Nutrition/Interventional - NORWAY

Competent authority

Contact Details	**Contact Name 1** The Norwegian Medicines Agency – NoMA (Statens legemiddelverk) **Contact Name 2** Section for Preclinical Assessment and Clinical Trials **Phone** +47 22 89 77 00 **Fax** +47 22 89 77 99 **Email Department** klut@noma.no **Address** PO Box 63 / Kalbakken **ZIP/City** 0901 Oslo **Country** Norway (NO) **Web address** http://www.legemiddelverket.no/English/ **Additional Information** No local CA
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Regional Ethics Committee **Regulatory and ethics bodies involved in approval process for trials including patients** Regional Ethics Committee Medicines Agency in some cases additionally involved **Regulatory and ethics bodies involved in approval process for trials including including healthy participants** Regional Ethics Committee Medicines Agency in some cases additionally involved **Regulatory and ethics bodies involved in approval process for trials including vulnerable population** Regional Ethics Committee **CA - Registration/ notification without approval required for** – **CA - Registration requirements for clinical trials** –

Registration requirements for clinical trials including patients

Registration mandatory

Registration requirements for clinical trials including healthy participants

Registration mandatory

Registration requirements for clinical trials including vulnerable population

Not applicable

CA - Submission required to

National CA
Institutional CA
International CA
International CA involved in some cases

Studies including patients - submission required to

–

Studies including healthy participants - submission required to

–

Studies including vulnerable population - submission required to

–

Submission Format

Standard application form available

Yes

Standard application form

Regional Committees for Medical and Health Research Ethics

Language of Submission

Language(s) of application

Norwegian
English

Language(s) of application for trials including patients

–

Language(s) of application for trials including healthy participants

–

Language(s) of application for trials including vulnerable population

–

Preferred language of application

–

English accepted

Yes
For attachments (other than information material for study participants): any Scandinavian language also accepted

Documents mandatory to be in official national language

Basic application form
Information material, Documents and Forms intended for study participants and patient information

Documents mandatory to be in local language of study site

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	Documents mandatory to be in language of the study participant –
Timelines Authorisation	**Additional Information** Time in days from submission to positive approval (maximum): 60 days

Ethics committee

Contact Details	**Contact Name 1** Regional Committees for Medical and Health Research Ethics REK/ REC **Contact Name 2** 4 Regional REC according to geographical region: **Contact Name 3** (1) REC South East; (2) REC West; (3) REC Central; (4) REC North; **Country** Norway (NO) **E-Mail** post@helseforskning.etikkom.no **Web address** https://helseforskning.etikkom.no/ **Additional Information** • REC South East: Vestfold, Buskerud, Telemark, Aust-Agder, Vest-Agder, Akershus, Østfold, Hedmark, Oppland and Oslo • REC West: Rogaland, Hordaland and Sogn og Fjordane • REC Central: Møre og Romsdal, Sør-Trøndelag and Nord-Trøndelag • REC North: Nordland, Troms and Finnmark ad Email (post@helseforskning.etikkom.no): the name of the respective REC (South East, West, Central, North) should be included in the subject field The secretariats of the individual RECs can also be contacted directly by telephone, email or via their office addresses, provided on the REK website in section Committees and Meetings.
Ethical Review – General	**Submission for Ethical review mandatory for** – **Submission of study mandatory** Yes **Submission to CA and EC to be performed in the following order** – **National declaration on Ethical requirements exists** Yes **National declaration** https://helseforskning.etikkom.no/ikbViewer/page/forside?_ikbLanguageCode=us
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Regional Ethics Committee

	Ethical approval (favourable opinion) for trials including patients to be obtained from Regional Ethics Committee **Ethical approval (favourable opinion) for trials including healthy participants to be obtained from** Regional Ethics Committee **Ethical approval (favourable opinion) for trials including vulnerable population to be obtained from** Regional Ethics Committee
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Regional EC (authorised to issue a single opinion) **Ethical approval in trials including patients obtained from** Regional EC (authorised to issue a single opinion) **Ethical approval in trials including healthy participants obtained from** Regional EC (authorised to issue a single opinion) **Ethical approval in trials including vulnerable population obtained from** Regional EC (authorised to issue a single opinion)
Submission of Application	**Entitled to study submission** Principal Investigator **Entitled to submission of trials including patients** Principal Investigator **Entitled to submission of trials including healthy participants** Principal Investigator **Responsible for submission of trials including vulnerable population** Principal Investigator **Prerequisites for submission / approval** –
Submission Format	**Standard application form available** Yes **Standard application form** https://helseforskning.etikkom.no/ikbViewer/page/forside?_ikbLanguageCode=us
Language of Submission	**Language(s) of application** Norwegian **Language(s) of application for trials including patients** – **Language(s) of application for trials including healthy participants** – **Language(s) of application for trials including vulnerable population** –

Preferred language of application

–

English accepted

Yes
For attachments (other than information material for study participants): any Scandinavian language also accepted

Documents mandatory to be in official national language

Basic application form
Information material, Documents and Forms intended for study participants and patient information

