

Guideline

«Ethics submission with the DKF»

Are you planning a clinical trial or research project that requires approval by the Ethics Committee and would you like to receive feedback from a DKF regulatory expert before submission? In this case, this guideline should help you to proceed efficiently to be able to start your study quickly.

1. Allocation to the correct ordinance and category according to the Human Research Act (HRA)

This step is important because the ordinance determines which documents must be submitted. Decisive criteria for the correct allocation are:

- whether your study involves an intervention, i.e. it intervenes in the treatment of participants and is conducted in accordance with the Ordinance on Clinical Trials (ClinO),
- whether a medical device is being evaluated in your study (CTO-MedD),
- whether you are planning an observational study (without intervention) (HRO-Chap. 2),
- or whether you want to further use existing biological material and/or health-related data (HRO-Chap. 3 to 5).

After allocation to the ordinance, the risk categorisation must be carried out. A study falls into category A if the therapeutic product, medical device or health-related intervention investigated is authorised on the Swiss market and is used as intended. The higher categories B and C apply if deviations from this are implemented. In the case of observational studies, category A applies if the collection of data or samples is associated with "only minimal risk".

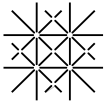
If you are not sure under which ordinance and category your study falls, the following website provides help: <https://www.kofam.ch/en/categoriser/>

If you are still not sure, please contact the DKF regulatory staff. We will help you find the correct assignments: regulatorik.dkf@usb.ch or study hotline + 41 61 328 66 11.

2. Required documents

First of all, you need a list of the required documents. Here you can find an overview for clinical trials (ClinO and CTO-MedD):

https://swissethics.ch/assets/basec/Basec_assets/210705_basec_list-of-all-documents_clinical-trials.pdf



And here for observational studies and further use projects (HRO-Chap. 2 and 3):
https://swissethics.ch/assets/basec/Basec_assets/200414_basec_list-of-all-documents_research-projects.pdf

3. Preparation of the documents

At <https://swissethics.ch/en/templates> you will find templates of the corresponding documents that need to be created. Please download the current templates and adapt them specifically for your project.

4. Access to BASEC

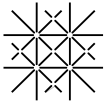
BASEC (<https://submissions.swissethics.ch/en/>) is the national portal for submissions to the ethics committees in Switzerland. If you do not yet have an account on BASEC, click on «Login» and then on «First Login - create an account». You can either create a personal account (firstname.lastname@usb.ch) or a study-specific account (e.g. best.studyever@usb.ch). The study-specific email address must be set up by your local ICT (at the USB via SOS Helpdesk) and has the advantage that it can be used by several staff members.

5. General information and uploading of documents

First, you will be taken to your access page, where you select «Submit a new Application».

Depending on which of the options described below you select, the corresponding forms will be made available for filling in on the following pages in the portal:

- «Research Project Application Form» for all clinical trials (ClinO) and observational projects (HRO-Chap.2 to 5)
- «Research Project Application Form for Medical Devices» for all studies with medical devices (CTO-MedD)
- «Safety Notification and Reporting» for safety reports after the start of the study
- «Application for a temporary authorization» for a limited application permit
- » Form to obtain advice on a data registry or biobank without concomitant submission of research project or for a project that is carried out abroad.
- «Pre-BASEC Research Project» for projects before the introduction of BASEC
- «Clarification of Responsibility» for example to clarify whether a submission to Ethics Committee is necessary



Next, please complete the general information on the study on pages 1-5 and upload your documents from page 6 onwards.

By selecting «Submission Summary» you can check at any time which details and documents are still missing.

6. Review by a DKF regulatory expert

If you would like a DKF staff member to review your documents and entries, you will find the field «Manage invitations» in BASEC on the left-hand side of the entry pages for your study/project.

Manage invitations

Select «Invite a contributor» there. Then add the email address regulatorik.dkf@usb.ch and give us «full access» for all points.

We will then receive an automated message confirming that we have received your request. A member of the Regulatory Affairs team will then look through your entries and documents and get back to you with feedback, usually within 3-5 days.

We note the review and return the project to you. After that, we can no longer view or edit the project entry in BASEC. After our review and any revisions, you can submit your application to the Ethics Committee by clicking on the «submit» button.

The last step after the submission in BASEC is to create the final submission summary by reopening your project in BASEC and downloading the document «Summary of submission». This document lists all submitted documents with date and version number.

Your project has now received a BASEC-ID number, which you can use to identify your project at any time. Furthermore, an automatically generated email will confirm the successful submission and within 7 days you will receive a confirmation of receipt with initial feedback from the Ethics Committee by email.

Please carefully file all submitted documents, the correspondence with the Ethics Committee and the document «Summary of submission».

7. After receiving a decision letter

The Ethics Committee will contact you after assessing your application. If you have any questions about the decision letter from the Ethics Committee, please feel free to contact us again via the study hotline (+ 41 61 328 66 11) or regulatorik.dkf@usb.ch.