Procedure

Research procedure - health research projects

1. Changes since the previous version

Changes in the document's structure and updated in accordance with the Research Instructions.

2. Purpose and scope

This procedure is a supplement to the research instructions (id 60) and the procedure describes which tasks and responsibilities must be taken care of and managed at the various stages of the implementation of research projects. The research instructions describe who has which roles and accompanying responsibilities for taking care of the tasks and responsibilities.

For testing of medicines and medical technical equipment, see also separate procedure.

3. Liability

Reference is made to the document Responsibilities and authority relations in research (The Research Instructions), which describes the responsibilities of managers, project manager/internal project manager, project staff and those who are otherwise subordinate to the health organization instructional authority in connection with health research projects (for example students and university employees without employment at OUS, which performs tasks in the project).

Definitions:

• The **co-project managers**' project manager in health research projects where OUS is coordinating activities in one multi-center study or sole research-responsible enterprise.

• **Internal project manager** means the local project manager at OUS in health research projects that are led by an external project manager from another institution responsible for coordinating research in a multicenter study.

• **Fellow project employee** means everyone who is involved in the project. Project staff must have the necessary competence to carry out tasks assigned by the project manager/internal project manager, as well as a good understanding of and knowledge of the regulations and governing documentation.

4. Procedure

All the tasks and responsibilities described must be taken care of so that the health research project is in line with internal routines by OUS and applicable regulations.

4.1. Before starting the health research project; anchoring and approval

Before starting health research projects, the project manager and internal project manager must ensure that:

• The project is internally anchored in own and collaborating departments and/or institutions (point 4.1.1).

• The project has been registered with the Data Protection Commissioner and given grounds for processing according to the GDPR (section 4.1.2).

• A privacy impact assessment (DPIA) is prepared where this is required (section 4.1.2).

• There is a decision on approval of the project from REK (REK approval) (section 4.1.3).

• Clinical studies are registered in a publicly approved database (section 4.1.4)

4.1.1 Internal anchoring of the project

Health research projects that are planned to be carried out at OUS must have an internal anchoring in the relevant research group and be approved by the head of department responsible for the project.

The project manager, in consultation with the research group leader and head of department, is responsible for assessing:

• Whether the project is medically and ethically justifiable to carry out (Risk-benefit assessment)

• Whether privacy and research participants' rights are safeguarded in a reassuring manner

• Assess the need for a special privacy impact assessment (id 131979). See more in section 4.1.2 below.

Whether the project is satisfactorily professionally, financially and administratively organized and planned in accordance with guidelines (id 64254).

For projects involving several departments within OUS, the project manager or internal project manager must also ensure that collaborating department(s) are sufficiently informed and have approved their own contributions to the project.

If the project is a multi-centre study, the project manager must ensure that collaborating institutions (research officers) are informed, have internal anchoring according to internal routines and that necessary binding agreements are made in place (See point 4.2.1).

4.1.2 Feedback from the Data Protection Commissioner (PVO) and data protection impact assessment (DPIA)

Health research projects planned to be carried out in OUS and that process personal data must be notified.

The data protection officer via an electronic registration form (Registration form), in accordance with procedure eHandbook -

Message to the Privacy Commissioner (ous-hf.no) The project must have received feedback from the Data Protection Commissioner before commencement, where the project's basis for processing according to the GDPR is stated. In the event of significant changes to a project, these must also be reported to PVO via the same registration form.

The following documentation must be uploaded in connection with filling in the notification form:

• Copy of REK application with all attachments

• Protocol / project description

• Information and consent letter

• REK approval, if the project has already been approved by REK

For projects where it is assumed that a privacy impact assessment has been carried out in accordance with Procedure – Assessment of privacy consequences in research – DPIA (id 131979), a separate template for DPIA must be filled in and uploaded to the registration form together with the documentation.

4.1.3 REK approval

A) The project manager is employed by OUS

Project managers are responsible for applying for prior approval from REK, and that there is a decision on approval of the project before commencement.

B) Where the coordinating research officer is another institution (external project leader)

The internal project manager at OUS must ensure that a copy of the REK approval is uploaded in connection with the completion of electronic notification form to the Data Protection Commissioner (section 4.1.2). The same applies to a copy of the personal impact assessment prepared by an external project manager.

In cases where there is no DPIA, but where OUS, through data protection representatives or research support, believes that there is a need for this, the question must be clarified with the institution responsible for coordinating research before the project can start.

The project manager is responsible for registering clinical studies in a publicly available, approved database before the project can start.

All drug studies subject to application within the EEA area must be registered in the EU Clinical Trials Register (EU CTR).

Other clinical intervention and observational studies are registered in ClinicalTrials.gov. In addition, clinical studies must be registered at Helsenorge.no when the study is ready for the inclusion of research participants. See procedure: Clinical studies - Registration and visibility of studies and results (id 13301).

4.2. Start-up and implementation of health research projects

There is no opportunity to start a health research project, including recruiting research participants or collecting money

research data, before the project is anchored and approved in accordance with point 4.1.

At the start and during the implementation of health research projects, the project manager and internal project manager must:

• Secure the necessary agreements and funding of the study before commencement (section 4.2.1)

• Report changes to REK and PVO (point 4.2.2)

• Report any unwanted incidents and deviations (section 4.2.3)

• Report to REK (point 4.2.4)

• Follow up on external registrations (section 4.2.5)

• Follow up on continuous, responsible data handling (section 4.2.6)

4.2.1 Ensure that necessary agreements have been entered into

The project manager or internal project manager is responsible for ensuring that the necessary agreements are entered into in cooperation with external institutions, including the import and export of biological material and research data. Normally, the institution is involved in the project manager's responsibility who starts drafting the agreement. Project staff and other collaborators' internal departments must be made aware of the agreement.

