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1. Changes since the previous version

This is the second version of the document, with an English translation.

2. Purpose and scope

This Guideline is part of ensuring good research practice and good handling of any breaches and system errors.

Oslo University Hospital (henceforth OUS) is responsible for ensuring that all research in which the hospital participates is conducted in a responsible and trust-building manner and that it is planned, carried out and concluded in accordance with statutory requirements and recognised norms for research ethics. This Guideline describes the norms for research ethics and research integrity that must form the basis for all research at the hospital. Research ethics encompasses laws, rules and norms intended to ensure that research is conducted in a responsible manner with regard to patients, employees and the interests of society. The term 'research integrity' is often used to mean that research must be conducted in a way that inspires trust and credibility, and that underpins the credibility of the results and trust in the research community and the institution. Research integrity can be summed up as reliability, honesty, respect and accountability in research.

The Guideline is a supplement to the Research Instructions (Forskningsinstruksen - ansvars- og myndighetsforhold i forskning andthe Guideline Mulige brudd på anerkjente forskningsetiske normer - behandling av saker). It should be distributed to all those involved in research, and form the basis for training and be followed in the planning, implementation and completion of research.

3. Responsibility

Chief Executive Officer (CEO): has the overall responsibility for research activities conducted at OUS.
Director of Research, Innovation and Education: is responsible for the Guideline
Managers within the various units: are responsible for ensuring that this Guideline is made known and and complied with, within each area of responsibility.
Head of Research at each Division (staff function for the Head of Division – *Forskningsleder*): is responsible for being constantly updated. The Head of Research will be a key point of contact in the dialogue/flow of information between the institutional research management and the divisions at the hospital.

All employees employed at or under the instructional authority of OUS with regard to research projects under the hospital's responsibilityare responsible for becoming familiar with, understanding and complying with the Guideline.

4. Procedure

Researchers have a legal obligation to "act with due care to ensure that research is conducted in accordance with recognised norms for research ethics"; see Section 4 of the Research Ethics Act (Forskningsetikkloven). There is also a legal obligation for the institution to ensure that research takes place in accordance with recognised norms for research ethics and that necessary training is provided in this; see Section 5 of the Health Research Act (Helseforskningsloven).*Justifiability:* "Medical and health research must be organized and conducted responsibly. Research must be based on respect for the research participants' human rights and human dignity. Consideration for the welfare and integrity of the participants shall take precedence over the interests of science and society. Medical and health research must address ethical, medical, health, scientific and privacy issues."

The Guideline is based on European standards, including the guidelines for research integrity entitled All European Academies (ALLEA) (All European Academies (ALLEA)- europeiske retningslinjer for forskningsintegritet) and the Standard for Research Integrity for the University of Oslo Standard for forskningsintegritet - For ansatte - Universitetet i Oslo (uio.no).

4.1 Terms and definitions

Research ethics
Research ethics encompasses a number of norms, values and institutional schemes that help govern research activities. Norms of research ethics also have points of contact with legal rules: this applies e.g. to norms for co-authorship, that have points of contact with the rules on works of joint authorship in Section 8 of the Act of 15 June 2018 no 40 on Copyright of Intellectual Property etc. (Åndsverksloven) and the norms for good reference practice that have points of contact with the right to quote and the attribution obligation in the Copyright Act.

In medicine and health sciences, the specific professional norms for research ethics are essentially stated in: Declaration of Helsinki, Oviedo Convention and The Health Research Act. Furthermore, a number of specific professional norms for medicine and health sciences are provided by The National Committee for Medical and Health Research Ethics (NEM). OUS has established a quality control system for medical and health research to facilitate compliance with the norms that apply to medical research (see the chapter "Other eHandbook documents"). For research in medicine and health, it is of the utmost importance to apply the specific professional norms in research. Research ethics also includes external norms. These are intended to protect research participants through informed consent, privacy protection, risk assessments etc., as well as ensure the contribution of research to the benefit and welfare of society.

