|  |
| --- |
| **Project identification** |
| Project name/description |  |
| Principal Investigator |  |
| Representative of person or entity responsible for research |  |
| Identification in continuous record of project activities |  |

|  |
| --- |
| **Information about the trial subject** |
| Trial subject's ID in the project[[1]](#footnote-1) |  |
| Trial subject's age |  |
| Trial subject's gender |  |
| Date of inclusion in the project |  |

|  |
| --- |
| **Information about the adverse event** |
| Event started on | date |
| Event first reported | date |
| Event reported to/observed by | date |
| Event ended on[[2]](#footnote-2) | date |

**Description of the event**

|  |
| --- |
|  |

Is the event unexpected? Yes □ No □
Is the event serious? Yes □ No □
Is the event assumed to be related to the research? Yes □ No □

Has the event been reported to the Norwegian Board of Health?[[3]](#footnote-3) Yes □ No □

Date of report \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 dd.mm.yyyy

Principal Investigator’s signature

1. Pseudonymised, i.e. the subject's number or code in the project - not name [↑](#footnote-ref-1)
2. Or "ongoing" [↑](#footnote-ref-2)
3. Duty to inform of events that are serious as well as unexpected and adverse, and which may conceivably be related to the research [↑](#footnote-ref-3)