Nutrition/Interventional - 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** – **Regulatory and ethics bodies involved in approval process for trials including patients** Institutional Competent Authority Regional Ethics Committee **Regulatory and ethics bodies involved in approval process for trials including including healthy participants** – **Regulatory and ethics bodies involved in approval process for trials including vulnerable population** – **CA - Registration/ notification without approval required for** – **CA - Registration requirements for clinical trials** Registration mandatory **Registration requirements for clinical trials including patients** – **Registration requirements for clinical trials including healthy participants** –

	Registration requirements for clinical trials including vulnerable population – **CA - Submission required to** Institutional CA **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
Language of Submission	**Language(s) of application** Official national language Finnish Swedish English Swedish may also be accepted in certain cases **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 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** – **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of the study participant** Information material, Documents and Forms intended for study participants and patient information
Timelines Authorisation	**Time to approval of CA in weeks (minimum)** 2 **Time to approval of CA in weeks (minimum) in trials including patients** 12

Time to approval of CA in weeks (minimum) in trials including healthy participants

6

Safety Reporting

Sponsor must declare reportable events to

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Ethics committee

Contact Details

Contact Name 1

National Committee on Medical Research Ethics (TUKIJA)

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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

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Submission of study mandatory

Yes

Submission of study mandatory - Additional information

Responsibility lies within the Regional / institutional Ethics committees

Submission to CA and EC to be performed in the following order

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National declaration on Ethical requirements for trials including patients

Yes

Single-Centre Studies - Ethical Review

Ethical approval (favourable opinion) to be obtained from

Institutional EC

Ethical approval (favourable opinion) for trials including patients to be obtained from

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Ethical approval (favourable opinion) for trials including healthy participants to be obtained from

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	Ethical approval (favourable opinion) for trials including vulnerable population to be obtained from –
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Lead EC (authorised to issue a single opinion) **Ethical approval in trials including patients obtained from** – **Ethical approval in trials including healthy participants obtained from** – **Ethical approval in trials including vulnerable population obtained from** –
Submission of Application	**Entitled to study submission** Principal Investigator Investigator Physician Depends on study population **Entitled to submission of trials including patients** Principal Investigator Investigator Physician **Entitled to submission of trials including healthy participants** Principal Investigator Investigator Physician Dietitian Nutritionist **Responsible for submission of trials including vulnerable population** Principal Investigator Investigator Physician **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 **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 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 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 **Investigator shall report SAE in trials with patients to** – **Investigator shall report SAE in trials with healthy participants to** – **Investigator shall report SAE in trials with volunteers to** –

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes **Contracts with external sponsor** No
Investigator	**Entitled to be principal investigator** Depends on study population **Entitled to be principal investigator for trials with patients** Physician **Entitled to be principal investigator for trials with healthy participants** Physician Dietitian Nutritionist

	Entitled to be principal investigator for trials with vulnerable population Physician
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 **Reimbursement for patients** – **Reimbursement for healthy participants** – **Reimbursement for vulnerable population** – **Compensation is limited to/provided for** Time effort 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 generally financially supported by industry** No **Funding is an issue during the approval process** Yes **Additional Information** only pharmaceuticals/drug trials are generally sponsored by industry
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 **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** – **Insurance fee in € value indicated as** – **Insurance fee in € value indicated as** –
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** – **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 **Regularly performed audits** –

Regularly performed audits in trials including patients

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Regularly performed audits in trials including healthy participants

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Regularly performed audits in trials including vulnerable population

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Regularly performed audits - Additional information

Audit, Inspections, Monitoring, SOPs, Audit trails, CRFs are not regularly performformed methods for quality assurance and quality control.

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

Other ethical principles for medical research (other than Declaration of Helsinki)
Other guidelines for good clinical practice (other than ICH-GCP)
Institutional 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

Applicable national laws for patients

–

Applicable national laws for healthy participants

–

Applicable national laws for vulnerable population

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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
Blood & Tissue Samples	**Tissue samples permitted** Yes
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)** –
Invasive Catheters	**Invasive catheters permitted** Yes

Definition

Interventional Study	**Definition in national law** A study in which a defined intervention is performed - usually this is medical, but could also be nutritional.