BASEC Submission Guide for Clinical Trials with Medical Devices

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DOCUMENT APPROVAL

Approver	Title	Approval Date
Ellefsen-Lavoie Kim	Chief of Sponsor research	26/05/2021

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DOCUMENT REVISION

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BASEC Submission Guide for Clinical Trials with Medical Devices

1. PURPOSE

The purpose of this document is to provide a step-by-step guide to submit a clinical trial with medical devices to the Ethics Committee of Canton Vaud (CER-VD) using the official BASEC portal.

The objective is to promote throughout the CHUV a uniform and consistent way to enter the required information and provide a reference document to the personnel in charge of these submissions.

2. SCOPE

The current work instruction applies to all CHUV personnel who submits a clinical trial with medical devices to the Ethics Committee of Canton Vaud (CER-VD) using the official BASEC portal.

3. RESPONSIBILITIES

All CHUV personnel covered by the above scope is responsible for understanding and following this work instruction.

4. DEFINITIONS

BASEC. Acronym for **B**usiness **A**dministration **S**ystem for **E**thics **C**ommittees; it is the portal for the submission to the regional/cantonal Ethics Committees in Switzerland: research projects, including clinical trials, research involving persons but not clinical trials, further use of health-related personal data and/or biological material etc, amendments, notification of safety events, clarification of responsibilities, requests for temporary authorizations, general questions, etc.
CER-VD. Acronym for « Commission cantonale d'éthique de la recherche sur l'être humain du Canton de Vaud »
IRB/IEC. Institutional Review Board/Independent Ethics Committee.
swissethics. The Swiss association of Research Ethics Committees focusing on the harmonisation and coordination of working procedures of the Ethics Committees and the promotion of high ethical research standards in Switzerland.

5. MATERIALS

Not Applicable

6. EQUIPMENTS

Not Applicable

7. PRECAUTIONS

Not Applicable

8. REFERENCES

Human Research Act, HRA (in French, « Loi relative à la recherche sur l'être humain », LRH)
« Ordonnance sur les essais cliniques de dispositifs médicaux », OClin-Dim.

9. RELATED QUALITY DOCUMENT(S)

Not Applicable

10. INSTRUCTIONS

All clinical trials with medical devices (from now on also "trials" or "studies") covered under the definitions provided in the « Ordonnance sur les essais cliniques de dispositifs médicaux », OClin-Dim, must be submitted for review to the competent cantonal Ethics Committee (the CER-VD for Canton Vaud) through the BASEC portal of swissethics.
In case of doubts while answering the questions of the BASEC portal, do not hesitate to contact the CER-VD at scientifique.cer@vd.ch or the SRO/BPR at bpr@chuv.ch so that your answers are more clear, complete and accurate as possible.

Important: The trials conducted with the aim to obtain a degree (master or other) must be submitted in BASEC by the thesis supervisor.

Important: Please use only professional email addresses in your submission dossier (e.g. @chuv.ch) ; do not use personal ones (e.g. @gmail.com or similar)

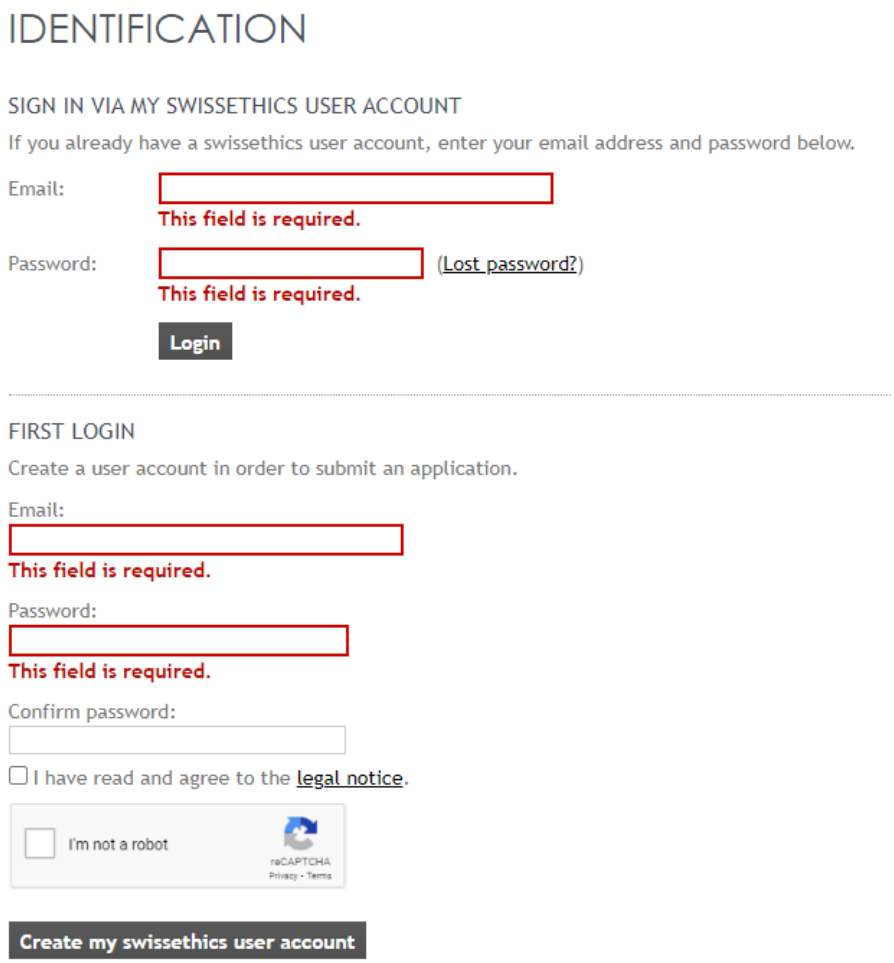
Please be aware that the dossier of the **trial must be reviewed by the CHUV Sponsor Research Office** (SRO), (Bureau du Promoteur de Recherche, BPR) before submission to the Ethics Committee. Instructions on how to do so are provided at steps **60. ("other contact information") and 70. ("contributor")** of this document.

To start please follow these steps:

1. Visit the BASEC portal at the following address: https://submissions.swissethics.ch/en/

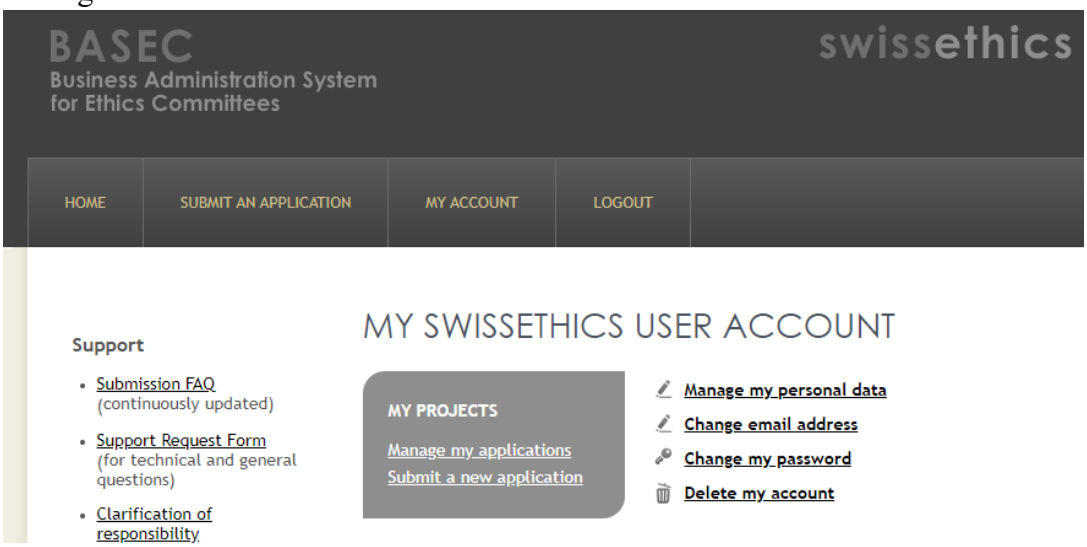
2. Click on the Login button on the home page:

3. Enter your login credentials or create a user account as indicated, in order to start the submission process. All personnel in charge of submitting the application can create a BASEC account.

