Nutrition - FINLAND

Competent authority

Contact Details	**Contact Name 1** Finnish National Agency for Medicines (Fimea) **Phone** +358 29 522 3341 **Fax** +358 29 522 3001 **Email General** clinicaltrials@fimea.fi **Address** P.O. Box 55 **ZIP/City** 00034 FIMEA **Country** Finland (FI) **Web address** http://www.fimea.fi
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Institutional Competent Authority Regional Ethics Committee **CA - Registration requirements for clinical trials** Registration mandatory **CA - Submission required to** Institutional CA
Submission Format	**Standard application form available** Yes
Language of Submission	**Language(s) of application** Official national language Finnish Swedish English Swedish may also be accepted in certain cases **Preferred language of application** – **English accepted** Yes Partly, not for all documents depending on EC if or if not patient documents need to be in Finnish

	Documents mandatory to be in official national language 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 the study participant** –
Timelines Authorisation	**Time to approval of CA in weeks (minimum)** 2 **Time to approval of CA in weeks (maximum)** 12 **Time to approval CA in weeks (average)** 6
Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Contact Details	**Contact Name 1** National Committee on Medical Research Ethics (TUKIJA) **Address** Postal Adress: TUKIJA, Valvira; P.O. Box 210 **ZIP/City** 00531 Helsinki **Country** Finland (FI) **E-Mail** tukija@valvira.fi **Web address** http://tukija.fi/en **Additional Information** TUKIJA operates under the auspices of Valvira. It previously operated as sub-committee on Medical Research Ethics of the National Advisory Board on Health Care Ethics (ETENE)/ Ministry of Social Affairs and Health.]
Ethical Review – General	**Submission for Ethical review mandatory for** – **Submission of study mandatory** Yes **Submission of study mandatory - Additional information** To regional or institutional EC **Submission to CA and EC to be performed in the following order** –

	National declaration on Ethical requirements exists Yes
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** International EC
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Central EC (authorised to issue a single opinion)
Submission of Application	**Entitled to study submission** Principal Investigator Investigator Physician Dietitian Nutritionist **Prerequisites for submission / approval** –
Submission Format	**Standard application form available** No
Language of Submission	**Language(s) of application** Official national language Finnish Swedish English depending on the EC - Swedish may also be accepted in certain cases **Preferred language of application** – **English accepted** Yes Partly, not for all documents depending on EC if or if not patient documents need to be in Finnish **Documents mandatory to be in local language of study site** Information material, Documents and Forms intended for study participants and patient information **Documents mandatory to be in language of study participant** –
Timelines Ethical Review	**Time in weeks from submission to positive approval (minimum)** 2 **Time in weeks from submission to positive approval (maximum)** 8 **Time in weeks from submission to positive approval (average)** 4
Safety Reporting	**Investigator shall report SAE to** Institution

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes

Investigator	**Entitled to be principal investigator** Physician Dietitian Nutritionist **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 **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** Optional **Compensation is limited to/provided for** Time effort Expenses arising from study participation (e.g. Travel)
Funding	**Trials generally financially supported by industry** Not specified

	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** Patients/Volunteers Researchers **Insurance fee in € value indicated as** – **Insurance fee in € value indicated as** –
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** – **Regularly performed methods - Additional information** Audits, inspections, Monitoring, Standard Operating Procedures (SOP), Audit Trail, Case Report Form are not performed regularly in observational trials. **Standards concerning quality assurance and quality control exist** Yes **Regularly performed audits** –
Archiving & Data Management	**Study documents must be kept at least (in years)** – **Legal framework for data management exists** Yes

National legislation

General Information: Applicable Legislation & Conventions	**Applied regulatory conventions** Other ethical principles for medical research (other than Declaration of Helsinki) Other guidelines for good clinical practice (other than ICH-GCP) Institutional regulatory requirements **Applicable national laws** Hospital Act Data protection Act **National regulations for volunteers exist for** Nutrition intervention in healthy people Pharmaceuticals/drug trials Invasive procedures Catheters Isotopes Tissue samples

Nutrition	**Nutrition considered as drug** No
Data Protection	**Specific Requirements** No **Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** –

Definition

Nutrition Study	**Definition available in national law** Yes