

## BASEC submission guide for human research projects

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### DOCUMENT APPROVAL

Approver	Title	Approval Date
Ellefsen-Lavoie Kim	Chief of Sponsor research	11/06/2021

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### DOCUMENT HISTORY

Version	Change to previous version	Effective Date
1.0	New document	09/11/2020
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3.0	Amending regulation on medical devices (26 May 2021)	11/06/2021

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### DOCUMENT REVISION

Next document revision date: 11/06/2023

# BASEC submission guide for human research projects

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## 1. PURPOSE

The purpose of this document is to provide a step-by-step guide to submit a human research project 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 human research project 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.

**Research projects.** In this document, all human research projects, including clinical trials, clinical trials with medical devices, research involving human participants but not clinical trials, further use of data and biological samples etc are referred to as “research projects” or simply “projects”) and correspond to the definitions provided in the [Clinical Trials Ordinance \(ClinO\)](#) , [Ordinance on Clinical Trials with Medical Devices, OClin-Dim](#) and [Human Research Ordinance \(HRO\)](#).

**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)

[Human Research Ordinance, HRO](#) (in French, « Ordonnance relative à la recherche sur l'être humain », ORH)

[Clinical Trials Ordinance, ClinO](#) (in French, « Ordonnance sur les essais cliniques », OClin)

[Ordinance on Clinical Trials with Medical Devices, OClin-Dim](#) (in French, « Ordonnance sur les essais cliniques de dispositifs médicaux »)

## 9. RELATED QUALITY DOCUMENT(S)

SPO-320-WI-003, « BASEC Submission Guide for Clinical Trials with Medical Devices »

## 10. INSTRUCTIONS

All human research projects, including clinical trials, clinical trials with medical devices, research involving human participants but not clinical trials, further use of data and biological samples etc (from now on also “research projects” or simply “projects”) covered respectively under the definitions provided in the [Clinical Trials Ordinance \(ClinO\)](#) , [Ordinance on Clinical Trials with Medical Devices, OClin-Dim](#) and [Human Research Ordinance \(HRO\)](#) 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](mailto:scientifique.cer@vd.ch) or the SRO/BPR at [bpr@chuv.ch](mailto:bpr@chuv.ch) so that your answers are more clear, complete and accurate as possible.



**Important:** This submission guide must be used to submit new projects covered under the [Clinical Trials Ordinance \(ClinO\)](#) and the [Human Research Ordinance \(HRO\)](#) , as well as to submit amendments to clinical trials with medical devices which were approved

before the entry into force on 26<sup>th</sup> of May 2021 of the [Ordinance on Clinical Trials with Medical Devices, OClin-Dim](#) (or to notify their termination).

For the submission of new projects with medical devices, please refer to the separate guideline: SPO-320-WI-003, « BASEC Submission Guide for Clinical Trials with Medical Devices ».



**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 all dossiers of the **human research projects for which the CHUV is the sponsor (sponsor-investigator) or the CHUV is the sponsor representative in Switzerland** are 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 step **70. (“other contact information”)** and **80. (“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:

BASEC – SUBMISSION OF RESEARCH PROJECTS TO  
SWISS ETHICAL COMMITTEES

(BASEC = Business Administration System for Ethics Committees)

Login

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.

## IDENTIFICATION

### SIGN IN VIA MY SWISSETHICS USER ACCOUNT

If you already have a swissethics user account, enter your email address and password below.

Email:   
**This field is required.**

Password:  ([Lost password?](#))  
**This field is required.**

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### FIRST LOGIN

Create a user account in order to submit an application.

Email:   
**This field is required.**

Password:   
**This field is required.**

Confirm password:

I have read and agree to the [legal notice](#).

I'm not a robot   
reCAPTCHA  
Privacy - Terms

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 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”:

The screenshot shows the 'MY SWISSETHICS USER ACCOUNT' page. At the top, there is a navigation bar with 'HOME', 'SUBMIT AN APPLICATION', 'MY ACCOUNT', and 'LOGOUT'. Below this, the page is divided into three main sections. On the left, under 'Support', there are links for 'Submission FAQ', 'Support Request Form', and 'Clarification of responsibility'. In the center, under 'MY PROJECTS', there are links for 'Manage my applications' and 'Submit a new application'. On the right, there are links for 'Manage my personal data', 'Change email address', 'Change my password', and 'Delete my account'.

