Research- Procedure for Research

Document ID: D01115

Prepared by: Annette Marie Juelsen

Approved by: Anne Catrine Trægde Martinsen

Version number: 2.00

Effective from: 30.11.2023

PURPOSE AND SCOPE

Medical and health research requires ethical pre-approval by the Regional Committee for Medical and Health Research Ethics (REK) before the project can start, cf. the Health Research Act § 33. The same applies to research involving pilot studies and experimental treatment. REK shall conduct an ethical assessment of all aspects of the project, including considerations of privacy.

Definition of health research is "Medical and health research conducted with scientific methodology aimed at generating new knowledge about health and disease. Pilot studies and experimental treatment.

The research procedure applies to the anchoring, approval, and implementation of health research projects requiring pre-approval by the regional committee for medical and health research ethics (REK), as well as projects requiring notification to the Data Protection Officer and SIKT.

TARGET GROUP

The procedure applies to the following researchers:

- Employees with project management responsibility.
- Employees responsible for conducting health research projects at Sunnaas hospital, but with an external project leader.
- Researchers without formal employment but subject to the hospital's authority.

For the trial of drugs and medical-technical equipment, see separate procedure.

RESPONSIBILITY

Describes who is responsible for carrying out the content of the document. Each individual should be able to clearly clarify their role. The responsibilities of collaborating units must be clarified before this is described.

In accordance with Responsibility and authority in research (Research Instruction) and with the following clarifications:

- By project leader in the procedure, a researcher who formally applies for pre-approval from REK is meant.

- By responsible researcher in the procedure, a researcher responsible for the part of a multicenter study to be conducted at Sunnaas without being the project leader themselves.

- By researcher, any employee participating in the project and subject to Sunnaas's authority is meant.

PROCEDURE

Anchoring and Approval

All health research projects at Sunnaas shall be anchored in one of the thematic research groups.

Before starting health research projects, the project leader or responsible researcher must ensure that the project is anchored and has the necessary approvals, cf. the points 4.1.1-4.1.4 below:

- The project is internally anchored in a thematic research group and in own and collaborating departments and/or institutions (cf. point 4.1.1)
- Report the project to NSD via their notification form https://meldeskjema.nsd.no/ no later than 30 days before data collection starts, and inform the data protection officer by email that this has been done (cf. point 4.1.2).
- Ensure that a data protection impact assessment is conducted where required according to the procedure for assessing data protection impact in DPIA (cf. point 4.1.2).
- REK approval has been obtained, and there is written feedback on the legal basis for processing personal and health information in the project (cf. point 4.1.3)

Requirements for Defense Assessment and Anchoring of the Project

Health research projects planned to be conducted at Sunnaas must, according to the research instruction, be subject to a defensibility assessment, anchored in a thematic research group, and approved by the research director.

The project leader, in consultation with the leader of the thematic research group, is responsible for assessing:

- Whether the project is medically and ethically defensible to conduct (Risk-benefit assessment)
- Whether privacy and the rights of research participants are adequately safeguarded
- Assess the need for a special data protection impact assessment. See more in point 4.1.2 below.
- Whether the project is satisfactorily academically, economically, and administratively organized and planned according to the guideline.

For projects involving several units internally at Sunnaas, the project leader or responsible researcher must also ensure that the collaborating unit(s) are sufficiently informed and have approved their contributions to the project.

If the project is a multicenter study, the project leader must ensure that collaborating institutions (research responsible) are informed and that necessary binding agreements are in place.

Electronic Notification Form and Data Protection Impact Assessment (DPIA)

Health research projects planned to be conducted at Sunnaas must be reported via a joint email to the Research Department projectmelding@sunnaas.no, and REK approval must be obtained. The project must then be reported to SIKT via their notification form https://meldeskjema.nsd.no/. The Data Protection Officer at Sunnaas will have access to all projects reported from Sunnaas through the SIKT portal and has the opportunity to quality assure the recommendations given.

In case of significant changes requiring REK approval, this must also be reported to the Data Protection Officer and the Research Director.

The following documentation should be attached to the notification to the Data Protection Officer and the Research Director:

- Copy of REK application with all attachments
    - Protocol / project description
    - Information and consent letter
    - REK approval, if the project is already approved by REK
    - SIKT approval, if already available
- A data protection impact assessment (DPIA) must be carried out in projects where the processing of personal data will entail a high risk for the rights and freedoms of physical persons. Before processing personal data starts, such projects should conduct a more comprehensive assessment of the consequences the planned processing will have for the protection of personal data. When the project is reported to SIKT, they will assess whether it is necessary to conduct a data protection impact assessment, and they will then assist the project with this.

For projects where a data protection impact assessment is required according to Procedure Assessment of Data Protection Impacts in Research DPIA, a separate DPIA template must be filled out and uploaded in the notification form together with the mentioned documentation.

Requirement for REK Approval and Processing Basis

1. A) Where Sunnaas is the coordinating research responsible

The project leader is responsible for applying for pre-approval from REK.

The project leader also has a responsibility to ensure that the project does not start until there is feedback from SIKT about the processing basis after data protection legislation according to point 3.1.3 C) below.

1. B) Where the coordinating research responsible is another institution (external project leader)

The responsible researcher at Sunnaas must ensure that a copy of REK approval is uploaded in connection with filling out the electronic notification form to SIKT (point 3.1.2).

In cases where there is no DPIA, but where SIKT, Sunnaas by the Data Protection Officer or the research department believes that there is a need for this, the issue must be clarified with the coordinating research responsible institution before the project can start.

