**DEVIATION**

is an act of deviating from requirements and procedures, i.e. something that has not been carried out as described in UiO’s current procedures. The most important aspect of deviation management is finding out why something went wrong, and taking measures to prevent it from happening again.

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| **Project identification** |
| Project name/description |  |
| Project manager |  |
| Research manager’s representative |  |
| Forskpro identification |  |

|  |
| --- |
| **Biobank identification, if applicable** |
| Biobank number |  |
| The person responsible for the biobank |  |
| Manager of the biobank (institution) |  |

|  |
| --- |
| **Deviation from the procedure in UiO’s quality assurance system for health research:** |
| Procedure no.: |
| Description of the deviation: (what, when, how): |
| **A critical deviation** is associated with a risk to life and health or serious information security breaches. Is the deviation critical? Yes □ No □Reasons: |

|  |
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| **Description of measures when identifying the deviation (what, when, how):** |
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**Deviation has been reported to the representative for the person with overall responsibility for research**

**Reported by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **Estimated cause of the deviation (root cause):** |
|  |

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| **Measures for preventing repeated/similar deviations:** |
|  |

**External reporting if applicable (report attached):**

Reported to the Norwegian Board of Health Supervision Yes □ No □

Reported to the Norwegian Medicines Agency Yes □ No □

Reported to the Norwegian Data Protection Authority Yes □ No □

**The deviation is closed by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_**

 **Representative for the person with overall**

**responsibility for research**

**Internal reporting in the line (if applicable):**

Reported to the University Director as the person with overall Yes □ No □

responsibility for research

**The deviation is closed by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_**

 **Representative for the person with overall**

**responsibility for research**