Research Instruction

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PURPOSE AND SCOPE

Brief description of the purpose/objective of the instruction.

Responsibility and authority in research

Sunnaas Hospital HF (hereafter Sunnaas) is responsible for ensuring that all research conducted by the enterprise is planned, implemented, and concluded in accordance with statutory requirements and recognized ethical norms in research.

The research instruction describes responsibilities and authority in the organization and execution of research projects where Sunnaas is responsible for research and data, including the statutory internal control responsibility.

For drug studies, roles, responsibilities, and tasks are specified in a separate guideline; Roles and responsibilities in clinical drug trials. The guideline is supplementary to the research instruction.

TARGET GROUP/RESPONSIBILITY

Who should use the document, professional groups, etc.

Responsibility:

Managing Director: As the daily leader of the organization, has the overall responsibility for research activities at Sunnaas.

Research Director: Has overall responsibility for strategy, policy, framework management, and monitoring of research activities at Sunnaas and is the enterprise system owner in the area. This includes, among other things, responsibility for establishing and maintaining the organization's system for internal control in research, including facilitating systematic measures for the implementation of internal control in research in the clinics.

Research Director is the administrative owner of research projects at Sunnaas and should be stated as the administrative owner in applications for external research funding.

Leaders: Leaders within various units are responsible for ensuring that this instruction is made known and complied with within their area of responsibility. Leaders are responsible for facilitating proper organization and execution of research in their unit.

All employees: Everyone employed by, or under the instruction authority of Sunnaas when it comes to research projects under the hospital's responsibility, shall familiarize themselves with and comply with the instruction.

In addition to line responsibility for research, the following tasks, among others, are assigned to staff and support functions;

Data Protection Officer: Advisory and controlling function regarding the processing of personal and health information in Sunnaas activities.

Information Security Manager: Controlling function that provides advice and ensures that ICT solutions at Sunnaas maintain consistent requirements for information security.

PROCEDURE

The various steps to be performed

Responsibility and tasks

Research is part of the ordinary operations at Sunnaas. The Managing Director has delegated the management and leadership of research to the Research Director. The Research Director takes care of and exercises the enterprise's responsibility and authority and leads the research activities. The Research Director shall ensure that the activities are planned, organized, and conducted in a proper manner, in accordance with regulations, requirements, recognized ethical norms in research, and within the limits of allocated resources.

The Research Director decides in collaboration with the clinic manager and chief physician whether research projects should be initiated in the clinic.

Responsibilities of the Research Director include:

- Assessing whether a research project is medically and ethically justifiable to conduct, including that privacy and information security are maintained in accordance with requirements and regulations.
- Assessing whether necessary advice has been obtained in the area of data protection where this is required according to the research procedure.
- Evaluating whether projects are satisfactorily professional, economically, and administratively organized and planned, including that the project leader has sufficient competence.
- Ensuring that projects do not start before all necessary statutory approvals (e.g., Regional Ethics Committee (REK), Norwegian Medicines Agency (SLV)) are in place, including feedback on the basis for processing in accordance with governing documents.
- Appointing a responsible person for the research biobank (see procedure for responsible person).

It is generally the Research Director who should be listed as the contact person for the responsible for research in the application for preliminary approval to REK. If the Research Director is the project leader, the Managing Director should normally be listed as the contact person.

Project Leader

All research projects where Sunnaas has an internal control responsibility must have a named project leader. The project leader is responsible for the daily operation of the research project and shall ensure that the project is planned, conducted, and concluded in accordance with the research procedure and/or other relevant governing documents, including:

- Ensuring that ethical, medical, health professional, data protection, and information security matters are taken into account in all phases of the project.
- Obtaining necessary advice in the area of data protection in connection with the processing of personal and health information in their own project, including ensuring that the necessary data protection impact assessment is carried out, where this is required according to governing documents.
- Ensuring that the project is internally anchored and approved in accordance with the research procedure and internal routines in the department, including collaborating departments.

