swiss clinical trial organisation

swissethics

Schweizerische Ethikkommissionen für die Forschung am Menschen
Commissions d'éthique suisses relative à la recherche sur l'être humain
Commissioni etiche svizzere per la ricerca sull'essere umano
Swiss Ethics Committees on research involving humans

HRO research project: Serious Event Report[1]

Please complete the form by replacing all text modules in square brackets. Use "x" for check boxes.

The project leader must report a serious event (SE), where causality cannot be excluded, to the ethics committee within 7 days. In the event that a sponsor[2] takes responsibility for the research project, reporting procedures are adapted accordingly.

Serious Event (SE) information

Participant ID	Year of birth	Sex	SE onset date	SE stop date	Report type
[code]	[year]	[ ] F / [ ] M	[day/month/year]	[day/month/year or cont.]	[ ] initial [ ] follow up [ ] final
Contact details of the site of SE occurrence [name and full address]					Check SE [ ] life-threatening or results in death
Describe the SE and the connection to project procedures (including relevant test/lab data) [free text]					[ ] results in permanent or significant incapacity or disability [ ] requires inpatient treatment not envisaged in the protocol or extends a current hospital stay

Evaluation of the event

Project start [day/month/year]	Date of project interruption [day/month/year]
The research project encompasses the [ ] sampling of biological material [ ] collection of health-related personal data	It cannot be excluded that the event is attributable to the [ ] sampling of biological material [ ] collection of health-related personal data
Was this an unexpected serious event? [ ] yes [ ] no	Did the SE occur in connection with an investigation involving a radiation source (according to HRO Art. 19)? [ ] yes → FOPH must be informed within 7 days from the SE onset date [ ] no
Did the situation improve upon discontinuing the project? [ ] yes [ ] no [ ] n/a	

Concomitant intervention(s) and history

Concomitant intervention(s) and dates of conduct (exclude those used to treat event) [free text]
Other relevant history (e.g. diagnostics, allergies, etc.) [free text]

Proposal how to proceed

[ ] continuation, no adjustments required	[ ] definitive termination of research project
[ ] change protocol/safety section	[ ] other: [free text]

General and reporter information

Sponsor name and address (if different from project leader) [name and address]	Contact details of the site of SE occurrence [name and full address, contact telephone, email address]		
Title of research project (short title) [short title]	BASEC research project number [year-xxxxx]	EC name (concerned EC) [EC name]	EC name (lead EC, if applicable) [EC name]
Name and contact information of project leader [name, contact telephone, email address]	Place, date and signature of project leader		

[1] Refer to HRO Art. 21
[2] Responsibilities of project leader and sponsor according to HRO Art. 3