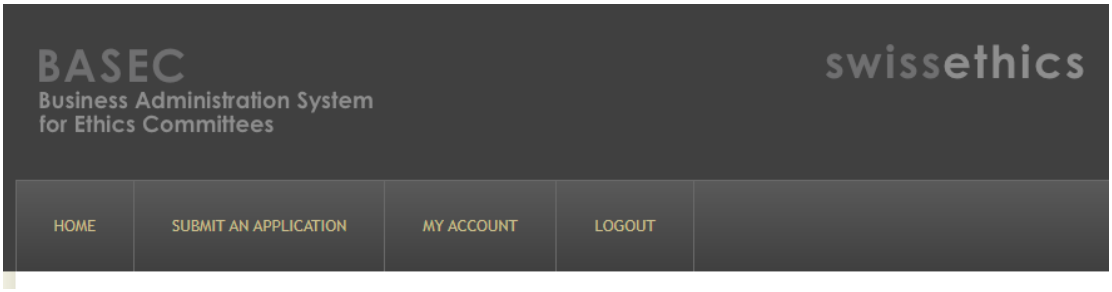


Please use only your professional email address (e.g. @chuv.ch) when creating a BASEC account. Do not use personal email addresses.

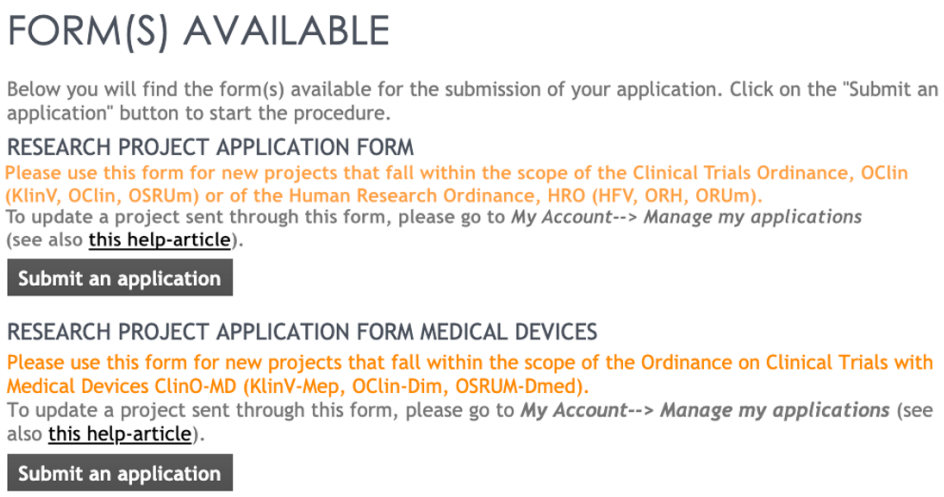
NOTE: If you already have an account with your personnel email address, please update it a with your professional email address, to be used for all new submissions onwards. You can update it by accessing to the "my account" page and choosing "change email address":



4. Once logged in, click on "submit an application", on the top of the page:



5. The subsequent page provides you with multiple submission options, depending on the type of document/information you need to submit.
   For new submissions of clinical trials with medical devices, refer to the second option "research project application form medical devices" and click on the button "submit an application":



FORM(S) AVAILABLE

Below you will find the form(s) available for the submission of your application. Click on the "Submit an application" button to start the procedure.

RESEARCH PROJECT APPLICATION FORM

Please use this form for new projects that fall within the scope of the Clinical Trials Ordinance, OClin (KlinV, OClin, OSRUm) or of the Human Research Ordinance, HRO (HFV, ORH, ORUm).
To update a project sent through this form, please go to *My Account--> Manage my applications* (see also this help-article).

Submit an application

RESEARCH PROJECT APPLICATION FORM MEDICAL DEVICES

Please use this form for new projects that fall within the scope of the Ordinance on Clinical Trials with Medical Devices ClinO-MD (KlinV-Mep, OClin-Dim, OSRUM-Dmed).
To update a project sent through this form, please go to *My Account--> Manage my applications* (see also this help-article).

Submit an application

You then access to the following page:

6. BASIC PROJECT INFO AND FUNDING 1/14.

This page allows you to start entering the trial-related information to be submitted. Take the time to read the general instructions therein provided to make sure to fill the forms correctly (e.g. language allowed, requirements for multicentric trials etc.):

Please read before starting your submission

- ***Use this form to submit clinical trials with medical devices that fall within the scope of the Ordinance ClinO-MD of 1 July 2020.***
- ***Category C clinical trials must be submitted in parallel to Swissmedic.***
- ***Language: For all multicentric studies, text fields must be filled out in English for reasons of linguistic simplification throughout Switzerland. The submission can nonetheless be done in the language of the canton(s) when only one language is concerned (e.g. submission done in French for a research project with centres in Lausanne and Genève; submission done in German for centres in Bern, Zürich and Luzern, etc.).***
  For monocentric projects, the local language of the ethics committee (French, German or Italian) or English is acceptable.
- *What is displayed on these screens depends on your answers. Therefore **it is recommended to follow the order of the screens to answer all questions**, although you may navigate through screens at any time.*
- *Fields marked with * are required.*
- *For **multicentric projects** you need to visit the screens for local documents of all the ECs that are responsible for 1 or more of your research sites.*
  *A site qualifies as a **"research site"** if it has at least a local investigator who signs the protocol and is responsible for its faithful execution.*
- *On the last screen 'Submission Summary' your input will be validated prior to submission. If the validation fails, the system will show you where additional input is needed.*
- *After you have started your application, it will be available in the section "My account / Manage my applications". You can edit it until you decide to submit.*
- *For the submission of additional documents / amendments etc., please follow the instructions described here.*
- *For the submission of safety reports (SAE, SUSAR, DSUR, etc.), please use the separate safety form and follow the instructions in this FAQ-article.*

7. Enter the trial title, acronym and internal identification number:

Title *

Should be the same as the title of the protocol.

1000 remaining characters

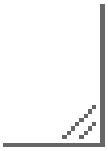
Acronym

Internal identification number

This could for instance correspond to an identification given by a company to their own studies.

- "Title"
  The full protocol title exactly as indicated in the protocol.

Please note that the size of the comment field can be increased/decreased as needed by clicking and dragging with your mouse on the following symbol in the bottom right corner of the field:



- "Acronym"
  Although not mandatory, a trial acronym can be indicated in the protocol to facilitate the identification of the trial.

- "Internal identification number"
  Although not mandatory, the creation of a unique number/code for the identification of the trial is highly recommended. The trial number must be clearly indicated in the protocol, together with the title and, if applicable, the acronym.

8. If your trial foresees the combination of new data and/or material with data and/or material already existing, tick the option below:

Combined with already existing data / biological material

☐ This clinical trial also includes further use of existing data and/or material

9. Specify the development stage of your trial by choosing one of the three options below:

Development stage *

○ Pilot stage
○ Pivotal stage
○ Post-market stage

10. Specify if the trial is taking place also in other countries, besides Switzerland:

Is the project taking place in other countries than Switzerland ? *

○ no
○ yes

If yes, list the countries in the comment field using the following format: 1) "country A"; 2) "country B"; 3) "country C" etc.:

Please list countries by name *

1) country A; 2) country B; 3) country C

360 remaining characters

Then, if available, enter the Eudamed identification number:

Eudamed Clinical Investigation identification number (CIV ID)

If the trial is conducted in Europe under the Medical Device Regulation of 5 April 2017 (MDR), indicate the European Clinical Investigation Identification number (CIV ID).

And, if available, the EU registration number:

Clinical trial registration number for clinical trials also conducted under the regulation EU No 536/2014

If an application is submitted in parallel with an application for a clinical trial in Europe in accordance with the European regulation no 536/2014 (DE, FR, IT) , indicate the official registration number of the clinical trial.

11. Select the Ethics Committee that will be competent for your submission. If your trial is monocentric and conducted at the CHUV please select the CER-VD and the option "one site in Switzerland":

Ethics Committee *

Overview of all ECs and the Canton(s) they are responsible for.