Documents mandatory to be in local language of study site

–

Documents mandatory to be in language of study participant

–

Timelines Ethical Review

Additional Information

Time in days from submission to positive approval (maximum): 60 days

Study specific Requirements

Sponsor

Sponsorship mandatory

Yes

Co-sponsorship allowed

Yes

Contracts with external sponsor

Yes

Investigator

Entitled to be principal investigator

Physician
Dietitian
Nutritionist
Nurse
Pharmacist
PhD
Each investigator

Entitled to be principal investigator for trials with patients

–

Entitled to be principal investigator for trials with healthy participants

–

Entitled to be principal investigator for trials with vulnerable population

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Study Participants - Informed Consent (IC)

Standard IC form (ICF) available

Yes

Standard IC form (ICF)

https://helseforskning.etikkom.no/ikbViewer/page/forside?_ikbLanguageCode=us

	Accepted format of Informed Consent (IC) form Written consent **Accepted format of IC form for studies including patients** – **Accepted format of IC form for studies including healthy participants** – **Accepted format of IC form for studies including vulnerable population** –
Study Participants - Vulnerable Population	**Considered as vulnerable population** Children Elderly Pregnant women (Pregnancy) Lactating women Unconscious Persons Incapacitated adults People with psychiatric disorder People with dementia Prisoners **Regulations concerning the inclusion or exclusion available** Yes **Applicable ethical regulations** Institutional National International EU directive (2001/20/EC)
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Are not reimbursed Not specified **Reimbursement for patients** – **Reimbursement for healthy participants** – **Reimbursement for vulnerable population** – **Compensation is limited to/provided for** Expenses arising from study participation (e.g. Travel) **Compensation for patients is limited to/provided for** – **Compensation for healthy participants is limited to/provided for** – **Compensation for vulnerable population is limited to/provided for** –
Funding	**Trials in patients financially supported by industry** Yes

	Trials in healthy participants financially supported by industry Yes **Name of public company/institution supporting financially** Ministry of Health and Care Services. The Regional Liaison Committees between the Regional Health Authority and the University. **Name of private company/institution supporting financially** Cancer Society. Patient organizations. **Name of industry company/institution supporting financially** Medicines Industry **Funding is an issue during the approval process** Yes
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** No **Mandatory to inform participant of clinical trial outcome** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** – **Obligation to contract a liability insurance for trials including patients for** – **Obligation to contract a liability insurance for trials including healthy participants for** – **Obligation to contract a liability insurance for trials including vulnerable population for** – **Name and contact insurance companies insuring clinical research** PDF "Biotekforum" (PDF only in Norwegian) Link to: "Legemiddelansvarsforeningen"/ "Drug Liability Association" (link only in Norwegian) **Insurance fee in € value indicated as** – **Insurance fee in € value indicated as** –
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Monitoring Standard Operating Procedures (SOP) Case Report Form (CRF) **Regularly performed methods in trials including patients** – **Regularly performed methods in trials including healthy participants** –

Regularly performed methods in trials including vulnerable population

–

Standards concerning quality assurance and quality control exist

Yes

Standards concerning quality assurance and quality control

Applicable in Nutrition interventions (in patients) and Pharmaceuticals/Drug trials

Regularly performed audits

–

Regularly performed audits in trials including patients

–

Regularly performed audits in trials including healthy participants

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Regularly performed audits in trials including vulnerable population

–

Regularly performed audits - Additional information

Only in Pharmaceuticals/Drug trials

Archiving & Data Management

Study documents must be kept at least (in years)

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Legal framework for data management exists

Yes

National legislation

General Information: Applicable Legislation & Conventions

Applied regulatory conventions

Declaration of Helsinki
Other ethical principles for medical research (other than Declaration of Helsinki)
ICH-GCP Guidelines
Other guidelines for good clinical practice (other than ICH-GCP)
National regulatory requirements
Regional regulatory requirements

Applied regulatory conventions in studies including patients

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Applied regulatory conventions in studies including healthy participants

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Applied regulatory conventions in studies including vulnerable population

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Applicable national laws

Hospital Act
Data protection Act
Genetical engineering act
Medical device act
Drug act

	Applicable national laws for patients – **Applicable national laws for healthy participants** – **Applicable national laws for vulnerable population** – **National regulations for volunteers exist for** Nutrition intervention in healthy people Pharmaceuticals/drug trials Invasive procedures Catheters Isotopes Tissue samples **Official website providing relevant national legislation** REK website in section Acts of Legislation **Additional Information** Official governmental legal database: The Lovdata Foundation: Norwegian regulations are publicly available in the legal information system run by the Ministry of Justice and the Faculty of Law in Oslo. English translation of the Norwegian legislation can be found in the Law Library of the University of Oslo.
Nutrition	**Nutrition considered as drug** Depends on dose If a study is considered a drug trial, all the regulations that concern medicinal products for human use will apply. This document concerns interventional studies other than drug trials.
Blood & Tissue Samples	**Tissue samples permitted** Yes
Data Protection	**Specific Requirements** Yes **Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** –
Invasive Catheters	**Invasive catheters permitted** Yes

Definition

Interventional Study	**Definition in national law** Interventional studies includes all trials based on random allocation of interventions and also non-randomised interventions where participants or groups of participants are given treatments