Overview on safety reporting and other notifications to the ethics committee in clinical trials according to ClinO and research projects according to HRO

General notes:

The following tables give an overview on safety reporting and other notifications obligations to the ethics committee in clinical trials according to ClinO and research projects according to HRO.

An overview on safety reporting in clinical trial on medical devices to the ethics committee, according to ClinO-MD is available on swissethics.ch / checklists / notifications.

Safety reporting and notifications to the ethics committee are done electronically through BASEC.

Instructions on how to do notifications can be found on the FAQ page in BASEC.

Consult ClinO for safety reporting and other notifications obligations to Swissmedic and FOPH.

To ensure safety reporting is not delayed, the investigator/project leader may provisionally submit incomplete reports.

Instead of the investigator, the sponsor may assume the notification and reporting obligations vis-à-vis the ethics committee, if this is provided for in the application documents (Art. 44a, ClinO).

Abbreviations:

HRA: Human Research Act

ClinO: Clinical Trials Ordinance (KlinV, OClin, OSRUm)

ClinO-MD: Ordinance on Clinical Trials with Medical Devices

HRO: Human Research Ordinance (HFV, ORH, ORUm)

TPA: Therapeutic Products Act (HMG, LPTh, LATer)

Content:

Clinical trials (ClinO)

Clinical Trials of Medicinal Products, Products under Article 2a paragraph 2 TPA and Transplant Products (Art. 23a, 29, 37, 38, 41-43, chapter 2, ClinO)

Notifications requirements:

Enrolment of the first participant (Art. 23a, ClinO)

The investigator notifies the ethics committee the enrollment of the first participant within 30 days.

Note: The first participant must be enrolled within two years after the last authorisation required has been granted. If the first participant is not enrolled in the clinical trial within the deadline, then the clinical trial is considered to be interrupted as specified in Art. 38. The clinical trial may only be commenced if a request for a deadline extension has been approved.

Substantial modifications to an authorised research project (Art. 29, ClinO)

The investigator submits to the ethics committee any application documents specified in Annex 3 which are affected by the modification. The investigator also provides information on the reasons for the modifications.

Other modifications must be notified to the ethics committee annually in the report specified in Article 43 ClinO (see below).

Note: A list of modifications considered to be substantial modifications is available on swissethics.ch / checklists / notifications.

Safety and protective measures (Art. 37, ClinO)

If immediate safety and protective measures have to be taken during the conduct of a clinical trial, the investigator notifies the ethics committee of these measures, and of the circumstances necessitating them, within 7 days.

In the case of clinical trials of products under Article 2a paragraph 2 TPA, this notification is made within 2 days.

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

The investigator notifies the ethics committee of a SUSAR with life-threatening or fatal consequences occurring in Switzerland within 7 days, and of any other suspected unexpected serious adverse reaction within 15 days.

The notification is due also if the investigator or the sponsor become aware of a SUSAR which has occurred after completion of the clinical trial in Switzerland, or if the investigator or the sponsor only become aware of a suspected reaction of this kind after completion of the clinical trial.

Note: Only initial SUSARs and the final reports ("outcome") must be notified to the ethics committee. In the case follow-up reports contain new important safety-information, these should also to submitted to the ethics committee.

Serious adverse events (SAE) and deficiencies in clinical trials of products under Article 2a paragraph 2 TPA (Art. 42. ClinO)

The investigator notifies the ethics committee within 7 days of the following:

a. serious adverse events which occur in participants in Switzerland in the course of a Category C clinical trial of products under Article 2a paragraph 2 TPA and where it cannot be excluded that the events are attributable:
   1. to the product under investigation, or
   2. to an intervention undertaken in the clinical trial;
b. deficiencies in the product under Article 2a paragraph 2 TPA under investigation 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 favourable.

Completion, premature termination, interruption and resumption of the clinical trial (Art. 38, ClinO)

The investigator notifies the ethics committee, within 30 days, of the completion of the clinical trial in Switzerland.

The investigator notifies the ethics committee, within 90 days, of the global completion of a multinational clinical trial.

Note: Completion of a clinical trial is marked by the last participant's final follow-up visit, in the absence of provisions to the contrary in the protocol.

The investigator notifies the ethics committee of the early termination, interruption or resumption of the clinical trial within 15 days. In the notification, the reasons for the early termination, interruption or resumption must be stated. An interruption lasting for more than two years is considered to be an early termination.

Note: A template for the notification of completion, discontinuation or interruption of the clinical trial is available on swissethics.ch.

The investigator submits a summary final report to the ethics committee within a year after completion or early termination of the clinical trial, unless a longer period is specified in the protocol.

Annual reporting on the safety of participants and general progress report (Art. 43, ClinO)

Once a year, the investigator presents to the ethics committee a list of events and deficiencies in the product under Article 2a paragraph 2 TPA under investigation and adverse reactions as specified in Articles 40–42. On this basis, the investigator shall report on their severity and causal relationship to the intervention, and on the safety of participants, and shall inform the ethics committee about the general progress of the clinical trial.

