediately (without delay)

Responsible for AE reporting to relevant EC(s)

Principal Investigator
Investigator

SUSAR being life-threatening or leading to death must be reported

Within a max of 7d upon first knowledge

All other SUSAR must be reported

Within a max of 15d upon first knowledge

SAE/SADE must be reported

—

National Standard Reporting form available

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Reporting format - Options

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Preferred reporting format

Online portal
BASEC (web portal): mandatory as of January 1st 2016.

Online Safety Reporting Portal

Starting from November 2nd 2015 all new projects should be submitted through the web-portal. As of January 1st 2016 the online-submission is mandatory for new and old projects and replaces all former submission methods.

Provision of Annual safety report mandatory

Yes

Guidance on AE reporting procedure available

Yes

Guidance on AE reporting procedure

Guidance is provided within the web portal BASEC (Registration required)

Applicable national legal framework/ Reference

Art 40, 41, 43 KlinV/ClinO

End of Trial

End of trial Declaration mandatory

Yes

Responsible for End of trial Declaration

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Regular Termination - Declaration timespan (max nr days)

90

Timespan counted from

—

Early/premature Termination - Declaration timespan (max nr days)

7 (interruption for safety reasons) / 15 (for other reasons)

Reasons for early termination shall be clearly stated

Yes

Guidance on End of trial declaration

A standard trial termination form to be used for declaration to the EC is available on the Swissethics website in section: Templates.

Applicable national legal framework/ Reference

Art. 37 + 38 KlinV/ClinO

Additional Information

A fundamental definition for the end of the trial should be explicitly mentioned in the trial protocol. It is usually the date of the final visit by the final trial participant: LPLV (last patient, last visit).

Multi-centre trials: In case of an interruption or premature termination at one of the trial site, the coordinating investigator informs the responsible EC concerned.

Additional Information & Specifics**Additional Information**

(1) Templates for EC:

The use of the templates and standard forms provided on the Swissethics website in section Templates is binding for both applicants and ECs!

(2) Since 1.1.2014, it is the AGEK's responsibility (used to be Swissmedic's) to validate GCP courses and to assess the required qualification of the Principal Investigator.

A "List of recognized GCP course providers" is available on the Swissethics website in section: Aus-, Fortbildung.

Study specific Requirements**Study Participants - Informed Consent (IC)****Standard ICF - Additional Information**

A detailed guidance for the preparation of appropriate written patient information material and Informed Consent Forms are provided on the Swissethics website in section Templates > Study information and Informed Consent for Research Projects in Humans (HRA 7,16).

Informed Consent - Definition/ Requirements

Informed consent of study participants must be obtained in writing before (exemptions possible) the commencement of a clinical trial. The persons concerned must receive comprehensible oral and written information on the nature, purpose, duration, procedures, foreseeable risks, burdens and expected benefits of the research project as well as the measures taken to protect the personal data collected and their rights. The trial participants must be given an appropriate reflection period .

Applicable national legal framework/ Reference

Art 16 -18 HRA; Art 7-9 KlinV/ClinO

Additional Information

Specific provisions apply to vulnerable groups of persons (Art 11 and 21-31 HRA; and 15-17 KlinV/ClinO) as well as for research on imprisoned persons (Art 28-29 HRA).

Study Participants - Vulnerable Population**Minors / Children - Studies allowed**

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Specific provision

Studies with minors (children and adolescents < age of 18) are possible under special provisions (Art 11, 21-23 HRA).

Legal framework/Reference (Minors/Children)

Art 11, 21-23 HRA

A detailed guidance for research with minors, a related checklist and template for Informed Consent Form are provided on the Swissethics website in section Templates > Research with Children.

An interesting opinion on research involving children has been published by the Swiss National Advisory Commission on Biomedical Ethics NEC-CNE – Zur Forschung mit Kindern, Nr. 16/2009 (English: NEC-CNE - Research involving children (en), Nr. 16/2009).

Incapacitated persons - Studies allowed

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Emergency situations - Studies allowed

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Emergency situation without prior consent of patient or proxy - Studies allowed

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Pregnant or breastfeeding women - Studies allowed

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Additional Information

ADDITIONAL PAEDIATRIC INFORMATION

LEGAL AGE OF CONSENT:

18 Years (legal age)

14 Years for studies with minimal risks

MANDATORY / SUGGESTED AGE RANGES DEFINED FOR ASSENT:

Oral information for children up to 10 years of age

11 to 14 Years: beside oral information, written information according to the age is mandatory

14-18 Years: same information as adults, but not in informal form of address

Specifications regarding assent: On the consent form parent and investigator have to declare that the minor has been informed and consents or did not disapprove. After 14 years of age the patient consents with signature together with parent/legal representative.