***Studies with only one research site in Switzerland**: select the EC responsible for the Canton where the research is conducted.*

***Studies with several research sites in Switzerland**: select the EC responsible for the Project at the **Project Coordinator's location**. This EC is the lead EC for the project.*

***If only one site is submitted with the initial submission of a multicentric clinical trial**, an explanation is required in the cover letter (to be uploaded on screen 6). The remaining site(s) will need to be submitted with (an) amendment(s).*

Commission cantonale d'Éthique de la Recherche sur l'être humain Vaud (CER-VD)

How many research sites in Switzerland are involved in the project? *

A site qualifies as a "research site" if it has at least a local investigator who signs the protocol and is responsible for its faithful execution.

one site in Switzerland

If your trial is multicentric, select the lead Ethics Committee as applicable (in this example, the CER-VD) and select "several sites in Switzerland":

Ethics Committee *

Overview of all ECs and the Canton(s) they are responsible for.

***Studies with only one research site in Switzerland**: select the EC responsible for the Canton where the research is conducted.*

***Studies with several research sites in Switzerland**: select the EC responsible for the Project at the **Project Coordinator's location**. This EC is the lead EC for the project.*

***If only one site is submitted with the initial submission of a multicentric clinical trial**, an explanation is required in the cover letter (to be uploaded on screen 6). The remaining site(s) will need to be submitted with (an) amendment(s).*

Commission cantonale d'Éthique de la Recherche sur l'être humain Vaud (CER-VD)

How many research sites in Switzerland are involved in the project? *

A site qualifies as a "research site" if it has at least a local investigator who signs the protocol and is responsible for its faithful execution.

several sites in Switzerland

Then select all the other Ethics Committees competent for the additional sites in Switzerland participating to the trial. The Ethics Committees selected here will trigger the respective pages described in step **65.**

Region(s) of responsibility for additional research sites *

*Select **all ECs** that are competent for **additional** research sites involved in your project.*
***If the lead EC is also competent for additional sites, please select it again.** (Overview of all ECs / regions)*

This field is required.

- ☐ Kantonale Ethikkommission Bern
- ☐ Ethikkommission Nordwest- und Zentralschweiz EKNZ
- ☐ Commission Cantonale d'éthique de la recherche Genève (CCER)
- ☐ Ethikkommission Ostschweiz (EKOS)
- ☐ Comitato etico cantonale Ticino
- ☐ Commission cantonale d'Éthique de la Recherche sur l'être humain Vaud (CER-VD)
- ☐ Kantonale Ethikkommission Zürich

12. Select the category the trial belongs to:

Who initiated the clinical trial? *

Indicate here who had the original idea for the clinical trial (do not indicate here who is financing, conducting or leading the clinical trial)

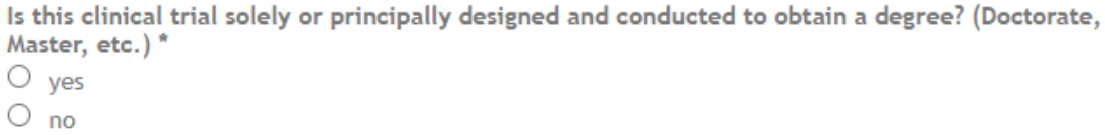
- ○ industry
- ○ investigator
- ○ other

- "Industry" must be selected for all trials initiated by private industry

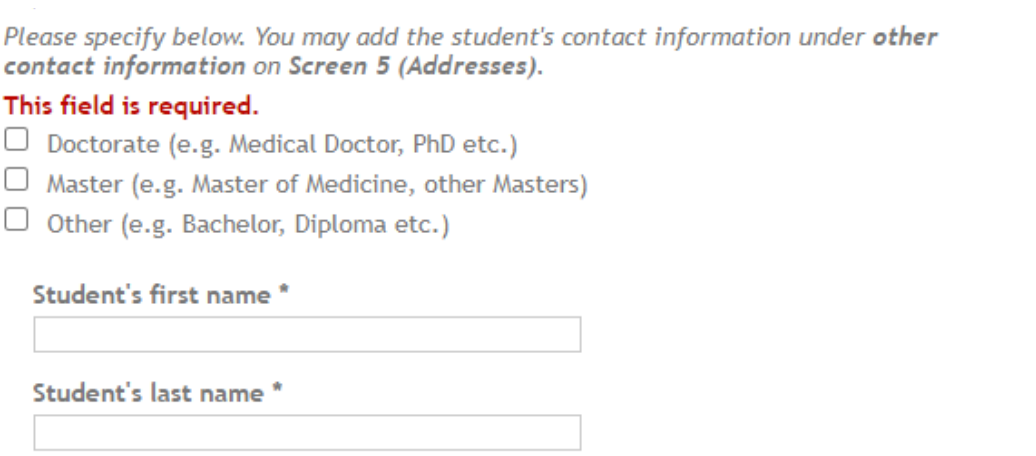
- "Investigator" must be selected for all trials initiated by an investigator. If your trial is an "Investigator-Initiated Trial", select this one.

- "Other" must be selected for all other cases, e.g. a trial/project initiated by an academic group, foundation, etc. If this is the case, please provide further details:

13. Indicate if the trial is conducted with the main purpose to obtain a degree, e.g. Doctorate, Master etc.



If yes, you must specify the type of degree and the student's name:



As indicated in the instructions, the student's contact information can be added in the Address screen (step **60.**).

14. Provide any relevant information applicable to the financing setup of your trial. Then specify each financing source in the next steps.

Information on Financing

You may indicate up to 4 different sources of financing.
Example:
Your clinical trial is mainly financed by the SNF. In addition, you have received a grant from the Swiss Society of Cardiology, and from your hospital. See the result here.

Special cases:

- *In international trials, only list Swiss specific financing*
- *If financing occurs on a per-case basis, multiply by the number of cases planned in Switzerland (e.g. 400'000 CHF for 50 patients at 8'000 CHF per patient).*
- *If your funding is not yet complete (for instance, if funding depends on approval by the Ethics Committee) indicate how you plan to fund your clinical trial*

Only list resources paid to investigators. For instance, if a CRO is responsible for the trial with 50 patients at 8'000 CHF per case, do not consider the costs incurred by the CRO for monitoring etc.

Comments about the financing of your clinical trial

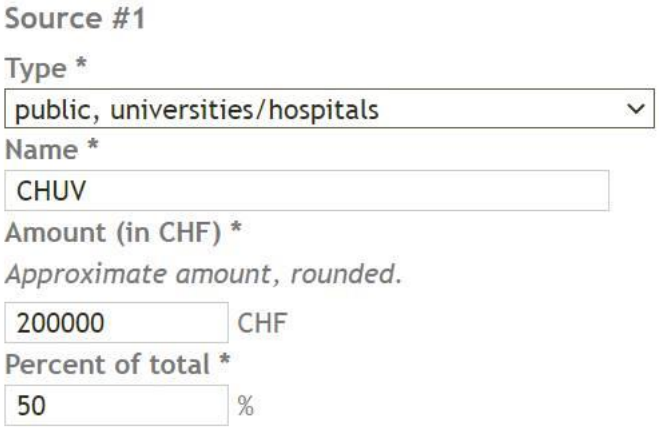
500 remaining characters

15. Select the number of financing sources according to the number you mentioned above. In this example, 3:

Source(s) *

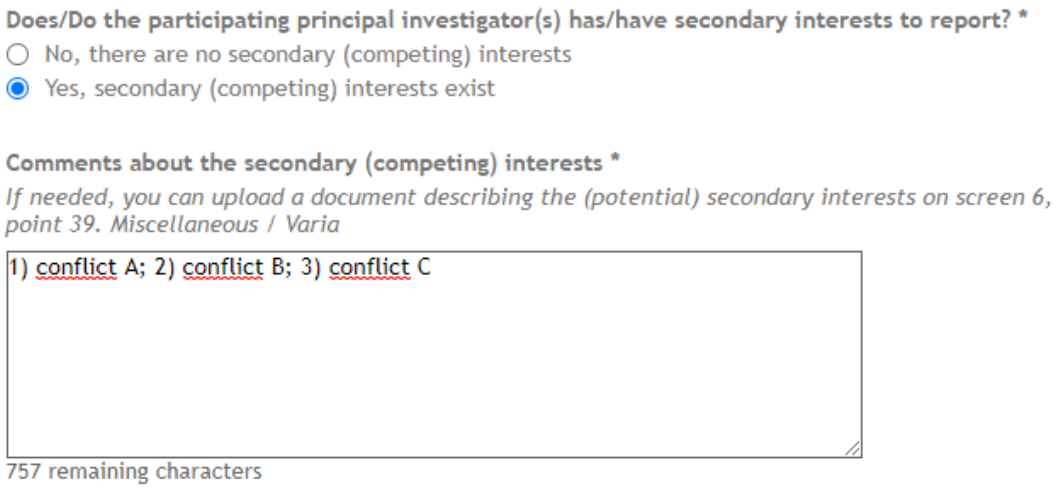
- ○ No funding
- ○ 1
- ○ 2
- ◉ 3
- ○ 4

16. For each financing source provide the requested information in terms of type of source, the amount financed by the source and the percentage of contribution of this financing source to the overall financing figure.
In case of the CHUV being a financing source, select “public, universities/hospitals” and then enter “CHUV”.
Do not use other variations such as Lausanne university hospital etc.