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

This screenshot shows the top navigation bar of the BASEC swissethics system. It includes the 'BASEC Business Administration System for Ethics Committees' logo on the left and the 'swissethics' logo on the right. Below the logos is a horizontal menu with four items: 'HOME', 'SUBMIT AN APPLICATION', 'MY ACCOUNT', and 'LOGOUT'.

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 research projects, refer to the first option “research project application form” 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, ClinO (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**

You then access to the following page:

## 6. BASIC PROJECT INFO AND FUNDING 1/14.

This page allows you to start entering the trial/project-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.):

## BASIC PROJECT INFO AND FUNDING 1 / 14

*Please read before starting your submission*

- › **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. Choose the category your trial/project belongs to, among the ones proposed:

## Basic info about your project

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### Your application concerns \*

- A clinical trial
- Research involving persons, but not a clinical trial
- Further use of health-related personal data and/or biological material
- Research involving Embryos and Fetuses from induced Abortions or Stillbirths
- Research involving deceased persons

#### Examples and links to the relevant legal paragraphs (click to expand):

- ▶ clinical trial
- ▶ Research involving persons, but not a clinical trial
- ▶ Further use of health-related personal data and/or biological material
- ▶ Research involving Embryos and Fetuses from induced Abortions or Stillbirths
- ▶ Research involving deceased persons

- “Clinical trial”  
Choose this option for clinical trials covered under the scope of the [Clinical Trial Ordinance \(ClinO\)](#). **Go to step 8.**
- “Research involving persons, but not a clinical trial”  
Choose this option for the research projects covered under the scope of the [Human Research Ordinance, Chapter 2](#). **Go to step 8.**
- “Further use of health-related personal data and/or biological material”  
Choose this option for the research projects covered under the scope of the [Human Research Ordinance, Chapter 3](#). **Go to step 9.**
- “Research involving embryos and fetuses from induced abortions and stillbirths”  
Choose this option for the research projects covered under the scope of the [Human Research Ordinance, Chapter 5](#). **Go to step 9.**
- “Research involving deceased persons”  
Choose this option for the research projects covered under the scope of the [Human Research Ordinance, Chapter 4](#). **Go to step 9.**

8. If your trial/project 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**

*E. g. existing data as a control.*

This clinical trial / non-clinical project involving persons also includes further use of existing data and/or material

**9. Enter the trial/project title, acronym and internal identification number:**

**Title \***

*Should be the same as the title of the protocol. Needs to be in English for clinical trials.*

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/project acronym can be indicated in the protocol to facilitate the identification of the trial/project.

- “Internal identification code”

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

- Please note that if you selected “Research involving persons, but not a clinical trial”, “Further use of health-related personal data and/or biological material”, “Research involving embryos and fetuses from induced abortions and stillbirths” or

“Research involving deceased persons” in step 7., you must also provide a brief description of the project research plan in the following field:

**Brief description of your research plan \***

*Clearly describe what you plan to do. For instance: “Charts from all patients with a coronary stent implanted from 2000 to 2010 will be reviewed. Survivors will be invited to undergo exercise testing, and to fill out a questionnaire regarding their quality of life.”*

700 remaining characters

- 10.** Select the Ethics Committee that will be competent for your submission. If your trial/project 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 study, 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/project 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 study, 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/project. The Ethics Committees selected here will trigger the respective pages described in step **75**.

**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

**11. Select the category the trial belongs to:**

**Who initiated the project? \***

*Indicate here who had the original idea for the research project (do not indicate here who is financing, conducting or leading the project)*

investigator ▼

- “Industry” must be selected for all trials/projects initiated by private industry
- “Investigator” must be selected for all trials/projects initiated by an investigator. If your trials/project 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.

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

Is this research project solely or principally designed and conducted to obtain a degree? (Doctorate, Master, etc.) \*

- yes
- no

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

*Please specify below. You may add the student's contact information under **other contact information on Screen 5 (Addresses).***

**This field is required.**

- Doctorate (e.g. Medical Doctor, PhD etc.)
- Master (e.g. Master of Medicine, other Masters)
- Other (e.g. Bachelor, Diploma etc.)

Student's first name \*

Student's last name \*

As indicated in the instructions, the student's contact information can be added in the Address screen (step 70.).

13. Provide any relevant information you may want to add in relation to the financing setup of your trial/project. Then specify each financing source in the next steps.

Comments about the financing of your project

500 remaining characters

14. 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

- 15.** 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.

**Source #1**

Type \*

public, universities/hospitals

Name \*

CHUV

Amount (in CHF) \*

*Approximate amount, rounded.*

200000 CHF

Percent of total \*

50 %

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).

