

Soumettre les mises à jour (amendements etc.) sur le site BASEC

- Préparer les fichiers des documents (Format word de préférence)
 - Pour les projets avec consentement des participants, il faut au moins le protocole d'étude mis à jour, et les feuilles d'information et de consentement
 - Si vous avez l'intention de demander une exemption de consentement, dans le cas d'études sur données ou échantillons déjà existants, consultez [l'art 34 LRH](#) et l'article [39 ORH](#), ainsi que la diapositive suivante
- RDV sur le site <https://submissions.swissethics.ch/en/>
- Marche à suivre sur le site en 3 étapes seulement :
 - utiliser votre identifiant et sélectionner le projet existant
 - télécharger les nouveaux documents et/ ou corriger le formulaire (screen)
 - Valider votre demande

Recommandation pour préparer vos documents

- Protocole et information patient: Vérifier que les versions des pieds de pages (toutes les pages) correspondent aux dates et n° de versions annoncées sur BASEC.
- Une lettre de soumission (cover letter) est toujours bienvenue pour expliquer en quelques phrases la raison de cette soumission.
- Si la soumission concerne des réponses aux remarques du comité, le tableau des remarques complété doit être téléchargé à la place de la cover letter.
- Surligner en jaunes les modifications (ou utiliser le "track change" sur word).

Sur Basec

- Surtout bien **réutiliser le même dossier avec la même référence BASEC**, pour ne pas créer un doublon (en particulier pour les projets "pré-BASEC" c'est-à-dire ceux acceptés avant la mise en place du logiciel) .
- Vous pouvez remplacer les documents par les nouveaux dans la section uploads.

Support

- [Submission FAQ](#)
(continuously updated)
- [Support Request Form](#)
(for technical questions and clarification of responsibility)
- [swissethics homepage](#)

Tools

- [abbreviations & acronyms](#)
- [glossary](#) (DE, FR, IT)
- [case studies](#) (DE, FR, IT)
- [categoriser \(wizard\)](#) (DE, FR, IT)

Links to Websites of Swiss ECs

- [EKNZ](#)
- [EC Bern](#)

IDENTIFICATION

SIGN IN VIA MY SWISSETHICS USER ACCOUNT

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

Email:

Password: ([Lost password?](#))

FIRST LOGIN

Create a user account in order to submit an application.

Email:

Password:

Confirm password:



Utiliser votre accès personnel

HOME

SUBMIT AN APPLICATION

MY ACCOUNT

LOGOUT

MY SWISSETHICS USER ACCOUNT

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MY PROJECTS

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

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

Cliquer ici pour
gérer vos projets

<https://submissions.swissethics.ch/en/>

MANAGE MY APPLICATIONS

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Links to Websites of Swiss ECs

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- [EC Bern](#)
- [EC Geneva](#)
- [EKOS](#)
- [EC Ticino](#)
- [EC Vaud](#)
- [EC Zürich](#)

UNTITLED
Research Project Application Form

Status: Draft
Last edited on: 04.07.2017, 11:28

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

UNTITLED
Pre-BASEC Research Project


Status: Draft
Last edited on: 24.05.2017, 10:12

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

FRE
Research Project Application Form

Status: Draft
Last edited on: 17.05.2017, 08:42

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



Sélectionner le projet et accéder au projet pour le modifier

Télécharger les documents modifiés ici

LEAD EC: GENERAL AND MAIN SITE'S DOCUMENT

6 / 14


*This screen is for the upload of documents that concern the **whole project** and the **main research site**.*

*If your project involves more than one research site, you will have to upload **additional documents** on screens 7 to 14, depending on which Ethics Committee is responsible for the additional sites involved (examples).*

Please be aware that the required documents depend on the answers you have entered on previous screens.

- › *To see a table of all possible project types with the required / optional documents, please click here.*
- › *To see an overview of all questions that have an influence on the set of required documents, please click here.*

1. Screen 1
2. Screen 2
3. Screen 3
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](#)

Support

- [Submission FAQ](#)
(continuously updated)
- [Support Request Form](#)
(for technical questions and clarification of responsibility)
- [swissethics homepage](#)

How to proceed:

1. *Click on the name of each document category to expand it.*
2. *Upload a document or refer to the content of another document you are uploading on this screen.*

Notes:

- › *Files are uploaded automatically after confirming the file selection*
- › ***For most files you must specify a document date and a version number. These have to be the same as written on the document (usually in the header or footer).***
- › *The participant information sheet and informed consent (ICF), the study protocol and the*

Tools

Bas de page du
screen 14:
sélectionner le

type de soumission

MISSION SUMMARY 14 / 14

1. Screen 1
2. Screen 2
3. Screen 3
4. SNCTP
5. Addresses
6. Lead EC: General information 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
- 4. Submission Summary**

[Download / print this project](#)

As of December 2016 the Ethics Committees no more need a signed copy of your submission.

*You may still download a PDF version of your submission. To do this go to **MY ACCOUNT**-->**Manage my applications**, click on **view** below your project(s). you'll find a pdf download link.*

Your form has errors. Click on an error in order to fix it.

SCREEN 1

[Manage invitations](#)

Support

- [Submission FAQ](#)
(continuously updated)
- [Support Request Form](#)
(for technical questions and clarification of responsibility)
- [swissethics homepage](#)

Help links (click to expand):

Your application concerns

Research involving persons, but not a clinical trial

(click here for an example and links to the relevant legal paragraphs)

Tools

Ethics Committee

Commission Cantonale d'éthique de la recherche Genève (CCER)

- 12. EC VD: additional sites
- 13. EC ZH: additional sites
- 14. **Submission Summary**

Sélectionner
le type de
soumission

- **Support Request Form**
(for technical and general questions)
- **Clarification of responsibility**
("Zuständigkeitsabklärung", "Clarifications des compétences", "Esame della competenza")

Contacts

for questions regarding your submission,
links to websites of the ECs:

- **EKNZ**
- **EC Bern**
- **EC Geneva**
- **EKOS**
- **EC Ticino**
- **EC Vaud**

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)

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

Comment

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

Pour le type
d'amendement
(voir liste en cas
de doute)

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

Notifications

With acknowledgement of EC

- Flyer/advertisement
- Notification of safety and protective measures
- SUSAR(Suspected Unexpected Serious Adverse Reaction)
- Local SAE / SE
- changes to SNCTP information
- other

Silently approved by EC

- Investigator's Brochure (IB)
- Annual safety report / Development safety update report (DSUR)
- Termination (regular or premature) / Final report

► Explanation: Urgent Safety Notifications for Swiss

IMPORTANT INFORMATION ABOUT UNBLINDED DATA

If you submit safety reports (SUSAR, SADE, DSUR) that contain information on treatment assignment in a double-blind study, submit the safety report in accordance with the instructions given on [this FAQ page](#).

Comment

500 remaining characters

* Required field

[Previous screen](#)

[Submit](#)

N'oubliez pas de soumettre les modifications

Voir aussi :

- **How to submit amendments, new documents or update fields of a submission?**
- [How to submit amendments, new documents or update fields of a submission? \(swissethics.ch\)](#)
- **Notez qu'en cas de changement de catégorie**, certainement champs vont disparaitre et de nouveaux seront à compléter.
I filled out the form for non-clinical trial and just realised it's a clinical trial. Will I lose all my data?
- [I filled out the form for non-clinical trial and just realised it's a clinical trial. Will I lose all my data? \(swissethics.ch\)](#)