Fill the details for the remaining sources if applicable, making sure that all source percentages you indicated sum up to 100% (the portal does not calculate this for you).

17. Indicate if conflicts of interest exist for your trial.
If conflicts do exist, provide the details in the comment field by using the following format: 1) "conflict A"; 2) "conflict B"; 3) etc. according to the number of conflicts of interest to declare.
Do not enter any other comment, saying for example to refer to separate document etc.



18. Click on the "next screen" button to access the subsequent page:

19. PROJECT DETAILS 2/14

In the Project Details section, indicate if your trial investigates only medical devices or if it is a mixed trial of medical devices + drugs.

In the latter case, provide the detail of the involved drugs in the comment field by using the following format: 1) “drug A”; 2) “drug B”; 3) etc. accordingly:

Type of clinical trial *

- ○ medical devices
- ◉ drugs / medical devices

In case of uncertainties the applicant should seek advice from Swissmedic to confirm that the clinical trial with the combined drug/device does indeed fall within the scope of the Swiss ordinance on clinical trials with medical devices (ClinO-MD) before submitting the trial.

General note: If the principle intended action of the combination product is achieved by the medicine, the clinical trial is regulated under ClinO. Clinical trials conducted with medical devices that contain ancillary medicinal substances to support the proper functioning of the devices fall under ClinO-MD.

Please provide the medicinal substance(s) name(s) *

1) drug A; 2) drug B; 3) drug C

224 remaining characters

20. Specify the category of your clinical trial on the basis of the Oclin-Dim by choosing among the proposed options:

Category of the clinical trial *

For details on the categorisation see ClinO-MD Art.6 (DE, FR, IT)

- *Clinical trial category A1, A2 must be approved by the ethics committee, see ClinO Art.7 (DE, FR, IT)*
- *Clinical trials category C1, C2 and C3 must be approved by both the ethics committee and Swissmedic (ClinO-MD Art. 7, DE, FR, IT).*

This field is required.

- ○ A1
- ○ A2
- ○ C1
- ○ C2
- ○ C3

21. Then choose the class of the device investigated in your trial, on the basis of the European MDR Annex VIII :

Classification *

For details see MDR Annex VIII. Note: In Switzerland, the classification of the medical device does not affect the categorisation of the clinical trial that is based only on the CE mark and the instruction for use (IFU) of the product.

This field is required.

- ○ Class I (low risk): Devices that are non-sterile or that do not have a measuring function. Examples: wheelchairs, stethoscopes.
- ○ Class I (low/medium risk): Devices that are sterile and/or have a measuring function.
- ○ Class IIa (medium risk): Examples: syringes for infusion pumps, dental fillings, surgical clamps, tracheal tubes.
- ○ Class IIb (medium/high risk): Examples: lung ventilators, urethral stents, plates for setting bones.
- ○ Class III (high risk): Examples: drug-eluting stents, intrauterine devices, pacemakers, heart valves.

Please note: if you chose any category A in step **20.**, depending on the class you choose in step **21.**, you may need to provide the CE mark number:

Enter the full CE Mark of the device under investigation *

e.g.: CE1234

If you selected any category C in step **20.**, then continue with step **22.**, otherwise jump to step **25.**

22. Indicate if your device carries a CE mark, and provide the mark number if requested:

Does the medical device carry a CE mark?

- ◉ yes
- ○ no

Enter the full CE Mark of the device under investigation *

e.g.: CE1234

23. Indicate if your trial is conducted for any conformity assessment purpose:

Is this clinical trial conducted for conformity assessment purposes? *

This field is required.

- ○ yes
- ○ no

24. Go to step **25.**

25. Indicate if your trial is first-in-human:

First in human *
This field is required.
- ○ Yes
- ○ No

26. Specify the most relevant area of research your trial falls in:

Primary area of research *
If several areas apply, indicate primary area.
This field is required.
- ○ treatment
- ○ safety
- ○ prevention
- ○ diagnosis
- ○ palliation
- ○ rehabilitation
- ○ other

27. Provide a description of the interventions planned in your trial, making sure to follow the recommendations and examples provided in the instructions:

Interventions *
For each arm of the trial record a brief intervention name plus an intervention description.
This field is required.

700 remaining characters

▾ **(click here for more information about the field 'Interventions')**

Clearly describe what you plan to do. For instance: "The study seeks primarily to determine the effect of an implanted subcutaneous insulin pump on glucose levels in blood compared to Insulin Pen A."

The description must be sufficiently detailed for it to be possible to distinguish between the arms of a study.

For controlled trials, the identity of the control arm should be clear. The control intervention(s) is/are the interventions against which the study intervention is evaluated (e.g. placebo, no treatment, active control).
If an active control is used, be sure to detail what it is. For each intervention, describe details as applicable (duration, mode of administration).

28. The following four questions ask you to provide details on the type of allocation, masking technique, type of control and the arms/distribution design applicable to your trial:

Note about the 4 following questions

Some trials may include more than one methodological category. For instance: if a period with double-blind randomized assignments is followed by a period with open treatment for all. In such cases, always choose the more stringent methods (i.e. randomized controlled trial, double blind, and parallel group).

Allocation *

This field is required.

- ○ randomised controlled trial
- ○ non-randomised controlled trial
- ○ not applicable

Masking technique *

This field is required.

- ○ open
- ○ single-blind
- ○ double-blind

Type of control *

This field is required.

- ○ sham, placebo
- ○ active
- ○ before-after (historic)
- ○ dosage comparison
- ○ none

Arms/distribution *

This field is required.

- ○ single-armed
- ○ parallel groups
- ○ cross-over
- ○ factorial
- ○ other or n/a

29. Specify if your trial contains another medical device as comparator:

Is there a comparator included in the clinical investigation and is the comparator a medical device? *

This field is required.

- ○ yes
- ○ no

If yes, specify if the medical device comparator has a CE mark:

Is the comparator medical device CE marked? *

This field is required.

- ○ yes
- ○ no

If yes to this last question, you must also specify if the medical device comparator is used in the trial according to its approved indication:

Will the CE marked comparator medical device be used in the clinical investigation within the scope of the CE mark? *

This field is required.

- ○ yes
- ○ no

Then provide the requested information about the medical device comparator in the corresponding fields:

Generic denomination of the comparator device *

200 remaining characters

Comparator device name, comparator device trade name *

200 remaining characters

Comparator device model

200 remaining characters

30. Specify the primary outcome/endpoint of your trial:

Outcomes / endpoints

Outcomes are events, variables, or experiences that are measured because it is believed that they may be influenced by the intervention.

Primary outcome / endpoint *

The Primary Outcome should be the outcome used in sample size calculations, or the main outcome(s) used to determine the effect of the intervention. Most trials have only one Primary Outcome.

This field is required.

200 remaining characters

31. Then specify the secondary endpoints/outcomes of your trial, as and if applicable, limiting your list to a maximum of four and using the following format: 1) "outcome A"; 2) "outcome B"; 3) etc.

Secondary outcomes /endpoints *

(List a maximum of 4)

This field is required.

400 remaining characters

32. Indicate the number of participants planned to be enrolled in your trial in Switzerland:

Number of individuals to be enrolled in the clinical trial in Switzerland *

This field is required.

33. The subsequent two fields allow you to list the main inclusion and exclusion criteria.
Use the following format: 1) inclusion A; 2) inclusion B; 3) inclusion C etc.:

Key inclusion criteria *

1) inclusion A; 2) inclusion B; 3) inclusion C

754 remaining characters

Key exclusion criteria *

1) exclusion A; 2) exclusion B; 3) exclusion C

754 remaining characters

34. Specify if your trial plans to include vulnerable participants, by selecting all categories that apply:

Vulnerable persons *

This field is required.