- 16.** Indicate if conflicts of interest exist for your trial/project.

If conflicts do exist, provide the details in the comment field by using the following format: 1) “conflict”; 2) “conflict”; 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.

**Does/Do the participating principal investigator(s) has/have secondary interests to report? \***

- No, there are no secondary (competing) interests
- Yes, secondary (competing) interests exist

**Comments about the secondary (competing) interests \***

*If needed, you can upload a document describing the (potential) secondary interests on screen 6, point 39. Miscellaneous / Varia*

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

757 remaining characters

17. Indicate if the trial/project takes place also in other countries outside of Switzerland. If yes, list the countries in the comment field using the following format: 1) “country”; 2) “country”; 3) “country” etc.:

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

- no

**Please list countries by name \***

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

- yes

360 remaining characters

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

**Next screen**

## 19. PROJECT DETAILS 2/14

- If you selected “Clinical trial” in step 7., follow steps 20. to 30., then jump to step 40.
  - If you selected “Research involving persons, but not a clinical trial” in step 7., follow steps 31. to 36., then jump to step 40.
  - If you selected “Further use of health-related personal data and/or biological material”, “Research involving embryos and fetuses from induced abortions and stillbirths” or “Research involving deceased persons” in step 7., follow steps 37. to 39., then jump to step 41.
- 

20. In the Project Details section, indicate the type of your trial and the risk category (A/B/C). Please note that depending on the type of trial you select, the risk categories available may change (i.e. drug trials have A/B/C, while medical device trials have only A/C), according to what specified in the related articles of the ClinO.

Example for a drugs trial, category C:

Type of clinical trial \*

drugs ▼

Risk category \*

A

B

C

*In general, category A = minimal risk.*

*For details, see the respective ordinances: [ClinO Art. 19, 20, 49 & 61](#)*

Depending on the type of trial you select, different questions will appear, such as the trial phase, or if the trial is “first in human”.

Example for a phase I/II trial , first-in-human:

Phase \*

phase 1/2 ▼

First in human \*

Yes

No

**NOTE:** the menu “type of clinical trial” allows you also to select a trial with medical devices. This option however should be used only in case of amendments to trials with medical devices already running, or to announce their termination. All **new** trials with medical devices must be submitted instead through the dedicated

application form available in BASEC. Please refer to separate guidelines: SPO-320-WI-003.

Should you be in the case of submitting an amendment or notifying the termination of an ongoing trial with medical devices, you will need to re-categorize the trial according to the latest legislation on medical devices ([OClin-Dim](#)):

Type of clinical trial \*

Risk category \*

**This field is required.**

- A1
- A2
- C1
- C2
- C3

*If you are submitting an amendment to an approved clinical trial, or if you are notifying the end of trial, then you must recategorize the clinical trial according to ClinO-MD Art. 48 Abs. 3 (KlinV-Mep, OClin-Dim, OSRUM-Dmed).*

*If you are submitting a new clinical trial of medical device that falls under ClinO-MD (KlinV-Mep, OClin-Dim, OSRUM-Dmed), then you must use the dedicated form "Research Project application form for medical devices". Submissions of new clinical trials of medical devices with the wrong submission form will be rejected.*

Then, additional questions will appear. Select the appropriate answer depending on what applies for your trial.

Example for a medical device trial, category C1, first in human, where the device already exists on the market but is investigated in the trial for a non-approved use:

Type of clinical trial \*

medical devices ▼

Risk category \*

- A1  
 A2  
 C1  
 C2  
 C3

*If you are submitting an amendment to an approved clinical trial, or if you are notifying the end of trial, then you must recategorize the clinical trial according to ClinO-MD Art. 48 Abs. 3 (KlinV-Mep, OClin-Dim, OSRUM-Dmed).*

*If you are submitting a new clinical trial of medical device that falls under ClinO-MD (KlinV-Mep, OClin-Dim, OSRUM-Dmed), then you must use the dedicated form "Research Project application form for medical devices". Submissions of new clinical trials of medical devices with the wrong submission form will be rejected.*

First in human \*

- Yes  
 No

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Medical devices

Does your project only involve standard use of existing medical devices with conformity marking? \*

- yes  
 no

New use of device / new device \*

- new use of existing device  
 new medical device

21. Select the primary area of research of your trial among the proposed options:

Primary area of research \*

*If several areas apply, indicate primary area.*

- treatment  
 PK / PD / safety  
 prevention  
 diagnosis  
 palliation  
 rehabilitation  
 other

22. In the "interventions" field, provide a free-text description of the interventions foreseen in your trial, following the recommendations provided under the field:

**Interventions \***

For each arm of the trial record a brief intervention name plus an intervention description.

