

Mon projet doit-il être soumis à la CCER ?

- Formulé autrement: Mon projet entre-t-il dans le champ d'application de la Loi sur la recherche humaine (LRH)?
- LRH, art. 2: Tout protocole de recherche sur l'être humain, qui se déroule en Suisse, qui étudie la maladie, la structure et le fonctionnement du corps humain et qui cherche à produire des connaissances généralisables, doit être soumis à la Commission d'éthique du canton compétent.
- **Depuis le 1^{er} janvier 2016, toutes les demandes se font par voie électronique** par le portail internet **BASEC** (Business Administration System for Ethics Committees) est accessible à l'adresse :

<https://submissions.swissethics.ch>

Des exemples de recherches à ne pas soumettre

- N'entrent pas dans le champ d'application de la loi:
 - *les projets de contrôle de qualité*
 - *les revues de littérature*
 - *les rapports de cas rétrospectifs incluant 5 cas ou moins*
 - *les enquêtes d'opinion, par exemple sur la qualité des soins*
 - *les recherches sur le matériel biologique **anonyme***
 - *les recherches sur les données personnelles liées à la santé **anonyme***
 - *les recherches sur les données personnelles liées à la santé collectées **anonymement***

Précisions sur le cas des données dites «anonymes» ou "anonymisées:"

- Attention la loi différencie les termes "anonyme" et « codé ». Anonymisation présuppose une destruction irréversible du lien entre les échantillons ou les données, et l'individu duquel ils proviennent. Au contraire, le codage signifie qu'il existe une liste de correspondance, permettant de lier le code à un individu.
- Exemple de recherche sur du matériel biologique anonyme: Teneur en plomb de 250 dents de lait collectés entre 1972 et 1978, trouvés dans le tiroir du bureau d'un professeur parti à la retraite...

Soumettre ma question sur le site BASEC

- La soumission de votre question se fait dorénavant par voie électronique sur BASEC :

<https://submissions.swissethics.ch>

- Pour préparer un **résumé du projet**, nous vous recommandons d'utiliser le modèle proposé au cours de la soumission :

https://swissethics.ch/assets/basec/Basec_assets/templatezustandigkeitsabklaerungen.docx

- Marche à suivre sur le site en 3 étapes seulement :
 - créer votre identifiant
 - poser votre question et télécharger les documents
 - renseignez vos coordonnées

Non entrée en matière ou prise de position ?

- Si votre projet est hors du champs d'application de la loi de la recherche sur l'être humain, la CCER vous répondra par message via BASEC. Cette déclaration ne correspond ni à une décision ni à une autorisation et ne comprend pas d'examen scientifique complet.
Un numéro de référence (ex: Req_2020-xxxx) sera attribué à la demande.
Voir : [Submission of a clarification of responsibility \(formerly : 'jurisdictional enquiry'\) \(swissethics.ch\)](#)

- Si vous souhaitez obtenir une évaluation d'un projet hors du champs d'application; mais dans un domaine proche de la recherche médicale, la CCER peut délivrer une prise de position (Base légale : art. 51, al. 2, LRH).
[Submission of an 'Advice on ethical questions/comments on research projects not subject to the HRA' \(swissethics.ch\)](#).

Exemple : registre, biobanque, projets hors de Suisse ...

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](#)
- [EC Geneva](#)
- [EC St. Gallen](#)
- [EC Thurgau](#)

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?](#))

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



Créer 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 sur
"new application"

Support

- [Submission FAQ](#)
(continuously updated)
- [Support Request Form](#)
(for technical and general questions)
- [Clarification of responsibility](#)
(Do I need to submit my project?)

Contacts

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

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

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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](#)

RESEARCH PROJECT APPLICATION FORM FOR MEDICAL DEVICES

Please use this form for new projects that fall within the scope of the Ordinance on Clinical Trials of 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](#)

SAFETY NOTIFICATION AND REPORTING

Please use this form to submit safety reports (SAEs, SEs, SADES, 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 treatment assignment (see [this help-article](#) 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 a safety project has already one.

[Submit an application](#)

APPLICATION FOR A TEMPORARY AUTHORISATION

Use this form to submit a temporary authorisation for the use of medicinal products in accordance with Article 9b paragraph 1 of Therapeutic Products Act, TPA.

[Submit an application](#)

ADVICE ON ETHICAL QUESTIONS/COMMENTS ON RESEARCH PROJECTS NOT SUBJECT TO THE HRA

Use this form to obtain an advice on a data registry or on a biobank (without a concomitant submission of a research project), to obtain comments on ethical questions and a research project not subject to the HRA, and specifically projects carried out abroad, or to obtain an advice on documents, informed consent forms, procedures, etc. The research project must be close to the ethics committee's area of expertise. The form fulfils the requirements set by [Article 51 lit 2 HRA](#).

[Submit an application](#)

PRE-BASEC RESEARCH PROJECT

Please use this form for updates 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](#)


CLARIFICATION OF RESPONSIBILITY / SUPPORT REQUEST / RESEARCH PROJECT IN ACCORDANCE WITH THE STEM CELLS RESEARCH ACT (STRA)

Use this form for to submit a clarification of responsibility ("Zuständigkeitsabklärungen", "Clarification des compétences", "Esame della competenza"), i.e. if you need an answer to the question: "Do I need to submit my project?". See [this help article](#) for an explanation on how to submit a clarification of responsibility.