- ☐ none
- ☐ embryos / foetuses intrauteri
- ☐ children (0-13, until one day before 14th birthday)
- ☐ adolescents (14-17, until one day before 18th birthday)
- ☐ emergencies (transient incapacity to consent, HRA art 30-31, ClinO art 15-17)
- ☐ pregnant women
- ☐ prisoners
- ☐ persons unable to consent (long-term incapacity to consent, HRA art 21-24)
- ☐ healthy volunteers

35. Provide the start and end date of your trial, according to the provided instructions, and making sure they match what specified in the trial protocol:

Start date *

Anticipated date of enrolment of first patient in Switzerland. (If only the month is known, please select the last day of the month.)

This field is required.

End date *

The anticipated date of last clinical trial visit of last patient in Switzerland. (If only the month is known, please select the last day of the month.)

This field is required.

36. In the last part of this section you must specify if your trial foresees the use of any ionizing radiation or not, and answer the questions accordingly. Depending on your answers, additional questions may appear asking for further details.

Here an example with all possible questions that can appear for ionizing radiations:

Ionising radiation

Depending on the type of research project, the therapeutic product to be investigated and/or the accompanying inquiries, different rules apply to the submission of applications and approval processes. An overview of the requirements applicable to a specific research project can be found using the wizard available from the kofam portal.

If your project involves ionizing radiation of any kind (conventional X-rays, Computed tomography, diagnostic or therapy with radiopharmaceuticals in nuclear medicine, radiotherapy, etc.), you may have to upload additional documents in the upload section. To determine which documents are needed, please answer the question(s) below:

Does your study involve ionising radiation? *

- ○ no
- ○ yes, and the main focus of the project is related to medical devices emitting ionising radiation
- ◉ yes, but the study is only using ionising radiation for accompanying evaluations (e.g. imaging)

The ionising radiation is used for *

select all that applies

This field is required.

- ☐ Diagnostic Radiology
- ☐ Nuclear Medicine

Is the radiopharmaceutical or medical device emitting ionising radiation authorised in Switzerland (Swissmedic authorisation or CE label) and used in conformity with the authorisation (standard use)? *

- ○ yes (authorised AND conform)
- ◉ no (not authorized OR not conform)

Is the effective dose higher than 5 mSv per year? *

- ◉ yes
- ○ no

Is the radiopharmaceutical / medical device emitting ionising radiation authorised in Switzerland but not used in conformity with the authorization? *

- ○ yes (authorised AND not conform)
- ◉ no (not authorised)

Note: You have to submit the application documents specified in annex 1 chapter 4 and chapter 5 of the ClinO-MD and a Pharmaceutical Quality Dossier for non-IMP (Investigational Medicinal Product) on screen 6 of this form to the ethics committee. A template for the Pharmaceutical Quality Dossier is available on the Swissmedic Webpage. The committee will obtain the opinion from the FOPH (Division for Radiation Protection) before granting authorization (according to article 14 ClinO-MD).

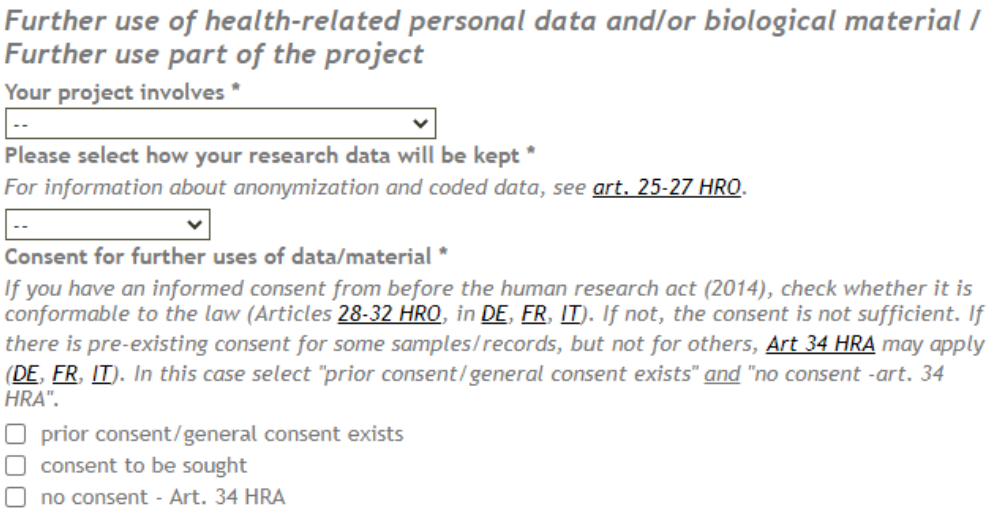
37. Once you finished to provide all information requested in this section, click on the "next screen" button to access the subsequent page:

38. FURTHER USE 3/14

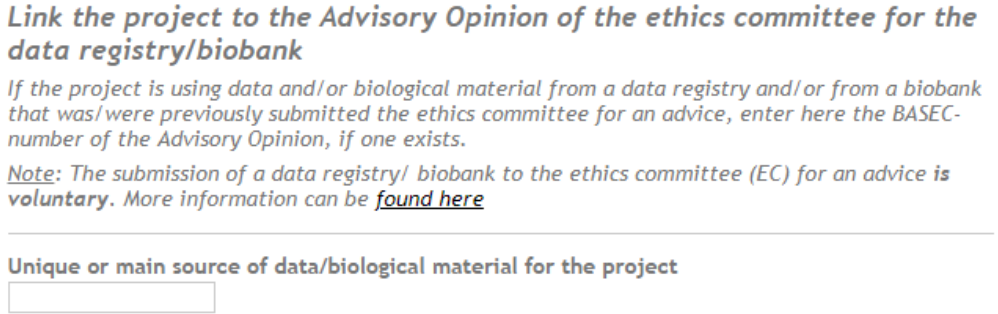
Unless you selected "Combined with already existing data / biological material" in step **8.**, this page is normally empty; you can skip to the next page by clicking again on the "next screen" button:

Then go to step **45.** If instead the page is not empty, continue with step **39.**

39. If you selected "Combined with already existing data / biological material" in step **8.**, provide the requested information in relation to the use of genetic data/biological material, data coding and consent type for data/material. **Several answers are possible for the consent type if your project includes a combination of consent procedures (prior general and/or specific consent or consent to be sough) and no consent**:



40. If your project re-uses data/material from another project, you must specify it here:



If there is more than one project your project refers to, you can indicate the BASEC ID numbers of these additional projects here:

Other sources of data/biological material for the project

If the project is using data and/or biological material from several data registries/biobanks, you can link the project to up to 3 additional data registries /biobanks

add an additional project

41. Then if applicable fill the remaining field according to instructions therein provided. This field is used for older projects for which a BASEC ID number is not available.

Reference to other BASEC-submission(s)

If your data registry / biobank was evaluated by the ethics committee through a "clarification of responsibility" or "support request" in BASEC, please enter the BASEC-request-ID / comment below.

500 remaining characters

42. If you selected "no consent – Art. 34 HRA" in step **39.**, the following additional fields will appear. In the last three fields, English is not accepted: enter the requested information in one of the three national languages (DE, FR, IT). **Please also refer to the CER-VD guidelines concerning article 34 of HRA ("**Formule-type article 34 LRH**") in order to correctly answer all questions prior to submitting your application**:

Justification and information for the use of Art. 34 HRA *

Reasons why it is impossible or disproportionately difficult to obtain consent / to provide information on the right to dissent or reasons why this would impose an undue burden on the persons concerned.

Example: "The approximately 500 samples and data we want to analyse derived from lung cancer patients from the 90s and early 2000s. Most if not all of these patients have died by now. It would be disproportionately difficult (if not impossible) to contact all the surviving patients or the remaining relatives to obtain an informed consent."

750 remaining characters

Confirmation that no data/samples will be used, if a document refusal exists *

This field is required.

☐ I confirm

Justification of interest of research *

How does the interest of research outweighs the interest of the persons concerned in deciding on the further use of his or her biological material and data?

750 remaining characters

The following information will be included in the authorisation by the ethics committee. It has to be in the local language (German, French or Italian). (See Art. 39 HRO, in DE, FR, IT)

Short description of the purpose *

A short description of the purpose for which further use may be made of the samples and/or health related data (Art. 39a HRO)

750 remaining characters

Example: "Screening biopsy material from confirmed lung cancer patients for biochemical and genetic markers with prognostic significance."