700 remaining characters

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

*Clearly describe what you plan to do. For instance: "We aim to evaluate the effect of xxx in the management of pancreatic cancer. XXX or placebo will be added to conventional gemcitabine-based chemotherapy."*

*The description must be sufficiently detailed for it to be possible to distinguish between the arms of a study (e.g. comparison of different dosages of drug). Use generic names if possible.*

*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 (dose, duration, mode of administration).*

*See also the description of this field in the [WHO Trial Registration Data Set](#) (point 13).*

23. Provide information about the allocation, type of control used and arm/distribution design of your trial as applicable. Make sure to follow the instructions therein provided, in case your trial contains more than one methodological category at the same time:

Here an example for a non-randomized, single-arm trial without control:

**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 \***

- randomised controlled trial  
 non-randomised controlled trial  
 not applicable

**Masking technique \***

open ▼

**Type of control \***

- placebo  
 active  
 before-after (historic)  
 dosage comparison  
 none

**Arms/distribution \***

single-armed ▼

24. Indicate if your trial fills the characteristics of a complex trial design, according to the recommendations provided in the embedded link (“[paper of the Clinical Trials Facilitation and Coordination Group \(CTFG\)](#)”):

**Complex trial design \***

*For the assessment of clinical trial applications of studies with complex designs, the ethics committees rely on the recommendation [paper of the Clinical Trials Facilitation and Coordination Group \(CTFG\)](#)*

the clinical trial has a complex trial design (umbrella, basket, adaptive design/platform)  
**Have you submitted the project for a pre-assessment to Swissmedic and did Swissmedic accept the project as one single trial? \***

- yes. Upload the pre-assessment on screen 6 under ‘39. Miscellaneous / Varia’  
 no

*Follow the instructions on the Swissmedic webpage for the submission of the project for a pre-assessment ([EN](#), [DE](#), [FR](#), [IT](#))*

the clinical trial does not have a complex trial design

25. Indicate the primary and secondary outcomes, if applicable in the corresponding fields, using this format: 1) “outcome”; 2) “outcome” etc.  
Please note that the outcomes must correspond to the respective objectives as indicated in your trial protocol.

**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.*

1) Outcome A; 2) Outcome B

174 remaining characters

**Secondary outcomes / endpoints \***

*(List a maximum of 4)*

1) Outcome C; 2) Outcome D; 3) Outcome E; 4) Outcome F

346 remaining characters

26. Indicate the number of patients targeted for enrollment in Switzerland in your trial:

Target sample size in Switzerland \*

10

*The target sample size is the number of individuals to be enrolled in the study.*

27. List the key inclusion and exclusion criteria of your trial, using the wording mentioned in your trial protocol, by respecting the following format: 1) “criterion”; 2) “criterion”; 3) “criterion” etc.

Key inclusion criteria \*

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

753 remaining characters

Key exclusion criteria \*

1) criterion D; 2) criterion E; 3) criterion F

753 remaining characters

28. Indicate if your trial involves any vulnerable persons as indicated in the provided categories:

Vulnerable persons \*

- 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, HRO art 11)
- pregnant women
- prisoners
- persons unable to consent (long-term incapacity to consent, HRA art 21-24)
- healthy volunteers

29. Indicate the estimated start and end dates of your trial according to the definitions therein provided:

**Start date \***

*Anticipated date of enrolment of first patient in Switzerland, or, in case of "further use" projects, the anticipated date of first data extracted from the registry or start of analysis of existing records or samples in Switzerland.  
(if only the month is known, please select the last day of the month.)*

**End date \***

*For a clinical trial, the anticipated date of last study visit of last patient in Switzerland. For a "further use" project the anticipated completion of the research project. For a "further use" project in the absence of informed consent, in accordance with Art. 34 HRA, the anticipated end of collection of data/samples in Switzerland, as defined in the research project protocol.  
(if only the month is known, please select the last day of the month.)*

30. Go to step 40.

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31. In the Project Details section, indicate the type of your trial and the risk category (A/B).