NUMBER OF REQUIRED SIGNATORIES:

One parent or legal representative

OFFICIAL LANGUAGE OF INFORMED CONSENT:

German, French, Italian

INFORMATION ON MATERIAL USED TO DESCRIBE THE CLINICAL TRIAL TO THE MINOR:

11 to 14 Years: beside oral information written information according to the age is mandatory

14-18 Years: same information as adults, but not in informal form of address

ADDITIONAL INFORMATION (INCLUDING REFERENCE FOR TEMPLATE):

- Reference legislation:

- o Human Research Act Art. 3 lit j,k, Art. 7, 16, 21, Art. 22-23, Art. 31 (3), Art. 32-34

- o Ordinance on Clinical Trials ClinO: Art. 7-8, Art.15b, Art. 19-25, Art. 30

- o Ordinance on Research in Humans HRO: Art. 7, 8, 9, 13

- IC template(s) / guidelines / information sources

<https://www.swissethics.ch/templates.html>

SOURCE(S):

- Human Research Act: <https://www.admin.ch/opc/en/classified-compilation/20061313/index.html>

- ClinO: <https://www.admin.ch/opc/en/classified-compilation/20121176/index.html>

- HRO: <https://www.admin.ch/opc/en/classified-compilation/20121177/index.html>

Data Protection

Notification to DP Authority/ Ombudsmann is mandatory

No

Approval/ authorisation required

Not specified

Specific notification timelines before operations start

—

Language of notification

—

Notification format

—

Data Protection Authority/ Agency - Contact Details

Federal Data Protection and Information Commissioner - FDPIC

Web address

<http://www.edoeb.admin.ch>

	<p>Additional Information</p> <p>Data protection is safeguarded by the Federal Act on Data Protection (Bundesgesetz über den Datenschutz- DSG; SR 235.1). Clinical trial related Data Protection issues are explicitly covered in Art. 57-61 HRA and Art 17-18 KlinV/ClinO.</p> <p>Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)</p> <p>—</p>
Insurance	<p>Liability insurance or alternative arrangements for damages mandatory for</p> <p>Investigator(s) Study participants</p> <p>Responsible for covering insurance</p> <p>Sponsor</p> <p>Insurance fee: A minimum coverage sum is defined</p> <p>Yes</p> <p>Minimum coverage sum</p> <p>The defined policy values for liability coverage are at least: Cat A trials: Entire trial: CHF 3 000 000.- Per person: CHF 250 000.- All other clinical trials: Entire trial: CHF 10 000 000.- Per person: CHF 1 000 000.-</p> <p>Applicable national legal framework/ Reference</p> <p>19 (1) HRA; Art 13, Annex 2 and 14 KlinV/ClinO</p> <p>Additional Information</p> <p>The liability coverage must cover damage occurring up to ten years after the completion of the clinical trial (extension of this period is attributable to the use of ionising radiation and GMOs (Art. 11 KlinV/ClinO).</p> <p>Exemptions from liability coverage requirements in relation to clinical trials are attributable in special cases such as low- risk Cat A trials, pursuant to Art.12 KlinV/ClinO. The insurance certificate needs to be sent to the EC. The General Insurance Conditions (GIC) and a master Certificate of Insurance is provided on the Swissethics website in section Templates > Insurance.</p>
Archiving & Data Management	<p>Study documents must be kept at least (in years)</p> <p>10</p> <p>Applicable national legal framework/ Reference</p> <p>Art. 45 KlinV/ClinO;</p> <p>Additional Information</p> <p>Clinical trials with transplant products and blood products: at least 20 years (according to Art 40(1) TPA)</p>
National legislation	
General Information: Applicable Legislation & Conventions	<p>Official website providing relevant national legislation available</p> <p>Yes</p>

	<p>Official governmental legal database available</p> <p>Yes</p> <p>Additional Information</p> <p>Further regulatory information is provided by Swissmedic and Swissethics. Swiss legislation is available on the website on the Bundesamt für Gesundheit BAG (Federal Office of Public Health FOPH).</p>
Clinical Trials on IMPs in Humans	<p>Applicable national regulations</p> <p>General Act(s) on Medical/Clinical Research in Humans National Act on Medicinal Products Other</p> <p>Transposition of (CT) Directive 2001/20/EC (or comparable national legal framework)</p> <p>Heilmittelgesetz (HMG), Bundesgesetz über Arzneimittel und Medizinprodukte, SR 812.21 (2000)/ Therapeutic Products Act (TPA), Federal Act on Medicinal Products and Medical Devices (en, non-official translation)</p> <p>Applicable to ATMP/ GMO trials</p> <p>Yes</p> <p>Transposition of (GCP) Directive 2005/28/EC</p> <p>—</p> <p>General legislation on Medical/ Clinical Research in Humans</p> <p>Humanforschungsgesetz (HFG), Bundesgesetz über die Forschung am Menschen, SR 810.30 (2011)/ Human Research Act (HRA), Federal Act on Research involving Human Beings (en, non-official translation)</p> <p>Other applicable regulations/ implementing provisions (Acts, laws, decrees, ordinances, circulars, etc)</p> <p>The Federal Council has approved three ordinances on the law on research involving humans, effective as from 01.01.2014: Verordnung über klinische Versuche (KlinV), Verordnung über klinische Versuche in der Humanforschung, SR 810.305 (2013)/ Clinical Trials Ordinance; ClinO (NB: en, non-official translation) NB: KlinV/ClinO is also applicable to Gene Therapy trials; however, it does not consider clinical trials on vital organs, tissues or cells of human or animal origin including ex-vivo gene therapy! Organisationsverordnung HFG (OV- HFG); Organisationsverordnung zum Humanforschungsgesetz; SR 810.308 (2013)/ HRA Organisation Ordinance (OrgO-HRA) (en, non-official translation) Humanforschungsverordnung (HFV); SR 810.301 (2013)/Human Research Ordinance (HRO) (NB: en, non-official translation)</p>
Radiation & Radiotherapy	<p>Use of radiation or radioactive compounds - Specific requirements</p> <p>Yes</p> <p>Applicable legal framework</p> <p>Strahlenschutzgesetz (StSG); SR 814.50 (2007)/ Radiological Protection Act (RPA) (NB: en, non-official translation) Strahlenschutzverordnung (StSV), SR 814.501 (1994, as amended) / Radiological Protection Ordinance (RPO) (en, non-official translation)</p> <p>Additional Information</p> <p>Applicable to trials with radioactive substances (in addition)!</p>
Gene Therapy	<p>Specific requirements</p> <p>Yes</p>

