

HRO research project: Serious Event Report¹

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 sponsor² takes responsibility for the research project, reporting procedures are adapted accordingly.

Serious Event (SE) information

Participant ID [code]	Year of birth [year]	Sex [] F / [] M	SE onset date [day/month/year]	SE stop date [day/month/year or cont.]	Report type [] 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