Example for a cohort study, category B:

**Study type \***

- case control study
- cohort study
- registry / quality control
- other or n/a

**Risk category \***

- A
- B

*In general, category A = minimal risk. For details, see the respective ordinance: [HRO Art. 7](#)*

32. Select the primary area of research of your trial among the proposed options:

**Primary area of research \***

*If several areas apply, indicate primary area.*

- basic science
- drugs
- medical devices
- surgery
- psychology
- physiology/anatomy
- healthcare services research
- dentistry
- epidemiology
- qualitative research
- other

33. Indicate the number of patients targeted for enrollment in Switzerland in your project:

**Target sample size in Switzerland \***

10

*The target sample size is the number of individuals to be enrolled in the study.*

34. Indicate if your trial involves any vulnerable persons as indicated in the provided categories:

**Vulnerable persons \***

- none
- embryos / fetuses 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, HRO art 11)
- pregnant women
- prisoners
- persons unable to consent (long-term incapacity to consent, HRA art 21-24)
- healthy volunteers

35. Indicate the estimated start and end dates of your trial according to the definitions therein provided:

**Start date \***

*Anticipated date of enrolment of first patient in Switzerland, or, in case of "further use" projects, the anticipated date of first data extracted from the registry or start of analysis of existing records or samples in Switzerland.  
(if only the month is known, please select the last day of the month.)*

**This field is required.**

**Is the research project open-ended? \***

- no
- yes

**End date \***

*For a clinical trial, the anticipated date of last study visit of last patient in Switzerland. For a "further use" project the anticipated completion of the research project. For a "further use" project in the absence of informed consent, in accordance with Art. 34 HRA, the anticipated end of collection of data/samples in Switzerland, as defined in the research project protocol.  
(if only the month is known, please select the last day of the month.)*

Please note that if you answer Yes to the question **Is the research project open-ended?** you have to provide a rationale in the respective comment field:

**Start date \***

*Anticipated date of enrolment of first patient in Switzerland, or, in case of "further use" projects, the anticipated date of first data extracted from the registry or start of analysis of existing records or samples in Switzerland.  
(if only the month is known, please select the last day of the month.)*

**This field is required.**

**Is the research project open-ended? \***

- no
- yes

**Justification for no End date**

*Please add a short explanation why your project has no end date.*

150 remaining characters

36. Go to step 40.

---

37. Indicate the number of patients targeted for enrollment in Switzerland in your project:

**Target sample size in Switzerland \***

*For studies involving biological material, bodies or body parts of deceased persons, or deceased embryos and fetuses, the target sample size is the **estimated** number of samples to be investigated.*

*For studies involving data only, the target size is the **estimated** number of data sets investigated.*

- 38.** Indicate the estimated start and end dates of your trial according to the definitions therein provided. **The start date should never be before the date you have received the authorization by the competent IEC and other involved authorities (Swissmedic, Federal Office of Public Health etc)::**

**Start date \***

*Anticipated date of enrolment of first patient in Switzerland, or, in case of "further use" projects, the anticipated date of first data extracted from the registry or start of analysis of existing records or samples in Switzerland.*

*(if only the month is known, please select the last day of the month.)*

**End date \***

*For a clinical trial, the anticipated date of last study visit of last patient in Switzerland. For a "further use" project the anticipated completion of the research project. For a "further use" project in the absence of informed consent, in accordance with Art. 34 HRA, the anticipated end of collection of data/samples in Switzerland, as defined in the research project protocol.*

*(if only the month is known, please select the last day of the month.)*

- 39.** Go to step **41**.
- 

- 40.** Specify if your trial/project involves the use of ionizing radiations 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, but the ionising radiation is only used for accompanying / supporting exams (the results obtained by using ionising radiation are not the main focus of the study)

The ionising radiation is used for \*

select all that applies

- Diagnostic Radiology
- Nuclear Medicine

Is the radiopharmaceutical or medical device emitting ionising radiation authorized in Switzerland and used in conformity with the authorization? \*

(Swissmedic authorization or CE label, standard use and FOPH authorization according to [article 28 \(DE, FR, IT\)](#) of the Swiss Radiological Protection Act. Here, standard use refers to Swissmedic authorization or CE label only, it doesn't refer to medical guidelines or medical practices.)

- yes
- no

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

- yes
- no

Note: According to [article 19 HRO \(DE, FR, IT\)](#) you have to submit the application documents specified in Annex 2 chapter 3 (HRO) to the FOPH ([Division Radiological protection](#)) in parallel to this submission.

Is the radiopharmaceutical / medical device emitting ionising radiation authorised in Switzerland? \*

- yes
- no

You will have to provide a **Pharmaceutical Quality Dossier** for non-IMP (Investigational Medicinal Product) on screen 6 of this form. A template for the Pharmaceutical Quality Dossier is available on the [swissmedic Webpage](#) -->Guidelines for CTA dossiers submitted

Then go to step **41**.