- Ensuring that necessary approvals (e.g., REK, SLV) and feedback on the basis for processing personal and health information are in place before the start of the project.
- Ensuring that the project is conducted in accordance with formal approval, feedback on the processing basis, and in compliance with other requirements in the research procedure, other relevant governing documents.
- Ensuring notification of changes where this is required according to governing documents.
- Ensuring that all project staff have sufficient competence to carry out assigned tasks in the project.
- Ensuring necessary agreements in connection with research collaboration with external partners, including that the agreement is formalized in accordance with the current authorization structure at Sunnaas.
- Preparing necessary reports, etc., to relevant bodies. Ensuring that all project documentation and research data are collected, stored, and processed in accordance with the current governing documents.

In REK-approved projects, the project leader's responsibility is a personal responsibility.

For multicenter studies (collaboration projects), where the formal project leader responsibility is assigned to another institution, there must be a named employee at Sunnaas responsible for the part of the project carried out in the enterprise. In such cases, the tasks mentioned above apply as far as they fit.

Responsible Person for Research Biobank

Every research biobank must have a responsible person with higher degree medical or biological education. The person must have an employment relationship with Sunnaas.

The responsible person has the daily operational responsibility for the research biobank and must ensure that the collection, registration, storage, processing, and destruction of material are carried out in an ethically responsible manner in accordance with relevant regulations and internal guidelines. Normally, this will be the project leader.

Project Employee

Project employees should be specified by the project leader. Project employees must possess the necessary competence to perform the tasks they are assigned by the project leader.

Project employees have an independent responsibility to familiarize themselves with relevant regulations governing research, including relevant internal governing documents. External project employees, who are to be given access to information systems at Sunnaas, must be subject to the hospital's instruction authority.

Special Responsibility for Doctoral Work

Employees with supervisor responsibility for fellows who are employed at Sunnaas are responsible for ensuring that the agreement between the relevant doctoral program and Sunnaas is followed, including familiarizing themselves with and following up on their own supervisor responsibility in accordance with the Ph.D. regulations at the relevant institution.

Supervisors employed at Sunnaas are also responsible for keeping the Research Director informed about deviations and possible conflict cases as part of the implementation of a doctoral project.

For fellows employed at Sunnaas, the research instruction and responsibilities as a project employee apply. In addition, the fellow is responsible for familiarizing themselves with and following up on their own obligations in accordance with the Ph.D. regulations at the relevant institution.

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 Handling unwanted events, deviations, and improvement suggestions in EK Health.

REFERENCE

Links to more detailed information internally/externally.

For example; method report, patient information (link to internet), other governing documents, literature list

Relevant laws, etc. Act of June 20, 2008, No. 44 on medical and health research (the Health Research Act) Act 2017-04-28 No. 23: Act on ethics and integrity in research (the Research Ethics Act) Act of December 5, 2003, No. 100 on the human medical use of biotechnology, etc. (the Biotechnology Act) Act 2001-05-18 No. 24: Act on health registries and processing of health information (the Health Registry Act) - Repealed and only available in Lovdata PRO Act 2018-06-05 No. 38 on the processing of personal data (the Personal Data Act) Act 1999-07-02 No. 64: Act on health personnel, etc. (the Health Personnel Act)

Act 1999-07-02 No. 63: Act on Patient Rights (the Patient Rights Act) Act of January 12, 1995, No. 06 on Medical Devices Act 1992-12-04 No. 132: Act on Medicines, etc. (the Medicinal Products Act) Act of December 23, 1988, No. 104 on Product Liability (the Product Liability Act)

Regulation of October 30, 2009, No. 1321 on clinical trials of medicinal products for humans Regulation of January 15, 1996, No. 23 on experiments with animals - Repealed and only available in Lovdata PRO

Convention on the protection of human rights and the dignity of humans in connection with the application of biology and medicine: Convention on Human Rights and Biomedicine - ETS No. 164

The Helsinki Declaration of 1964 with later revisions - English full text

Annex

Internal references

External references

This is a detailed research instruction document from Sunnaas Hospital HF, outlining responsibilities, procedures, and guidelines for conducting research, including roles of various staff members and adherence to ethical and legal standards. It has been adjusted to fit Sunnaas Hospital HF, based on the original document from Oslo University Hospital.