What is a "necessary agreement" will vary from project to project. Typical current agreements can be cooperation agreements, consortium agreements, data processor agreement or handover agreements (MTA/DTA). OUS Research support has templates available at its website https://forskerstotte.no/avtaler-maler.

Agreements as part of research collaboration must be quality assured by the Department for Administrative Research Support before signing. Authorization to sign collaboration agreements on behalf of OUS follows from the hospital's authorization structure (id 26).

Throughout the project period, the project manager must ensure that agreements are respected and that the financial conditions are taken care of.

4.2.2 Notice of change to REK and the Data Protection Ombudsman

If significant changes are planned in the project, the project manager must send a change notification to REK. See procedure eHandbook (id 13300).

The project manager or internal project manager must also report changes to the electronic reporting form in accordance with the procedure for notification to the Data Protection Commissioner and Information Security Manager (id 110411).

4.2.3 Notification of adverse medical events and notification of deviations in research

The project manager, internal project manager and project staff are obliged to report serious, unwanted or unexpected events and medical events believed to be related to the project. See separate procedure Research - adverse events and notice of deviation in research.

4.2.4 Reporting to REK and possibly other authorities

If REK has set conditions for annual or other extraordinary reporting, a copy of the report must be sentto :godkjenning@oslo-universitetssykehus.no.

4.2.5 External registration and reporting

ClinicalTrials.gov: The project manager must update every 6 months after registration, and the status of each center and the total as well as the date of completion are entered within 30 days.

EU CTR: Significant changes are reported to SLV (ref. id 13301). Helsenorge.no: The project manager must report on the end of recruitment of research participants.

4.2.6 Follow up on continuous, proper data handling

The project manager must ensure that all project documentation and personal information in the project is collected, stored and processed in accordance with the applicable governing documents, legislation and in line with current approvals. This in order to safeguard the rights and freedoms of the data subjects. More information can be found in the Research Instructions.

4.3. Completion of the health research project

At the end of a health research project, the project manager or internal project manager must ensure that the following is taken care of:

• Internal and external registration (section 4.3.1)

• Final report to REK (section 4.3.2)

• Notification to the Data Protection Commissioner about the deletion/anonymization/destruction of research data (section 4.3.3)

4.3.1 Internal and external registration

The project manager must register the completed study in ClinicalTrials.gov and in Helsenorge.no. For drug studies shall final notification is sent to the Directorate for Medical Products (formerly SLV) and results are registered in the EU CTR. See procedure: Clinical studies - Registration and visibility of studies and results (id 13301).

4.3.2 Final report to REK

A final report must be sent in a separate form to REK when the project has ended. The project manager or internal project manager must send a copy of the termination notice to e-mail: godkjenning@oslo-universitetssykehus.no.

4.3.3 Deletion/anonymization and destruction of personal data and human biological material

The project manager or internal project manager must ensure that personal data and human biological material also know the end of the project is processed in line with REK approval and the conditions set out there, including any conditions specified in feedback on treatment grounds. The project manager or internal project manager must report to the Data Protection Commissioner when personal data or material has been deleted/anonymized/destroyed via the notification form.

5. Deviation or dissent

Deviation reporting must take place in accordance with the hospital's internal deviation system. See also the guideline Notice of deviation - adverse events in research (id 53016).

Serious, unwanted and unexpected medical events believed to be related to the research are reported to the State health supervision. This must be done directly in the deviation system Achilles under Patient incident, see separate section with information and button for notification to the Norwegian Health Authority. Correspondingly, other significant deviations that affect the use of human biologicals apply material in research.

6. References

• Act of 20 June 2008 No. 44 on medical and healthcare research (Health Research Act)

• Regulations on the organization of medical and healthcare research (the health research regulations)

• Act 2017-04-28 no 23: Act on the treatment of ethics and honesty in research (research ethics act)

• Act of 5 December 2003 no. 100 on human medical use of biotechnology, etc. (Biotechnology Act)

• Act 2014-06-20 no 43: Act on health registers and processing of health information (health registers act)

• Act 2018-06-15 no. 38 on the processing of personal data (the Personal Data Act) with associated regulations

• Act 1999-07-02 no 64: Act on health personnel etc. (Health Personnel Act)

• Act 1999-07-02 no. 63: Patient Rights Act (Patient Rights Act)

• The Helsinki Declaration of 1964 with later revisions

• Convention for the protection of human rights and human dignity in connection with the application of biology and medicine: Convention on human rights and biomedicine - ETS No. 164

Other eHandbook documents

The research instructions - responsibility and authority in research

Genetic investigations in research projects

Instructions for powers of attorney in Oslo University Hospital HF

Clinical drug studies - roles and responsibilities. Roles and Responsibilities in Clinical Trials

Notification to the Privacy Commissioner

Risk assessment for new and changed IT solutions and data processing

Assessment of privacy implications - DPIA

Biobank - Creation of specific research biobank

Biobank - Creation and organization of a general research biobank

Clinical studies - Registration and visibility of studies and results

Notice of change in medical and healthcare research projects