Description of the samples, and/or health related data *

See Art. 39b HRO

750 remaining characters

Example: "Biopsy material and health related personal data (age, sex, smoker/non-smoker, biochemical and molecular diagnostic data) from patients of the University hospital X who have had a diagnosis of lung cancer from 1992 until 2004."

Description of the group of persons who are entitled to pass on samples and/or data *

See (Art. 39c HRO)

750 remaining characters

Example: "The attending physicians and personal involved in the institutes of pneumology and pathology of the University hospital X."

43. Indicate the person accountable for reception of data/samples and for data protection. If this is the Principal Investigator, then click Yes; otherwise click No and provide the requested contact details:

Designate the person who is entitled to receive samples or data, and who is responsible for data protection

See Art 39d HRO. This person is responsible for the protection and safe handling of the data/samples.

Is the person who is entitled to receive samples or data / who is responsible for data protection the principal investigator? *

(Note: In multicenter studies each local investigator is responsible for data protection at his/her site. Information on local investigators and sites can be entered on the upload screen(s) for local documents.)

- (●) yes
- ( ) no

If this screen is empty, you can move on to the next screen.

44. Click on the "next screen" button to access the subsequent page:

45. SNCTP 4/14

This page allows you to enter the information about your trial that will be displayed in the Swiss National Clinical Trials Portal (SNCTP).

As mentioned in the instructions, the information you enter in this page cannot be in English but must be formulated in one of the Swiss national languages (German, French, Italian), as the SCNTP supports only these ones.
In addition, the language used in this page must not be too technical or specialized, but understandable by the public without specific medical or scientific knowledge.

Select the language chosen for the SNCTP:

Language used for SNCTP *
--

46. In the subsequent text fields, provide the requested details in non-specialized language, as mentioned above: trial title, disease or condition investigated in your trial, trial synopsis, intervention, inclusion and exclusion criteria.
Please note that the inclusion and exclusion criteria must be limited only to the 3 main ones.

47. Indicate the place where your trial takes place. A list of cities to choose among is pre-populated for your convenience. You have however the possibility to mention additional cities by selecting "Andere / Autre / Altri:"

Durchführungsorte / Lieux de déroulement / Luoghi di svolgimento dello studio *
- [ ] Aarau
- [ ] Basel
- [ ] Bellinzona
- [ ] Bern
- [ ] Chur
- [ ] Fribourg/Freiburg
- [ ] Genève
- [x] Lausanne
- [ ] Lugano
- [ ] Luzern
- [ ] Neuchâtel
- [ ] Sion
- [ ] St. Gallen
- [ ] Winterthur
- [ ] Zürich
- [ ] Andere / Autre / Altri:

Contact for further information? *

48. Provide the details of the contact person who must appear on SNCTP for your trial. It is recommended to enter a Sponsor contact (e.g. Medical Director). In case of Investigator-Initiated Trials, enter the contact details of the Principal Investigator who acts as Sponsor-Investigator.

Contact for further information? *

This will be published on the SNCTP website, and may therefore lead to enquiries by the general public.

Full name *

Telephone *

(Please include the country prefix. E.g.: +41...)

Email *

NOTE: use only professional telephone number and professional email address.

49. Besides SNCTP, your trial must be registered in one of the international primary registries. Indicate here the primary registry your trial is or will be recorded on, and enter the identification number your trial is identified with in such registry.

Here an example where ClinicalTrials.gov was chosen as primary registry, with a fictitious identification number:

Primary Registry

Note: At the time of your initial submission you may not yet have the information to fill in the next two fields. You can add the information later, after receiving the approval from the Ethics Committee (see this FAQ-entry on how to submit updates).

Name of Primary Registry *

For information about Primary Registries in the WHO Registry Network, please visit http://www.who.int/ictrp/network/primary/en/.

ClinicalTrials.gov

External identification number (ID) *

Number format for ClinicalTrials.gov: Prefix NCT + 8 digits
Example: NCT02217865

NCT00000000

50. Indicate the disease(s) investigated by your trial, by choosing among the proposed options. The categories you choose here will be used as search tags in SNCTP for your trial.

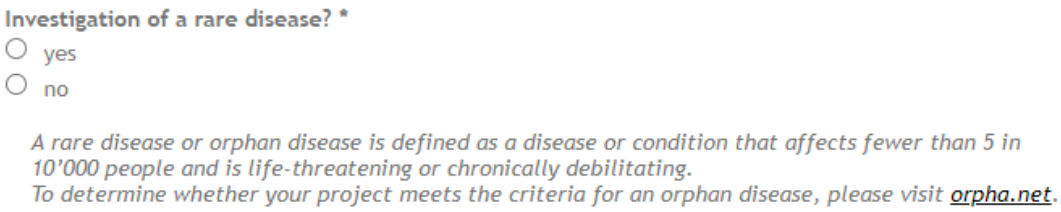
Disease under investigation

*Please **select 1 or more keywords** from the catalogue below.*
The keywords are used to narrow the search function for trials in the SNCTP.

Select keywords (click to expand) *

- ☐ Arterial and venous diseases including deep venous thrombosis and lung embolism
- ☐ Basic research (Anatomy/Physiology)
- ☐ Brain diseases (non cancer)
- ☐ Cancer: Bladder
- ☐ Cancer: Breast
- ☐ Cancer: Colon and Rectal
- ☐ Cancer: Endometrial
- ☐ Cancer: Head and Neck
- ☐ Cancer: Lymphoma
- ☐ Cancer: Kidney
- ☐ Cancer: Leukemia
- ☐ Cancer: Lung
- ☐ Cancer: Melanoma
- ☐ Cancer: Non-Hodgkin Lymphoma
- ☐ Cancer: Pancreatic
- ☐ Cancer: Prostate
- ☐ Cancer: Thyroid
- ☐ Cancer: Other
- ☐ Coronary Heart disease
- ☐ Dementia and Alzheimer disease
- ☐ Digestive Systems diseases (non cancer)
- ☐ Ear, Nose, and Throat diseases (non cancer)
- ☐ Endocrinological diseases (non cancer)
- ☐ Eye diseases
- ☐ Genetic disorders
- ☐ Hematologic diseases (non cancer)
- ☐ Infections and Infestations
- ☐ Injury
- ☐ Mental and Behavioural diseases
- ☐ Musculoskeletal diseases (non cancer)
- ☐ Neonatal diseases
- ☐ Nervous System diseases
- ☐ Nutritional and Metabolic diseases
- ☐ Occupational diseases
- ☐ Periodontal diseases
- ☐ Pregnancy and Childbirth
- ☐ Respiratory diseases (non cancer)
- ☐ Skin and Connective Tissues diseases (non cancer)
- ☐ Surgery
- ☐ Urological and Genital diseases (non cancer)
- ☐ Other

51. Specify if the indication investigated in your trial meets the criteria for rare/orphan disease:



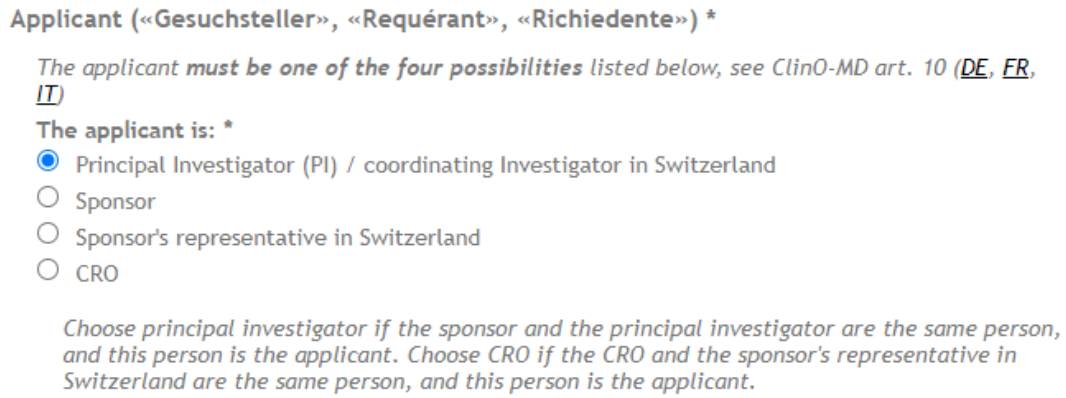
52. Once you have finished to complete all applicable sections, click on the "next screen" button to access the subsequent page:

53. ADDRESSES 5/14

This page allows you to specify the contact details of the applicant submitting the dossier, as well as of all other stakeholders.

