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[[1]](#footnote-1) 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  [ ] results in permanent or significant incapacity or disability  [ ] requires inpatient treatment not envisaged in the protocol or extends a current hospital stay |
| Describe the SE and the connection to project procedures (including relevant test/lab data)  [free text] | | | | |

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  [ ] change protocol/safety section | [ ] definitive termination of research project  [ ] 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. 1 Refer to HRO Art. 21

   Responsibilities of project leader and sponsor according to HRO Art. 3 [↑](#footnote-ref-1)