Research integrity
The Research Ethics Act primarily governs how work with research ethics is organized. However, the Research Ethics Act contains several norms that apply to research integrity. Integrity in research is a central and fundamental goal at OUS. Research integrity can be summed up as reliability, honesty, respect and accountability in research. It is fundamental for all research to demonstrate integrity in the planning, execution and publication of research. Striving for integrity in research requires more than avoiding scientific misconduct. It entails actively promoting transparency, accountability and

fairness in all aspects of research activity, defining criteria for good research practice, and responding adequately to threats to or violations of research integrity.

Scientific misconduct means "falsification, fabrication, plagiarism and other serious violations of recognised norms for research ethics, that have been committed intentionally or grossly negligently in the planning, implementation or reporting of research"; see Section 8(2) of the Research Ethics Act.

4.2 Institutional responsibility for training, as well as handling system errors

OUS has a clear statutory framework for its overall activities, including research activities. Research at OUS is governed by special legislation for health research. The Health Research Act is particularly important in this regard. Research is mentioned in particular in the Specialist Health Service Act, Section 3-8: *The tasks of hospitals.*

OUS also has an institutional responsibility to facilitate good research ethics and integrity; see Section 5(2) of the Research Ethics Act:

Research institutions must ensure that research at the institution is conducted in accordance with recognised norms for research ethics. The institution is responsible for:

a) necessary training of employees in the recognised norms for research ethics and
b) ensuring that everyone who conducts or participates in research is familiar with the established and recognised norms for research ethics.

At OUS, research is organized in research groups with a clear scientific leadership. All researchers must be affiliated with a research group. This is important for professional, ethical, social and culture-building reasons. Great emphasis is placed on raising awareness of group leaders and line management in relation to this responsibility; see the guidelines for research groups (Retningslinje - Forskningsgrupper, chapter 3 – Funksjonsbeskrivelse for forskningsgruppeledere).

4.3 Principles for research integrity

OUS uses the following principles as a basis for research integrity and fair conduct in research, generally consistent with the standard for research integrity at the University of Oslo (Standard for forskningsintegritet for UiO). The researchers have the right to choose the topic and method for their research within the OUS framework, resources and management power of attorney empower, but this must be granted by the line management, in accordance with the Research Instructions (Forskningsinstruksen - ansvars- og myndighetsforhold i forskning). Both the researcher and OUS must uphold the freedom and independence of research. Researchers are responsible for assessing acceptable risk and proportionality. Before projects are started, they have to be approved , in accordance with the hospital's Authorisation Instructions (Fullmaktsinstruks), and in accordance with the Health Research Act (helseforskningsloven) and the Research Procedures – Health Research Projects REC (Forskningsprosedyre – helseforskningsprosjekter REK).

- All research must follow good citation and referencing practices. Training in this is a necessary prerequisite for avoiding all forms of plagiarism.
- Researchers must assess and disclose conflicts of interest; see the Guidelines for Scientific Publication (Retningslinje for Vitenskapelig Publisering).
- The Vancouver Criteria set the minimum standard for eligible academic co-authorship for all subject areas.
- Researchers have a duty (see the Declaration of Helsinki) to publish their results and must ensure that such publication takes place, even if the results of the research are negative. This also applies to industrial cooperation. The terms for this are regulated in the cooperation agreements

with the industry; see the Guidelines for Cooperation with Industry in Research, Innovation and Development Projects (Retningslinjen – Samarbeid med industri i forsknings-, innovasjons-, og utviklingsprosjekter (ous-hf.no)) – agreements must be quality assured by Forskningsstøtte or Inven2 depending on the type of cooperation. Collaboration with industry in research shall be based on an agreement that ensures that the hospital and employees can fulfil their statutory duties, that commercial and academic interests are safeguarded responsibly and in accordance with the law, OUS internal guidelines and recognised standards for research ethics. Collaborative projects with the industry must be organized so that research participants, patients or society do not doubt the independence, integrity or professional assessments of the the hospital's actions or the actions of the hospital's employees.