**41.** Click on the “next screen” button to access the subsequent page:

**Next screen**

#### 42. FURTHER USE 3/14

Unless you selected “Further use of health-related personal data and/or biological material” in step 7., this page is normally empty; you can skip to the next page by clicking again on the “next screen” button:

**Next screen**

Then go to step 49. If instead the page is not empty, continue with step 43.

43. If you selected “Further use of health-related personal data and/or biological material” in step 7., 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 sought) and no consent:**

#### *Further use of health-related personal data and/or biological material / Further use part of the project*

Your project involves \*

Please select how your research data will be kept \*

For information about anonymization and coded data, see [art. 25-27 HRO](#).

Consent for further uses of data/material \*

*If you have an informed consent from before the human research act (2014), check whether it is conformable to the law (Articles 28-32 HRO, in DE, FR, IT). If not, the consent is not sufficient. If there is pre-existing consent for some samples/records, but not for others, Art 34 HRA may apply (DE, FR, IT). In this case select "prior consent/general consent exists" and "no consent -art. 34 HRA".*

- prior consent/general consent exists
- consent to be sought
- no consent - Art. 34 HRA

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

#### *Link the project to the Advisory Opinion of the ethics committee for the data registry/biobank*

*If the project is using data and/or biological material from a data registry and/or from a biobank that was/were previously submitted the ethics committee for an advice, enter here the BASEC-number of the Advisory Opinion, if one exists.*

*Note: The submission of a data registry/ biobank to the ethics committee (EC) for an advice is **voluntary**. More information can be [found here](#)*

Unique or main source of data/biological material for the project

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](#)

45. 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

46. If you selected **no consent - Art. 34 HRA** in step 43., the following additional fields will appear. In these 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:**

*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."*

47. Indicate the person accountable for reception of data/samples and for data protection. If this is the Project Leader, 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 project leader? \***

(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

48. Click on the “next screen” button to access the subsequent page:

**Next screen**

#### 49. SNCTP 4/14

- If you selected “Clinical trial” in step 7., follow steps 50. to 57., then continue with step 58.
- For all other cases click on the “next screen” button to access the subsequent page

**Next screen**

and jump to step 58.

---

50. 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 \*

51. 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.

52. 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
- Lausanne
- Lugano
- Luzern
- Neuchâtel
- Sion
- St. Gallen
- Winterthur
- Zürich
- Andere / Autre / Altri:

**Contact for further information? \***

53. 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.

54. 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](http://www.clinicaltrials.gov): Prefix NCT + 8 digits

*Example: NCT02217865*

NCT00000000

55. 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

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

Investigation of a rare disease? \*

- yes  
 no

*A rare disease or orphan disease is defined as a disease or condition that affects fewer than 5 in 10'000 people and is life-threatening or chronically debilitating.  
To determine whether your project meets the criteria for an orphan disease, please visit [orpha.net](http://orpha.net).*

57. The last section of this page asks your authorization for transferring automatically or not the trial information to SNCTP once all applicable regulatory approvals have been obtained:

**Registration in SNCTP**

**Agreement on automatic data transfer \***

*Clinical trials must be registered in the [Swiss Clinical Trials Portal SNCTP](#) before the trials are conducted. The relevant data will be automatically transferred into SNCTP:*

- › once the name of the primary registry and the external identification number (ID) are added in the two dedicated fields above, and:*
- › the trial is approved by the Ethics Committee and, if applicable, by [Swissmedic](#) and/or the [FOPH](#).*

*For more help about the agreement see also this [flowchart](#).*

- I agree to the automatic transfer of the relevant data into the SNCTP  
 Please wait with the automatic transfer, I will agree to the transfer later \*

*\* **Note:** Clinical trials in which the medicinal product under investigation is being administered to adult persons for the first time (Phase I clinical trials) must be registered **no later than one year after the completion** of the clinical trial.*

Make your choice, then click on the “next screen” button to access the subsequent page:

**Next screen**

and go to step 58.

---

**58. 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.

- If you selected “Clinical trial” in step **7.**, follow steps **59.** to **63.**, then jump to step **68.**
  - For all other cases, follow steps **64.** to **67.**, then continue with step **68.**
- 

- 59.** Select the applicable choice, among the four proposed ones, and pay attention to the instructions therein provided.

**Applicant («Gesuchsteller», «Requérant», «Richiedente») \***

Please **indicate first who will act as applicant** in your project.  
What address information is required, depends on this answer.