Use this form to submit a technical or general question.

Use this form to submit a research project which involves human embryonal stem cells in accordance with the [Stem Cell Research Act \(StRA\)](#).

[Submit an application](#)



Cliquez ici pour une demande de clarification

CLARIFICATION OF RESPONSIBILITY / SUPPORT REQUEST 1 / 2

1. Clarification of responsibility / support request
2. Summary

Support

- [Submission FAQ](#)
(continuously updated)
- [Support Request Form](#)
(for technical and general questions)
- [Clarification of responsibility](#)
(Do I need to submit my project?)

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

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- [EC Ticino](#)
- [EC Vaud](#)
- [EC Zürich](#)

Contact swissethics:

- info@swissethics.ch
- [swissethics homepage](#)

Tools

This form is for the following types of requests:

› **Clarification of responsibility** (de: "Zuständigkeitsabklärung", fr: "Clarification des compétences", it: "Esame della competenza").

Do I need to submit my project?, Muss ich mein Projekt einreichen?, Dois-je soumettre mon projet? Devo presentare il mio progetto?

The Ethics Committees evaluate projects that fall under the following definition from [art. 2](#) of the Federal Act on Research involving Human Beings ([DE](#), [FR](#), [IT](#)):

"This Act applies to research concerning human diseases and concerning the structure and function of the human body, which involves:

- › a. persons
- › b. deceased persons
- › c. embryos and fetuses
- › d. biological material
- › e. health-related personal data"

› **Technical support request:** technical problems regarding the form(s).

› **General question:** general non-technical questions about re submission of projects.

For any other questions please contact the EC you intend to submit to by phone. The websites of all ECs are linked on the left of this page.

Type of request *

Clarification of responsibility ▼

This request should be directed to *

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

Title or short description of your planned project

Choisir
«Clarification of
responsability»

This form is for the following types of requests:

- › **Support request:** technical problems regarding the use of the submission form(s).
- › **Jurisdictional inquiry:** clarification of responsibility (de: "Zuständigkeitsabklärung", fr: "Clarification des compétences", it: "Esame della competenza").

The Ethics Committees evaluate projects that fall under the following definition from [art. 2](#) of the Federal Act on Research involving Human Beings ([DE](#), [FR](#), [IT](#)):

"This Act applies to research concerning human diseases and concerning the structure and function of the human body, which involves:

- › a. persons
- › b. deceased persons
- › c. embryos and fetuses
- › d. biological material
- › e. health-related personal data"

For any other questions please contact the EC you want to submit to by Email or phone. The websites of all ECs are linked on the left of this page.

Type of request *

Jurisdictional inquiry ▼

This request should be directed to *

-- ▼

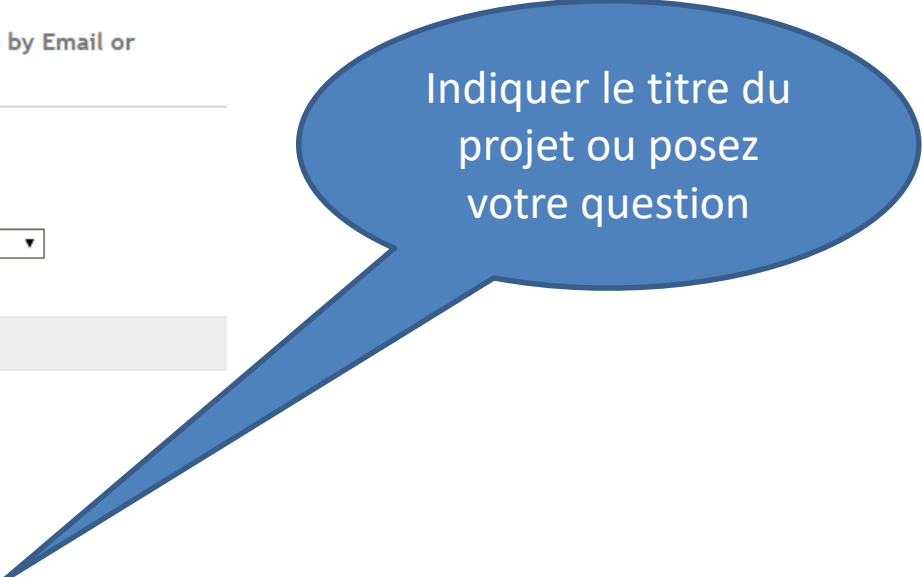
Your question(s) to the Ethics Committee *

Rich text editor toolbar with icons for bold, italic, underline, text color, list, link, and unlink.

Characters: 0

Contact information *

Ms/Mr *



Indiquer le titre du projet ou posez votre question

Compléter votre
adresse

Street Address *

255 remaining characters

Zip Code *

City *

Email *

Telephone *

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

File Uploads

The upload of the Synopsis is required. You may add any other documents that help the EC for the clarification of responsibility.

Synopsis of the study plan *

It's preferred but not mandatory to use the following template for the synopsis. Please write in English or the language of the (Lead) Ethics Committee.

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

 Upload

Other documents

[add a document](#) Upload

Comment

* Required field

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VALIDER VOTRE DEMANDE

Validate and send

Télécharger le
fichier