- The relevant foundation for the research shall be made available in accordance with good practice in the relevant field, provided that procedures for handling special categories of health data (sensitive data) are followed.
- All Norwegian scientific articles funded by public funds should be openly available by 2024, and the Ministry of Education and Research has established national goals and guidelines for open access to scientific articles (Nasjonale mål og retningslinjer for åpen tilgang til vitenskapelige artikler). For researchers, the guidelines imply that they "shall investigate the possibilities of publishing their articles in open access journals and choose open access journals where this is professionally justifiable" and the articles must be deposited in scientific archives no later than the time of publication. At the same time, it is necessary to ensure that data sharing in connection with publication takes into account necessary privacy requirements and according to the Guidelines for Data Sharing when Publishing (Datadeling ved publisering).
- Managers, heads of research, research group leaders and supervisors shall do their best to create and establish a culture of research integrity and compliance. Research results should be presented to the research group both before and after publication.
- All research should be judged on its scientific quality, not just by quantitative measures; see The San Francisco Declaration on Research Assessment (DORA erklæringen)
- For research that involves collaboration across disciplines, institutions or countries, collaboration agreements should be established that also adresses issues of research integrity.
- Researchers shall treat participants with respect and care, in accordance with legal and ethical provisions, be it people, animals, cultures, nature or the natural environment (ref. ALLEA, 2.4)
- Data shall be stored, managed and shared properly, in accordance with the FAIR Principles; see the FAIR Guidelines (Veileder for bruk av FAIR-prinsippene for helsedatakilder – ehelse) (ref. ALLEA, 2.5)

6. Deviations

Employees who become aware of possible violations of recognised norms for research ethics have a responsibility to report this; see also the Procedure: Mulige brudd på anerkjente forskningsetiske normer

7. References

Laws governing health research

- Lov av 20. juni 2008 nr. 44 om medisinsk og helsefaglig forskning (helseforskningsloven)
- Forskrift om organisering av medisinsk og helsefaglig forskning (helseforskningsforskriften)
- Lov 2017-02-10 nr 23: Lov om behandling av etikk og redelighet i forskning (forskningsetikkloven)
- Lov av 5. desember 2003 nr. 100 om humanmedisinsk bruk av bioteknologi m.m. (bioteknologiloven)
- Lov 2014-06-20 nr 43: Lov om helseregistre og behandling av helseopplysninger (helseregisterloven)

- Lov 2018-06-15-38: Lov om behandling av personopplysninger (personopplysningsloven) med tilhørende forskrift
- Lov 1999-07-02 nr 64: Lov om helsepersonell m.v. (helsepersonelloven)
- Lov 1999-07-02 nr 63: Lov om pasientrettigheter (pasientrettighetsloven)
- Lov 1992-12-04 nr 132: Lov om legemidler m.v. (legemiddelloven)
- Forskrift av 24. september 2003 nr. 1202 om klinisk utprøving av legemidler til mennesker

Legal codes included in the Guidelines for Research Integrity:

- All European Academies (ALLEA)- European Guidelines for Research Integrity.
- De nasjonale forskningsetiske komiteer (NEM): Retningslinjer
- Declaration of Helsinki
- Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations
- OpenAccess – National goals and guidelines for open access to scientific articles
- Oviedo Convention
- Vancouver Recommendations
- World Conference on Research Integrity

Other eHåndboks documents

- Forskningsinstruksen - ansvars- og myndighetsforhold i forskning
- Forskningsprosedyre - helseforskningsprosjekter REK
- Melding til Personvernombudet
- Mulige brudd på anerkjente forskningsetiske normer - behandling av saker
- Vitenskapelig publisering
- Datadeling ved publisering.
- Samarbeid med industri i forsknings-, innovasjons- og utviklingsprosjekter
- Retningslinje - Forskningsgrupper
- Forskningsstrategi 2021-2025