Select the applicable choice, among the proposed ones, and pay attention to the instructions therein provided. A maximum of four choices appear, depending on the presence or not of CRO and separate sponsor representative for your trial.

Here an example with the applicant being the Principal Investigator:



For Investigator-Initiated Trials conducted at the CHUV, select “Principal Investigator”.

54. Enter all contact details of the Principal Investigator.

Whenever the CHUV needs to be entered as organization, please use “CHUV”.
Do not use other variations such as Lausanne university hospital etc.

NOTE: use only professional telephone number and professional email address.

55. Enter all contact details of the Sponsor, similarly to what done above.

In case of Investigator-Initiated Trials conducted at the CHUV, re-enter the contact details of the Principal Investigator. However, if a specific person other than the Principal Investigator represents the Sponsor in your trial, then enter the corresponding contact details.

56. Choose the option that corresponds to your trial for the Sponsor’s representative in Switzerland.
In case of Investigator-Initiated Trials conducted at the CHUV, please select “There is no sponsor’s representative in Switzerland (i.e. the sponsor is located in Switzerland)”

▾ Sponsor's representative in Switzerland *

See ClinO-MD art. 4 (DE, FR, IT): The sponsor's representative in Switzerland must be designated by a sponsor that has neither a registered office nor a branch in Switzerland. The sponsor's representative must ensure compliance with the sponsor's obligations set in ClinO-MD art. 2.

- (•) There is no sponsor's representative in Switzerland (i.e. the sponsor is located in Switzerland)
- ( ) There is a sponsor's representative (i.e. the sponsor is located abroad)

57. Enter all contact details of the CRO, if applicable, similarly to what done above. Otherwise select "There is no CRO"

▾ CRO (Contract Research Organisation) *

- (•) There is no CRO
- ( ) There is a CRO

58. Enter all contact details of the medical device manufacturer, including the contact person communicated by the manufacturer itself.

59. Specify the address to be used by the Ethics Committee to bill the fees for the review of the dossier.
Select the applicable choice among the available ones. If needed, additional comments in relation to the billing process can be added in the respective comment field.

▾ Billing address *

Please note:

- *Fees apply to the evaluation of research projects submitted to ethics committees (art. 54 HRA).*
- *Fees are billed according to this scale of fees.*
- *the billing address must be located in Switzerland.*
- ***please take extra care to ensure that the billing information is correct.***

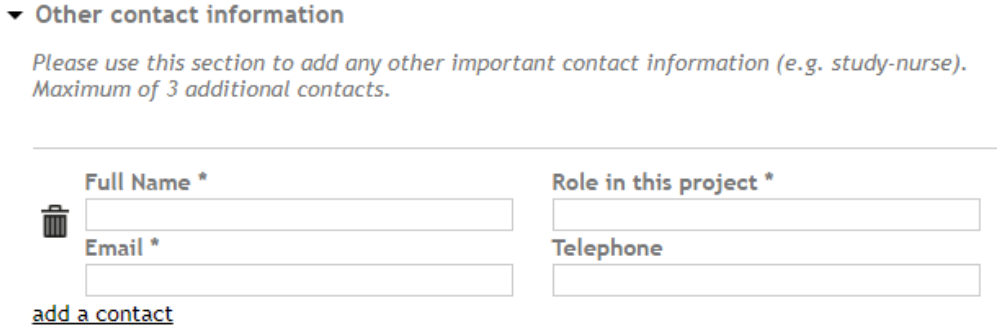
For billing use the address of the *
This field is required.

- ( ) Principal / coordinating investigator in Switzerland
- ( ) Sponsor
- ( ) Sponsor's representative in Switzerland
- ( ) Other

Additional billing instructions

255 remaining characters

60. In "Other contact information" you can enter up to three additional contacts, specifying their role in the project.



NOTE: use only professional telephone number and professional email address

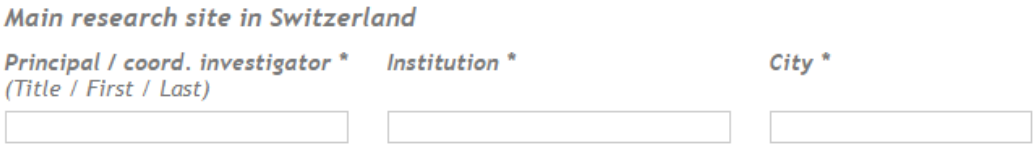
In case of Investigator-Initiated Trials conducted at the CHUV, or trials for which the CHUV acts as sponsor representative in Switzerland, please add the CHUV Sponsor Research Office / Bureau du Promoteur de Recherche as first additional contact, as follows:

Full name: "**BPR**"
Role in this project: "**Sponsor**"
Email: "**bpr@chuv.ch**"

61. Click on the "next screen" button to access the subsequent page:

62. LEAD EC: GENERAL AND MAIN SITE'S DOCUMENTS 6/14

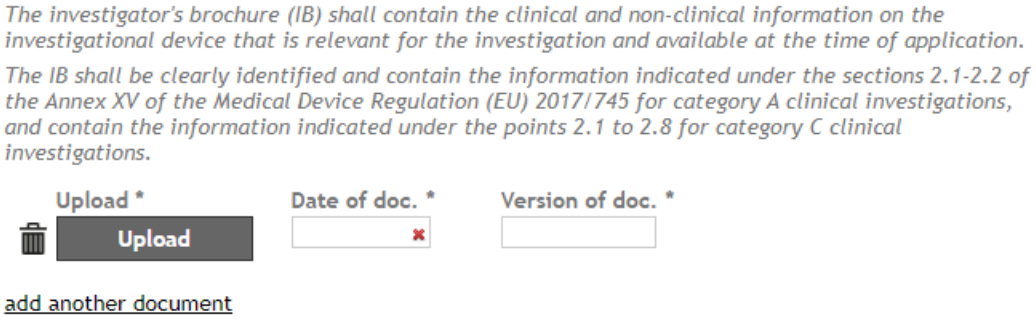
This page allows you to upload all documents necessary for the review of your trial/project by the Ethics Committee.
Make sure to comply with the instructions therein provided for the file format and naming, then enter the name of the Principal Investigator, the Institution and the city:



Should the CHUV need to be entered as organization, please use "CHUV".
Do not use other variations such as Lausanne university hospital etc.

63. Go through all subsequent points to upload all necessary documents, as indicated and as applicable.

When expanding each point by clicking on the arrow close to the number, specific instructions will appear as needed, to guide you on the type of document to upload.
Here an example for Art. 2 MDR Investigator's Brochure (IB):



64. Click on the "next screen" button to access the subsequent page:

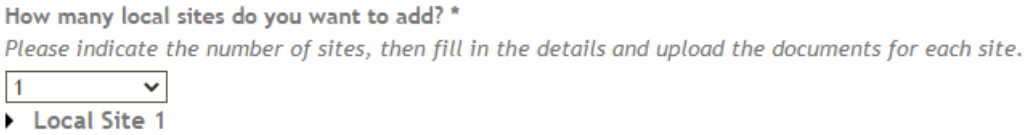
65. EC BE: ADDITIONAL SITES 7/14
EC EKNZ: ADDITIONAL SITES 8/14
EC GE: ADDITIONAL SITES 9/14
EKOS: ADDITIONAL SITES 10/14
EC TI: ADDITIONAL SITES 11/14
EC VD ADDITIONAL SITES 12/14
EC ZH: ADDITIONAL SITES 13/14

These pages allow you to upload all documents necessary for the review of your trial by the other local Ethics Committees in Switzerland.

