Notification and reporting to the ethics committee

Notifications and reporting to the ethics committee (EC) is done electronically through BASEC (https://submissions.swissethics.ch/en/). Instructions are given in BASEC (direct link here).

Clinical trials [Clinical Trials Ordinance, ClinO]

Reporting of safety and protective measures (Art. 37, ClinO)

Notification to the EC within 7 days.

Trials of medical devices: Notification to the EC within 2 days.

Completion, discontinuation or interruption of the clinical trial (Art. 38, ClinO)

Notification of completion to the EC within 90 days.

Notification of discontinuation or interruption to the EC within 15 days.

Note: A template for the notification of completion, discontinuation or interruption of the clinical trial is available on swissethics.ch. The applicant submits the notification through BASEC to the (Lead-) EC.

A final report must be submitted through BASEC to the (Lead-) EC within one year of completion, discontinuation or interruption of the clinical trial.

Serious adverse events (SAEs) in clinical trials of medicinal products (Art. 40, ClinO)

Unless otherwise specified in the protocol, SAEs with fatal consequences within 7 days

Note: A template for the notification is available on swissethics.ch. The applicant submits the SAEs through BASEC to the (Lead-) EC.

Suspected unexpected serious adverse reactions (SUSARs) (Art. 41, ClinO)

SUSARs with fatal consequences within 7 days, other SUSARs within 15 days.

Note: The applicant submits the SUSARs through BASEC to the (Lead-) EC.

Only initials SUSARs and the final reports ("outcome") must be notified to the ECs each time. In the case follow-up reports contain important ‚safety'-Information, these should also to submitted to the ECs.

Serious adverse events (SAEs) in clinical trials of medical devices (Art. 42, para 1a ClinO)

In Category C trials, SAEs where a connection is suspected with the investigational device or intervention, within 7 days.

Note: The applicant submits the SAEs through BASEC to the (Lead-) EC.

Device deficiencies in clinical trials of medical devices (Art. 42, para 1b ClinO)

Notification of device deficiencies that could have led to serious adverse events if suitable action had not been taken, intervention had not been made, or circumstances had been less fortunate, within 7 days

Note: The applicant submits the device deficiencies through BASEC to the (Lead-) EC.

Serious adverse events (SAEs) that may be related to the intervention under investigation in other clinical trials (Art. 63 ClinO)

Notification to the EC within 15 days.

Note: The applicant submits the SAEs through BASEC to the (Lead-) EC.

Annual reporting on the safety of participants (Art. 43 ClinO)

List of global events (Annual Safety Report [ASR]/ Development Safety Update Report [DSUR]) is submitted annually.

Note: The ASR/DSUR is submitted through BASEC to the (Lead-) EC. The report must also include the changes that do not require approval (i.e. all changes that are not significant according to Art. 29 ClinO). A Template for drafting an ASR for Investigator initiated trials' (IITs) is available on swissethics.ch

Notification on the use of radiation sources (Art. 44 ClinO)

In clinical trials involving therapeutic products capable of emitting ionising radiation, and in investigations using radiation sources, if the permitted dose guidance value is exceeded at any time, the investigator shall notify the (Lead-) EC within 7 working days of it becoming known.

Note: The notification is done via BASEC on screen 6, under the section for subsequent document submissions, chapter S.5.

Research projects not involving clinical trials [Human Research Ordinance, HRO]

Research with human subjects associated with measures for sampling biological material or the collection of health-related personal data

Safety and protective measures (Art. 20, HRO)

Notification of the EC within 7 days.

Serious events (SEs) (Art. 21, HRO)

Notification within 7 days and interruption of the research project.

Note: The applicant submits the SEs through BASEC to the (Lead-) EC. A template for the notification of SEs is available on swissethics.ch.

Notification on the use of radiation sources (Art. 23, HRO)

In case of investigation using radiation sources, if the permitted dose guidance value is exceeded at any time, the project leader shall notify the (Lead-) EC within 7 working days of it becoming known.

Note: The notification is done via BASEC on screen 6, under the section for subsequent document submissions, chapter S.5.

Completion or discontinuation of a research project (Art. 22, HRO)

Notification of the EC within 90 days.

Note: A template for the notification of completion or discontinuation of the research project is available on swissethics.ch.

Further use of biological material and health-related personal data for research purposes (Art. 36, HRO)

Change of project leader

Prior notification of the EC.

Completion or discontinuation of the research project

Notification of the EC within 90 days.

Note: A template for the notification of completion or discontinuation of the research project is available on swissethics.ch.

Further use of biological material and health-related personal data for research purposes in the absence of informed consent according to Article 34 HRA [Human Research Act, HRA] (Art. 40, HRO)

Changes to the information given in the authorisation

Prior notification of the EC.

Completion or discontinuation of the research project

Notification of the EC within 90 days.

Note: A template for the notification of completion or discontinuation of the research project is available on swissethics.ch.

Research on deceased persons (Art. 43, HRO)

Change of project leader

Prior notification of the EC.

Research projects involving deceased persons undergoing artificial respiration
Significant changes to the research protocol

Prior notification of the EC.

Completion or discontinuation of the research project

Notification of the EC within 90 days.

Note: A template for the notification of completion or discontinuation of the research project is available on swissethics.ch.