

## What is BASEC and how does it affect your submission process?

### What is BASEC?

- The acronym stands for Business Administration System for Ethics Committees. It is a web application with two main components: a Front End for applicants who intend to submit research projects, and a Back End for administration of submitted projects by the Ethics Committees.
- All information entered into BASEC will be stored in a secure data centre located in Switzerland, offering the necessary safeguards for back-ups and confidentiality

### What are the potential advantages of BASEC?

- The system is interactive: based on the information an applicant provides, BASEC will determine which documents need to be uploaded, and which form-fields need to be filled in. A project can only be submitted if all required information is entered, and all the required documents are uploaded. This should eliminate the frequent delays caused by incomplete submissions and will replace the current checklist system. The submission form stores incomplete applications: you can start an application and finish at a later date without losing already entered data.
- Abundant explanations and links are provided to guide the applicant through the application process.
- Administration of research projects (via the Back End) will be uniform among all Swiss Ethics Committees.
- Improved communication through BASEC will speed up the examination of multicentre projects.
- Statistics regarding the activity of the ECs will be easier to establish and more reliable than before

### Who developed BASEC ?

- A project group included representatives of the seven major Swiss ECs (BE, EKNZ, GE, SG, TI, VD, ZH) under the direction of Bernard Hirschel (Geneva).
- A commercially available program called Optimy was adapted to the needs of the Swiss ECs by Michael Tüller (Bern) and Arthur Zinn-Poget (Lausanne).

### How can I access BASEC?

- Go to <https://submissions.swissethics.ch>. You can register there to create an account. Starting on October 26, 2015 the submission form will be visible in your account, and you may start to enter projects. The 'submit' button on the form will be activated on November 2<sup>nd</sup> 2015. You will not lose data entered between October 26 and November 2<sup>nd</sup>.

### *I have a not yet approved study under evaluation by an EC: How does the introduction of BASEC affect this study?*

- Your application will not be affected by the start of BASEC. The procedure will remain the same as it was before November 2015.

### *I have a (paper/CD)-submission ready / am currently preparing a submission: do I need to re-enter it through BASEC, if I haven't submitted before 2.11.2015?*

- We encourage you to submit your project online, starting on November 2<sup>nd</sup> 2015. You may still submit by traditional methods until the end of 2015. If your project is indented for submission in 2016, you will have to use the online submission in BASEC.

*I need to send an update (amendment, SUSAR, yearly safety report etc.) for a running study: How do I proceed?*

- The process remains the same until the end of 2015 (paper/CD/Email etc). In 2016 swissethics will offer another submission form inside the web-portal for these projects. This form will only ask for minimal basic data about the project, and it will contain the necessary fields to submit the new information. After the release of this additional form, no submissions outside the web-portal will be accepted.

*Can I still use the old PDF-form (the Base form) and checklists to submit after 1.11.2015?*

- Base Form and Checklists won't be required when using BASEC, because BASEC will automatically fit the requirements to the contents of your application (see above "*What are the potential advantages of BASEC*"). The old Base Form and the checklists are still required, if you're not using BASEC during the transitional period (November/December 2015).

*How will you communicate about my submitted projects?*

- Documents will be submitted to the ECs through BASEC. Most subsequent communication will be electronic, through the email account indicated in the electronic submission form.

*What about the checklists for documents that are required?*

- In principle, checklists will no longer be necessary, because BASEC will automatically determine which documents need to be uploaded by analysing your answers on screens 1 to 3 in the submission form. The help in the form will specify which answers have an effect on the list of required documents.
- If you would like to know which documents are needed before starting to enter your project "for real", the online-form will offer a downloadable overview of all document requirements for all possible project types.

*I have an approved clinical trial not yet in SNCTP: how do I register it in SNCTP?*

- You first have to register the approved trial in a Primary Registry of the WHO Registry Network (<http://www.who.int/ictrp/network/primary/en/>) or <https://clinicaltrials.gov/>. You will obtain a trial identification number. With this number, go to <http://www.kofam.ch/en/snctp-portal/registering-a-clinical-trial> and register your trial. Please note that clinical trials only, but not other types of research projects, need to be registered.

*How does the registration in SNCTP work for projects submitted through BASEC ?*

- BASEC will simplify the SNCTP registration process, because information collected through BASEC will be transferred into SNCTP. You still have to register your trial in a Primary Registry of the WHO Registry Network (<http://www.who.int/ictrp/network/primary/en/>) or in [clinicaltrials.gov](http://clinicaltrials.gov). The interface between BASEC and SNCTP is under development.

For all other questions regarding the introduction of BASEC, please send an email to Bernard Hirschel: [Bernard.hirschel@hcuge.ch](mailto:Bernard.hirschel@hcuge.ch)