Notification and reporting to the ethics committee according to the Clinical Trials Ordinance (ClinO) and according to the Human Research Ordinance (HRO)

Notifications and reporting to the ethics committee (EC) is done electronically through BASEC.
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.

A final report must be submitted 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.

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

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

Note: 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) that may be related to the intervention under investigation in other clinical trials (Art. 63 ClinO)

Notification to the EC within 15 days.

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 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.

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 (HRO Chapter 2)

Significant changes to an authorised research project (Art. 18, HRO)
Prior notification of the EC.

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: 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.

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 (HRO Chapter 3)

Change of project leader (Art. 36, HRO)
Prior notification of the EC.

Completion or discontinuation of the research project (Art. 36, 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 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.