In case of monocentric trial/project, these pages appear empty, and you can skip them and access to the last section (**SUBMISSION SUMMARY 14/14**, step **66.**) by clicking on the "next screen" buttons at the bottom of each of these pages:

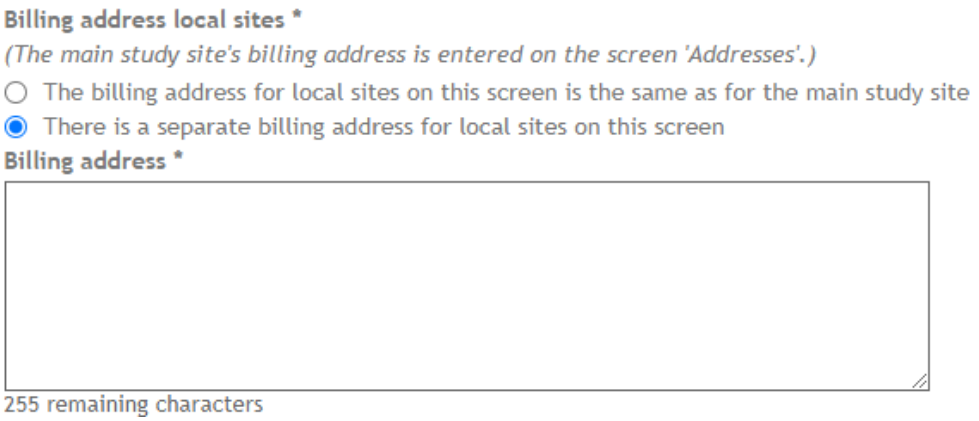
In case of multicentric trial involving additional sites in Switzerland, the page(s) of the Ethics Committee(s) corresponding to the options you indicated in step **11.** become active and must be filled.

In the page for each local Ethics Committee, select the number of sites falling under its responsibility (1 in this example):



Then upload all required documents and enter all required information similarly to what already done in step **63.**

Finally, specify if the billing address for the local site(s) is different or not from the billing address provided for the main site; if different, specify the new billing address in the respective comment field (please note: for Master projects, do not indicate the student's address):



Then Click on the "next screen" button to access the subsequent page:

Depending on the number of local Ethics Committes identified in step **11.** you may need to repeat step **65.** accordingly for each Ethics Committee. Once done, you will access to the page described in step **66.**

66. SUBMISSION SUMMARY 14/14

This page provides you with a summary of all information you provided in the previous sections, so that you can check it a last time before the Sponsor Research Office/SRO of the CHUV reviews your dossier, which will be then submitted to the Ethics Committee.

67. Before the summary section, you must however provide some additional information as follows:

Read carefully the instructions concerning the parallel submission to Swissmedic and the related timelines, then provide your confirmation:

Submission to Swissmedic

Confirmation of submission to Swissmedic *

Note: To allow for a seamless coordinated review and approval process with Swissmedic, the application must be made the same day to the ethics committee and to Swissmedic.

☑ I do confirm that I am submitting the clinical trial to Swissmedic in parallel to the submission to the ethics committee

Specify the context of your submission to the Ethics Committee:

Submission details and comments

I am submitting: *

☐ first submission of this project

Follow-ups

☐ Follow-up to the EC's formal review (follow up to list of deficiencies)
☐ Follow-up to the EC's preliminary decision (follow up to deficiencies)
☐ Follow-up to the EC's final decision (follow up to charges)

Amendments

(For an overview of what makes an amendment "substantial" or not, please see this document.)

☐ Substantial amendment: addition of new site(s)
☐ Substantial amendment: other
☐ Non-substantial amendment

In this section you must indicate whether:

- you are submitting your dossier for the first time
- you are re-submitting updated documents following a request for charges/conditions made by the EC following a previous review of the dossier
- or if you are submitting an amendment to an already-existing dossier

68. The subsequent lines allow you to indicate additional notifications and submissions.

Please note that these do not concern you in case of an initial submission, as you already uploaded all necessary documents during step **63.**, but only in case of subsequent updates to the document/information therein listed:

Notifications / submissions

With acknowledgement / approval of EC

- ☐ Informed consent form
- ☐ Flyer/advertisement
- ☐ changes to SNCTP information
- ☐ Investigator's Brochure (IB)
- ☐ Termination (regular or premature) / Final report
- ☐ other

69. Finally, a comment field allows you to provide details for any updates you made to the initial submission:

Comment

In case of an update to your original submission, please add a short description of the changes you have made.

500 remaining characters

70. Once you have entered and reviewed all information **please do not click yet** on the "Submit" button, as the dossier needs to be firstly reviewed by the CHUV Sponsor Research office (SRO). To send the dossier to the SRO, click on "Manage invitations" on the left side of the screen:

1. Basic project info and funding
2. Project details
3. Further use
4. SNCTP
5. Addresses
6. Lead EC: General and main site's documents
7. EC BE: additional sites
8. EC EKNZ: additional sites
9. EC GE: additional sites
10. EKOS: additional sites
11. EC TI: additional sites
12. EC VD: additional sites
13. EC ZH: additional sites
14. Submission Summary

Manage invitations

71. On the subsequent screen, click on "Invite a contributor":

MANAGE INVITATIONS

This interface allows you to ask other people to help you complete your form.
You can invite several people and limit their access to a part of your form.
Invite a contributor

72. You will be asked to enter the email address of the contributor to invite. Please enter bpr@chuv.ch

CONTRIBUTOR

E-mail address of the contributor to invite:
bpr@chuv.ch

73. Then select all steps of the submission dossier:

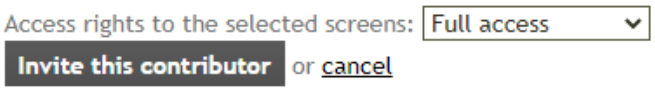
Allow the contributor to see and complete the following steps:

- ☑ Basic project info and funding
- ☑ Project details
- ☑ Further use
- ☑ SNCTP
- ☑ Addresses
- ☑ Lead EC: General and main site's documents
- ☑ EC BE: additional sites
- ☑ EC EKNZ: additional sites
- ☑ EC GE: additional sites
- ☑ EKOS: additional sites
- ☑ EC TI: additional sites
- ☑ EC VD: additional sites
- ☑ EC ZH: additional sites
- ☑ Submission Summary *

(*) The summary page can be viewed by all invited contributors. Though they can only view the content of the steps that they have access to.

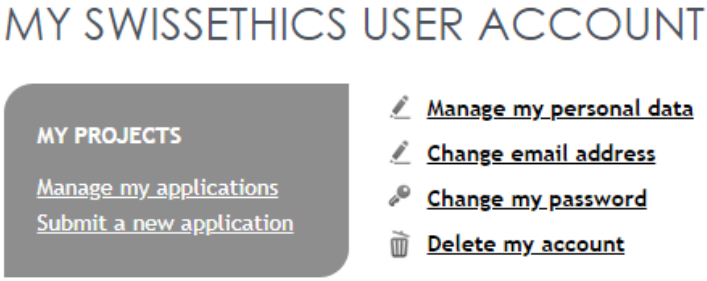
NOTE: should not be applicable in your case, you can de-select the boxes of the Ethics Committees not involved in the assessment of your trial/project.

74. Then select **"Full access"** and click on **"Invite this contributor"**

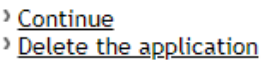


75. The SRO will then review the complete submission dossier and get back to you by email within 48h with any questions. You will be always informed in case this delay cannot be respected.

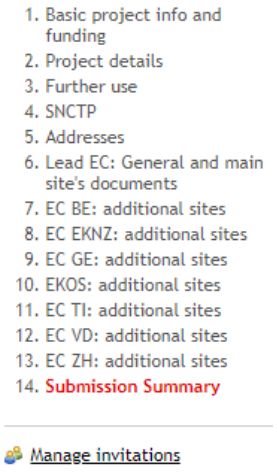
76. You will now be able to submit the dossier to the Ethics committee for their review. To do so, go back to the "Submission Summary" page described in step **66.**
To access this page, login to your account by following steps **1.** to **3.**, then click on "Manage my applications":



77. Then click on "Continue":



78. Select "14. Submission Summary" on the left side of the page:



79. Scroll down to the bottom of the page and click on the "Submit" button to transmit the complete dossier to the Ethics Committee for review:

11. TRAINING

☒ RU

☐ RO

☐ ROP

END OF PROCEDURE

BASEC Submission Guide for Clinical Trials with Medical Devices

1. **BUT**

2. **CADRE**

3. **RESPONSABILITÉS**

4. **DÉFINITIONS**

5. **MATÉRIAUX**

6. **ÉQUIPEMENTS**

7. **PRÉCAUTIONS**

8. **RÉFÉRENCES**

9. **DOCUMENT(S) QUALITÉ LIÉS**

10. **PROCÉDURE**

11. FORMATION

☐ RU

☐ RO

☐ ROP

FIN DE LA PROCÉDURE