1. C) Feedback on processing basis according to data protection legislation (GDPR)

All health research projects must, in addition to REK approval, have an explicitly stated processing basis according to GDPR Article 6 and Article 9 before the project can start. All projects must be reported to NSD for approval no later than 30 days before the planned start of data collection (https://meldeskjema.nsd.no/). The assessments are performed by SIKT and quality assured by the Data Protection Officer at Sunnaas. When the notification form is fully evaluated, this serves as documentation that the project processes personal data in a legal way. When the project leader has submitted relevant documentation to the research department and has received REK approval, the research department, in collaboration with the leader for information security at Sunnaas, will ensure feedback to the project leader about a valid processing basis according to GDPR.

If the project requires a DPIA (point 4.1.2), the project leader will receive feedback on the processing basis as soon as an assessment from the Data Protection Officer is available according to the procedure for data protection impact assessment DPIA.

External Registration of Clinical Studies

The project leader is responsible for registering clinical studies in ClinicalTrials.gov before the project can start. In addition, clinical studies must be registered in Helsenorge.no when the study is ready for the inclusion of research participants.

Start-up and Implementation

There is no opportunity to start a project, including recruiting research participants or collecting research data, before the project is anchored and approved in accordance with point 4.1.

If the project is a collaboration between several institutions, a cooperation agreement between the parties must also be in place before the start (point 4.2.1).

Requirements for Cooperation Agreements

The project leader or responsible researcher is responsible for ensuring the necessary agreement in connection with collaboration with external institutions, including import and export of biological material and research data. Normally, the institution with project management responsibility initiates the work of drafting an agreement. Cooperation agreements in research should include provisions on:

- Roles and responsibilities in the project, including obligations under relevant regulations and other binding guidelines that form the basis of the collaboration.
- The parties' rights to research data and research results.
- Sharing, storage, and use of research data.

At Sunnaas, it is recommended that one start with own templates that are available on the website of Regional Research Support (collaboration agreements).

Agreements as part of research collaboration should be quality assured by the Research Director before signing.

The authority to sign collaboration agreements on behalf of Sunnaas follows the hospital's power of attorney structure.

The project leader or responsible researcher is responsible for following up on entered collaboration agreements.

Project staff and other collaborating departments internally should be familiar with the agreement. If there is a need for changes or questions about breach of contract, the leader who has signed the agreement should be informed, and the question should be presented to the Research Director for assessment.

Handling of Research Data and Safeguarding of Participants' Interests

The handling (collection, use, storage, and disclosure) of research data as well as safeguarding the rights of research participants according to data protection legislation should be done in accordance with REK approval and governing documents at Sunnaas.

For the need for new and amended IT solutions and data processing, see the procedure in Helix.

Change Notification to REK and Possibly Other Authorities

If significant changes in the project are planned, the project leader must send notification to REK in a separate form in the SPREK case portal. In addition, a corresponding notification must be sent to SIKT.

The project leader or responsible researcher must also report changes to SIKT, the Data Protection Officer, and the Research Department.

Reporting of Adverse Medical Events and Deviation Reporting in Research

Researchers are obliged to report serious, unwanted, or unexpected medical events that are believed to be related to the project according to current procedures in Helix.

Reporting to REK and Possibly Other Authorities

If REK and/or others (for example, the funding source) have set conditions for annual or other extraordinary reporting, a copy of the report should be sent to the Research Department.

Change of External Registration

ClinicalTrials.gov: The project leader shall update every 6 months after enrollment, and the end date shall be entered within 30 days.

Completion of the Project

Internal and External Registration

The project leader must register the study as completed in ClinicalTrials.gov and in Helsenorge.no.

Final Notification to REK

A final notification in a separate form must be sent to REK when the project is completed. The project leader or responsible researcher must send a copy of the final notification to the Research Department.

Deletion/Anonymization and Destruction of Research Data

Research data must be treated at the end of the project in accordance with REK approval and the conditions set there, including any conditions indicated in feedback on the processing basis.

There is no opportunity to use research data in other projects unless new approvals are obtained in accordance with the research procedure.

DEVIATIONS OR DISSENT

Deviation reporting should be done in accordance with the hospital's internal deviation system EK for registration and follow-up of unwanted events, near misses, and dangerous conditions. Otherwise, deviation handling should be done in accordance with the quality document Unwanted events and risk conditions registration and analysis of deviations.

REFERENCE

Links to more detailed information internally/externally.

For example; method report, patient information (link to the internet), other management documents, bibliography

- Act of 20 June 2008 No. 44 on medical and health research (the Health Research Act)
- Regulation on the organization of medical and health research (the Health Research Regulation)
- Act 20170428 No. 23: Act on the treatment of ethics and integrity in research (the Research Ethics Act)
- Act of 5 December 2003 No. 100 on human medical use of biotechnology etc. (the Biotechnology Act)
- Act 20140620 No. 43: Act on health registries and the processing of health information (the Health Registry Act)
- Act 2018-06-15 No. 38 on the processing of personal data (the Personal Data Act) with accompanying regulation
- Act 19990702 No. 64: Act on health personnel etc. (the Health Personnel Act)
- Act 19990702 No. 63: Act on Patient Rights (the Patient Rights Act)
- The Helsinki Declaration of 1964 with later revisions

Convention for the Protection of Human Rights and Dignity of the Human Being in relation to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine - ETS No. 1

Attachments

Internal References

External References

The document has been modified to Sunnaas Hospital HF based on original document from Oslo University Hospital HF.