Soumettre les mises à jour sur le site BASEC

- Préparer les fichiers des documents (Format word de préférence)
 - Pour les projets avec consentement des participant, 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 <u>l'art 34 LRH</u> et l'article <u>39 ORH</u>, ainsi que la diapositive suivante
- RDV sur le site <u>https://submissions.swissethics.ch/en/</u>
- Marche à suivre sur le site en 3 étapes seulement :
 - créer votre identifiant
 - Répondre aux questions et télécharger les documents
 - renseignez vos coordonnées

Renseignements demandés en cas d'exemption de consentement: un exemple

Questions on BASEC screen 3

- 1. 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.
- 2. 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?
- 3. A short description of the purpose for which further use may be made of the samples and/or health related data (Art. 39a HRO)
- 4. Description of the samples, and/or health related data. See <u>Art. 39b HRO</u>
- 5. Description of the group of persons who are entitled to pass on samples or data (<u>Art. 39c HRO</u>)
- 6. Designate the person who is entitled to receive samples or data, and who is responsible for data protection
- 7. How long will the data and/or samples be stored?

Example of a possible answer

- 1. This is a study using stored biopsies of patients with lung cancer, from 2000 to 2010. Most, if not all of them are deceased.
- 2. Although the biopsy donors will not profit from this study), we are confident that this study will improve lung cancer diagnostics in the future
- 3. We plan to screen biopsy material from confirmed lung cancer patients for biochemical and genetic markers with prognostic significance
- 4. Biopsy material and medical data from patients of the University hospital X who have had a diagnosis of lung cancer between 2000 and 2010
- 5. The attending physicians and personal involved in the institutes of pneumology and pathology of the University hospital X
- 6. The Project Leader, Dr. Dupont
- 7. The copies of the data from the patient files will be destroyed after publication of our paper.

IDENTIFICATION

Support

- <u>Submission FAQ</u> (continuously updated)
- <u>Support Request Form</u> (for technical questions and clarification of responsibility)
- swissethics homepage

Tools

- <u>abbreviations & acronyms</u>
- glossary (DE, FR, IT)
- case studies (DE, FR, IT)
- <u>categoriser (wizard)</u> (<u>DE</u>, <u>FR</u>, <u>IT</u>)

Links to Websites of Swiss ECs

- <u>EKNZ</u>
- <u>EC Bern</u>
- <u>EC Geneva</u>
- EC St. Gallen
- <u>EC Thurgau</u>

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?)
Login	

FIRST LOGIN

Create a user account in order to submit an application.

Email:

This field is required.

Password:

This field is required.

Confirm password:

Create my swissethics user account



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

MY SWISSETHICS USER ACCOUNT

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

Support

 <u>Submission FAQ</u> (continuously updated)

<u>Support Request Form</u> (for technical and general questions)

<u>Clarification of</u> <u>responsibility</u>

("Zuständigkeitsabklärung", "Clarifications des compétences", "Esame della competenza")

Contacts

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

links to websites of the ECs

- <u>EKNZ</u>
- <u>EC Bern</u>
- <u>EC Geneva</u>
- <u>EKOS</u>
- <u>EC Ticino</u>
- <u>EC Vaud</u>
- EC Zürich

Contact swissethics:

- info@swissethics.ch
- swissethics homepage

Tools

- abbreviations & acronyms
- dlossarv (DF, FR, IT)

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.

To update a project sent through this form, please go to My Account--> Manage my applications (see also <u>this help-article</u>).

Submit an application

PRE-BASEC RESEARCH PROJECT

Please use this form for upates and amendments to projects that were initially submitted outside of the online submission system (BASEC).

After the first submitted update, please always update the project through the form in your account: go to *My Account--> Manage my applications* (see also this help-article).

Submit an application

Cliquer ici

SAFETY NOTIFICATION AND REPORTING

Please use this form to submit safety reports (SAEs, SEs, SUSARs, ASR/DSURs, ...) and for the notification of immediate safety and protective measures.

If the research project is double-blind the owner of the safety form must be authorized to see the treatment assignment (see <u>this help-article</u> for an explanation on the roles and responsibilities of the owner of the safety form).

After the first submission of a safety report, use the form in your account (go to *My Account--> Manage my applications*) to submit further safety reports. Do not open a new safety form if your project has already one.

Submit an application

CLARIFICATION OF RESPONSIBILITY / SUPPORT REQUEST

Use this form for **jurisdictional inquiries** ("Zuständigkeitsabklärungen", "Clarification des compétences", "Esame della competenza") and for **support-questions**.

Submit an application

Compléter votre
adresse

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City *		
Email *		
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It's preferred but not mandato or the language of the (Lead) E Template (.docx): <u>DE</u> , <u>FR</u> , <u>EN</u> ,	Ethics Committee.	e for the synopsis. Please write in English
Other documents		
		Comment
Upload add a document		

Voir aussi :

- Submissions concerning old multi-centric projects (pre-BASEC)?
- http://swissethics.ch/basec_frontend_faq/knowledgebase.php?article=18