Applicable legal framework

- (1) Heilmittelgesetz (HMG)/Therapeutic Products Act (TPA) (see also the non-official English translation - status 2014: HMG - Therapeutic Products Act (TPA), English version) and
- (2) Humanforschungsgesetz (HFG)/Human Research Act (HRA) (see also the non-official English translation - status 2014: HFG - Human Research Act (HRA)
- (3) Verordnung über klinische Versuche (KlinV)/Clinical Trials Ordinance (ClinO) (see also the non-official English translation status 2014: KlinV - Clinical Trials Ordinance (ClinO)
- (4) Arzneimittelbewillungsverordnung (ABMV)

Due to the fact that gene therapy medicinal products are covered by the Heilmittelgesetz and the Clinical Trials Ordinance (ClinO) the legal procedure is generally the same as for medicinal products for human use. Exceptions and peculiarities for gene therapy to be found in Art 35 and Annexes 3 & 4 KlinV/ClinO.

(5) As a matter of principle Good Manufacturing Practice (GMP) is required for the manufacture of medicinal products for human use. The EC-GMP-Guideline covers this issue.

Additional Information

Further information is available on the Swissmedic website in section "swissmedic - Clinical trials/Clinical trials on transplant products/ gene therapy/ genetically modified organisms " (e.g. checklist for gene therapy and application form).

Data Protection

Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)

National Data Protection Act

National DP act

Federal Act on Data Protection (FADP)/ Bundesgesetz über den Datenschutz (DSG)

Other applicable regulations (covering DP related issues)

Art. 57-61 HRA and Art 17-18 KlinV/ClinO

Additional Information & Specifics

Additional Information

In accordance with Art. 49 of the Federal Health Insurance Act, the research costs in the framework of clinical trials are not borne by health insurance schemes. The costs of the test and comparator products (IMPs) and all other trial-related examinations must therefore be borne by the sponsor.

Definition

IMP/IMP Study

IMP - Definition available in national law

Yes

IMP - Definition

"Medicinal products" according to Art. 4 (1a) TPA:

"...products of chemical or biological origin which are intended to have or are presented as having a medicinal effect on the human or animal organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and handicaps; blood and blood products are also considered to be medicinal products."

In order to classify a "medicinal product" as an "investigational medicinal product" a sponsor must consider both its intended use: a pharmaceutical form of an active substance as test or reference standard, active comparator or placebo, & the objectives of the clinical trial such as: to discover or verify: (a) its clinical, pharmacological and/or other pharmacodynamic effects or (b) to identify any adverse reactions associated with its use or (c) to study its absorption, distribution, metabolism and excretion; with the objective of ascertaining its safety or efficacy,

IMP Study - Definition available in national law

Yes

IMP Study - Definition

The definition of a "clinical trial" is provided in Art. 3 HRA.

Clinical trial categories with a medicinal product pursuant to Art.19 KlinV/ClinO as of 01-01-2014:

Cat. A: Trials with medicinal products authorised in Switzerland, used according to the SmPC (Summary of Product Characteristics: indication, dose, population, etc.)

Cat. B: Trials with medicinal products authorised in Switzerland, not used according to the SmPC.

Cat. C: Trials with medicinal products not authorised in Switzerland.

Additional Information

Definitions for clinical trials with transplant products and ATMP are provided in Art. 21 and 22 KlinV/ClinO.

The website of KOFAM (Koordinationsstelle Forschung am Menschen) provides a tool for assessing the category of a trial. The EC (not Swissmedic!) are responsible to check if the category is correct.