- Principal Investigator (PI) / Coordinating Investigator in Switzerland
- Sponsor
- Sponsor's representative in Switzerland
- CRO

*The applicant **must be one of the four possibilities** listed above (see [art. 24 ClinO](#)).  
(If Sponsor and Principal Investigator are the same person, choose Principal Investigator.  
If the CRO is also the sponsor's representative in Switzerland, choose CRO.)*

*For a definition of "Sponsor", see [ClinO art. 2, subs. c.](#): "Sponsor" means a person or institution headquartered or represented in Switzerland that takes responsibility for organising a clinical trial, and in particular for the initiation, management and financing of the trial in Switzerland.*

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

- 60.** Enter all contact details of the applicant as requested:

*(Note: please don't translate address details into English, such as department name, institution name etc.)*

▼ Applicant's address \*

*Please fill in the contact information for the party you have selected in the question above.*

Ms/Mr \*

Title

First Name \*

Last Name \*

Organisation

Address Lines \*

*(e.g.: Unit, department, street.)*

255 remaining characters

Zip Code \*

City \*

Country \*

Email \*

Telephone \*

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

Should the CHUV need 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.

61. Enter all contact details of the Sponsor, if separate, similarly to what done above. In case of Investigator-Initiated Trials conducted at the CHUV, please select instead “The Principal Investigator (PI) acts as the Sponsor”

▼ Sponsor \*

*see ClinO art. 2, subs. c.: “Sponsor” means a person or institution headquartered or represented in Switzerland that takes responsibility for organising a clinical trial, and in particular for the initiation, management and financing of the trial in Switzerland.*

- The Principal Investigator (PI) acts as the Sponsor  
 There is a separate Sponsor

62. 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 **The Sponsor or the organisation/person acting as Sponsor is headquartered in Switzerland**

▼ **Sponsor's representative in Switzerland \***

- The Sponsor or the organisation/person acting as Sponsor is headquartered in Switzerland
- The Sponsor has a representative in Switzerland for this project
- The CRO acts as the sponsor's representative (In this case, the CRO has to be headquartered in Switzerland)

63. Go to step 68.

---

64. Select the applicable choice, among the four proposed ones, and pay attention to the instructions therein provided.

**Applicant («Gesuchsteller», «Requérant», «Richiedente») \***

Please **indicate first who will act as applicant** in your project.  
What address information is required, depends on this answer.

- Project Leader
- Sponsor
- Sponsor's representative in Switzerland
- CRO

*The applicant must be one of the four possibilities listed here (see art. 14 HRO).  
(If Sponsor and Project Leader are the same person, choose Project Leader, see art. 3 HRO.  
If the CRO is also the sponsor's representative in Switzerland, choose CRO.)*

For research projects conducted at the CHUV and initiated by the Project Leader, select "Project Leader".

65. Enter all contact details of the applicant as requested:

*(Note: please don't translate address details into English, such as department name, institution name etc.)*

▼ Applicant's address \*

*Please fill in the contact information for the party you have selected in the question above.*

Ms/Mr \*

Title

First Name \*

Last Name \*

Organisation

Address Lines \*

*(e.g.: Unit, department, street.)*

255 remaining characters

Zip Code \*

City \*

Country \*

Email \*

Telephone \*

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

Should the CHUV need 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.

66. Enter all contact details of the Sponsor, if separate, similarly to what done above. In case of research projects conducted at the CHUV and initiated by the Project Leader, please select instead **The Project Leader acts as the Sponsor**

▼ Sponsor \*

*Usually the **project leader (art. 3 HRO)** also acts as “Sponsor”. If another person than the project leader assumes the Sponsor responsibilities, please enter the address below.*

- The Project Leader acts as the Sponsor  
 There is a separate Sponsor

67. Choose the option that corresponds to your trial for the Sponsor's representative in Switzerland.

In case of research projects conducted at the CHUV and initiated by the Project Leader, please select **The Sponsor or the organisation/person acting as Sponsor is headquartered in Switzerland**

▼ **Sponsor's representative in Switzerland \***

- The Sponsor or the organisation/person acting as Sponsor is headquartered in Switzerland
- The Sponsor has a representative in Switzerland for this project
- The CRO acts as the sponsor's representative (In this case, the CRO has to be headquartered in Switzerland)

Then go to step **68**.