In the case of clinical trials also conducted abroad according to the same protocol, the events and deficiencies in the product under Article 2a paragraph 2 TPA under investigation and adverse reactions occurring abroad must also be included in the list and the report.

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 writing a safety and progress report is available on swissethics.ch / templates / notifications

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

In clinical trials involving therapeutic products capable of emitting ionising radiation, if the permitted dose guidance value is exceeded at any time, the investigator notifies the ethics committee within 7 days of it becoming known.

Other clinical trials (chapter 4, ClinO)

Notifications requirements (applicable provisions Art. 62, ClinO):

The provisions which apply mutatis mutandis are (see previous table, chapter 2, ClinO):

a. Substantial modifications to an authorised research project (Art. 29, ClinO)
b. Enrolment of the first participant (Art. 38, ClinO)
c. Safety and protective measures (Art. 37, ClinO)
d. Completion, premature termination, interruption and resumption of the clinical trial (Art. 38, ClinO)
e. Annual reporting on the safety of participants and general progress report (Art. 43 ClinO);
f. Notification on the use of ionising radiation (Art. 44 ClinO)

Serious adverse events (SAEs) that may be related to the intervention under investigation (Art. 63, ClinO)

If, in the course of the clinical trial, SAEs occur in participants in Switzerland, and it cannot be excluded that the events are attributable to the intervention under investigation, the investigator reports these events to the ethics committee within 15 days.

Note: A SAE report form is available on swissethics.ch / templates / notifications

Note: Only initial SAEs and the final reports ("outcome") must be notified to the ethics committee each time. In the case follow-up reports contain new important ‚safety'-Information, these should also to submitted to the ethics committee.

Research projects (HRO)

Research with human subjects associated with measures for sampling biological material or the collection of health-related personal data (Art.18, 20-23, chapter 2, HRO)

Notifications requirements:

Substantial modifications to an authorised research project (Art. 18, HRO)

The project leader submits to the ethics committee any application documents specified in Annex 2 HRO which are affected by the modifications. The project leader also provides information on the reasons for the modifications.

Note: A list of modifications considered to be substantial modifications is available on swissethics.ch / checklists / notifications.

Notification of safety and protective measures (Art. 20, HRO)

If immediate safety and protective measures have to be taken during the conduct of a research project, the project leader notifies the ethics committee of these measures, and of the circumstances necessitating them, within 7 days.

Note: To ensure reporting is not delayed, the sponsor and investigator may provisionally submit an incomplete report.

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

The project leader notifies the ethics committee within 7 days.

The research project must be interrupted.

In addition, the project leader reports to the ethics committee on the connection between the event and the collection of health-related personal data or the sampling of biological material. At the same time, the project leader submits proposals concerning the next steps.

Note: A template for the notification of SEs is available on swissethics.ch / templates / notifications.

Note: To ensure reporting is not delayed, the sponsor and investigator may provisionally submit an incomplete report.

Completion or premature termination of the research project (Art. 22, HRO)

The project leader notifies the ethics committee of the completion or premature termination of a research project within 90 days.

Note: A template for the notification of completion or premature termination of the research project is available on swissethics.ch / templates / notifications

Assessment, notification and reporting on the use of ionising radiation (Art. 23, HRO)

In case of research project involving any use of ionizing radiations, if the permitted dose constraint is exceeded, the project leader notifies the ethics committee within 7 days of it becoming known.

Note: To ensure reporting is not delayed, the sponsor and investigator may provisionally submit an incomplete report.

Within a year of the completion or early termination of a research project which included accompanying investigations involving ionising radiation, the project leader submits to the FOPH a final report including all information of relevance for radiological protection, and in particular a retrospective dose estimation for the participants.

Further use of biological material and health-related personal data for research purposes (Art. 36, chapter 3, HRO)

Notification requirements:

The project leader notifies the ethics committee of a change of project leader in advance.

The project leader notifies the ethics committee of the completion or premature termination of the research project within 90 days.

Note: A template for the notification of completion or premature termination of the research project is available on swissethics.ch / templates / notifications

Further use of biological material and health-related personal data for research purposes in the absence of informed consent according to Article 34 HRA (Art. 40, chapter 3, HRO)

Notification requirements:

The project leader notifies the ethics committee in advance of any modifications to the information given in the authorisation.

The project leader notifies the ethics committee of the completion or premature termination of the collection process within 90 days.

Note: A template for the notification of completion or premature termination of the research project is available on swissethics.ch / templates / notifications

Research on deceased persons (Art. 43, chapter 4, HRO)

Notification requirements:

The project leader notifies the ethics committee in advance of the following modifications to the research project:

a. change of project leader;

b. for research projects involving deceased persons undergoing artificial respiration: substantial changes to the protocol.

The project leader notifies the ethics committee of the completion or premature termination of the research project within 90 days.

Note: A template for the notification of completion or premature termination of the research project is available on swissethics.ch / templates / notifications.