Nutrition - 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 **CA - Registration requirements for clinical trials** Not applicable **CA - Submission required to** National CA Institutional CA International CA International CA involved in some cases
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

Preferred language of application

–

English accepted

–

Documents mandatory to be in official national language

–

Documents mandatory to be in local language of study site

–

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

Other

Submission of study mandatory

Yes

	Submission of study mandatory - Additional information Examples of activities that require approval from REC: •Experimental treatments for which the primary purpose is other than the provision of health care to an individual patient. •Student assignments to fulfil scientific requirements and with the purpose of acquiring new knowledge about health and diseases. •Use and disclosure of identifiable personal information from one or several (connected) central health registers. •Use of information from central health registers connected to information from other registers. •Use of traceable human biological material. •Use of traceable personal information and evaluations of health conditions. **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
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Regional EC (authorised to issue a single opinion) Single Opinion
Submission of Application	**Entitled to study submission** 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 **Preferred language of application** – **English accepted** For attachments (other than information material for study participants): any Scandinavian language also accepted **Documents mandatory to be in local language of study site** Basic application form Information material, Documents and Forms intended for study participants and patient information **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** Not specified **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** –
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 Consent by proxy Consent by proxy in children and vulnerable population **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** National International EU directive (2001/20/EC)
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Are not reimbursed **Compensation is limited to/provided for** Expenses arising from study participation (e.g. Travel)
Funding	**Trials generally financially supported by industry** No **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** Yes **Mandatory to inform participant of clinical trial outcome** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** – **Name and contact insurance companies insuring clinical research** PDF "Biotekforum" (PDF only in Norwegian) **Insurance fee in € value indicated as** – **Insurance fee in € value indicated as** –
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Standard Operating Procedures (SOP) Case Report Form (CRF) **Standards concerning quality assurance and quality control exist** No **Regularly performed audits** –

Archiving & Data Management	**Study documents must be kept at least (in years)** 5 **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 **Applicable national laws** Hospital Act Data protection Act Genetical engineering act Medical device act Drug act **National regulations for volunteers exist for** Nutrition intervention in healthy people Pharmaceuticals/drug trials Invasive procedures Catheters Isotopes Tissue samples Projects involving volunteers have to be reviewed by Regional Ethics Committee **Official website providing relevant national legislation** REK website in section Acts of Legislation **Additional Information** 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.
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

Observational Study	**Definition in national law** In observational studies, the investigators observe the subjects and measure variables of interest without assigning treatments to the subjects