---

68. Enter all contact details of the CRO, if applicable, similarly to what done above. Otherwise select **There is no CRO in this project**

▼ **CRO (Contract Research Organisation) \***

- There is no CRO in this project
- There is a CRO for this project

69. Specify the address to be used by the Ethics Committee to bill the fees for the review of the dossier.  
Select the applicant's or a different address as applicable. 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 (if it's the same as the Applicant's address, please verify that it's correct).**

For billing use the address of the \*

- Applicant  
 Other

Additional billing instructions

255 remaining characters

70. Here you can enter up to three additional contacts, specifying their role in the project.

▼ Other contact information

*Please use this section to add any other important contact information (e.g. study-nurse).  
Maximum of 3 additional contacts.*

	<b>Full Name *</b> <input type="text"/>	<b>Role in this project *</b> <input type="text"/>
	<b>Email *</b> <input type="text"/>	<b>Telephone</b> <input type="text"/>

[add a contact](#)

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



In case of research projects sponsored by the CHUV or 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”**

71. Click on the “next screen” button to access the subsequent page:

**Next screen**

**72. 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:

*Main research site in Switzerland*

*PI / Project Leader \**  
*(Title / First / Last)*

*Institution \**

*City \**

Should the CHUV need to be entered as organization, please use “CHUV”.

Do not use other variations such as Lausanne university hospital etc.

**73. 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 point **2. Synopsis of the study plan** :

▼ **2. Synopsis of the study plan \***

*(In English or the language of the (Lead) Ethics Committee.)*

*Template (.docx): [DE](#), [FR](#), [EN](#), [IT](#)*

*A separate synopsis is no longer required for the submission of clinical trials (KlinV, OClin, OSRUm). A synopsis is generally already included in the protocol.*

**Can this information be found in another document you are uploading? \***

**74. Click on the “next screen” button to access the subsequent page:**

**Next screen**

- 75. 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 **76.**) by clicking on the “next screen” buttons at the bottom of each of these pages:

**Next screen**

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 **10.** 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):

How many local sites do you want to add? \*

Please indicate the number of sites, then fill in the details and upload the documents for each site.

▶ Local Site 1

Please note that, should you have more than five sites to add, the portal will ask you to upload the related documents as zip file:

*More than 5 sites: please click on "add a site" below and upload one zip file with all required documents per additional site.*

*Maximum of 5 additional sites. If you have more than 10 sites, please contact the **Lead Ethics committee** you want to submit to.*

[add a site](#)

Then upload all required documents and enter all required information similarly to what already done for steps **72.** and **73.**

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):

**Billing address local sites \***

*(The main study site's billing address is entered on the screen 'Addresses'.)*

- The billing address for local sites on this screen is the same as for the main study site
- There is a separate billing address for local sites on this screen

**Billing address \***

255 remaining characters

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

**Next screen**

Depending on the number of local Ethics Committees identified in step **10**, you may need to repeat step **75**, accordingly for each Ethics Committee. Once done, you will access to the page described in step **76**.

**76. 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.

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

*Submission details and comments*

---

**I am submitting: \***

- first submission of this project

**Follow-ups to EC decisions**

- Follow-up to charges/conditions

**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 (silently acknowledged by EC)

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

78. 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 **73.**, 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
- other

***Silently acknowledged by EC***

- Investigator's Brochure (IB)
- Termination (regular or premature) / Final report

The two categories above let you know whether you must expect an acknowledgment/approval by the Ethics Committee or not, depending on the document/information you have updated.

79. Finally, a comment field allows you to provide details for any updates you make 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



80. 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](#)

81. 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](#)

82. You will be asked to enter the email address of the contributor to invite. Please enter [bpr@chuv.ch](mailto:bpr@chuv.ch)

## CONTRIBUTOR

E-mail address of the contributor to invite:

83. 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.

84. Then select **“Full access”** and click on **“Invite this contributor”**

Access rights to the selected screens:  

**Invite this contributor** or [cancel](#)

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

86. 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 **76.**

To access this page, login to your account by following steps **1.** to **3.**, then click on “Manage my applications”:

## MY SWISSETHICS USER ACCOUNT

**MY PROJECTS**

- [Manage my applications](#)
- [Submit a new application](#)

-  [Manage my personal data](#)
-  [Change email address](#)
-  [Change my password](#)
-  [Delete my account](#)

87. Then click on “Continue”:

- › [Continue](#)
- › [Delete the application](#)

88. Select “14. Submission Summary” on the left side of the page:

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](#)

- 89.** 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:

**Submit**

## 11. TRAINING

- RU
- RO
- ROP

**END OF PROCEDURE**