

Nutrition/Interventional - FINLAND

Competent authority

Contact Details

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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

—

	<p>Registration requirements for clinical trials including vulnerable population</p> <p>—</p> <p>CA - Submission required to</p> <p>Institutional CA</p> <p>Studies including patients - submission required to</p> <p>—</p> <p>Studies including healthy participants - submission required to</p> <p>—</p> <p>Studies including vulnerable population - submission required to</p> <p>—</p>
Submission Format	<p>Standard application form available</p> <p>Yes</p>
Language of Submission	<p>Language(s) of application</p> <p>Official national language Finnish Swedish English Swedish may also be accepted in certain cases</p> <p>Language(s) of application for trials including patients</p> <p>—</p> <p>Language(s) of application for trials including healthy participants</p> <p>—</p> <p>Language(s) of application for trials including vulnerable population</p> <p>—</p> <p>Preferred language of application</p> <p>—</p> <p>English accepted</p> <p>Yes Partly, not for all documents depending on EC if or if not patient documents need to be in Finnish</p> <p>Documents mandatory to be in official national language</p> <p>—</p> <p>Documents mandatory to be in local language of study site</p> <p>—</p> <p>Documents mandatory to be in language of the study participant</p> <p>Information material, Documents and Forms intended for study participants and patient information</p>
Timelines Authorisation	<p>Time to approval of CA in weeks (minimum)</p> <p>2</p> <p>Time to approval of CA in weeks (minimum) in trials including patients</p> <p>12</p>

	Time to approval of CA in weeks (minimum) in trials including healthy participants 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 Address: 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 Responsibility lies within the Regional / institutional Ethics committees Submission to CA and EC to be performed in the following order — 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 — Ethical approval (favourable opinion) for trials including healthy participants to be obtained from —

	<p>Ethical approval (favourable opinion) for trials including vulnerable population to be obtained from</p> <p>—</p>
Multi-Centre Studies - Ethical Review	<p>Ethical approval (favourable opinion) required from</p> <p>Lead EC (authorised to issue a single opinion)</p> <p>Ethical approval in trials including patients obtained from</p> <p>—</p> <p>Ethical approval in trials including healthy participants obtained from</p> <p>—</p> <p>Ethical approval in trials including vulnerable population obtained from</p> <p>—</p>
Submission of Application	<p>Entitled to study submission</p> <p>Principal Investigator Investigator Physician Depends on study population</p> <p>Entitled to submission of trials including patients</p> <p>Principal Investigator Investigator Physician</p> <p>Entitled to submission of trials including healthy participants</p> <p>Principal Investigator Investigator Physician Dietitian Nutritionist</p> <p>Responsible for submission of trials including vulnerable population</p> <p>Principal Investigator Investigator Physician</p> <p>Prerequisites for submission / approval</p> <p>—</p>
Submission Format	<p>Standard application form available</p> <p>No</p>
Language of Submission	<p>Language(s) of application</p> <p>Official national language Finnish Swedish English depending on the EC - Swedish may also be accepted in certain cases</p> <p>Language(s) of application for trials including patients</p> <p>—</p> <p>Language(s) of application for trials including healthy participants</p> <p>—</p> <p>Language(s) of application for trials including vulnerable population</p> <p>—</p>

	<p>Preferred language of application</p> <p>—</p> <p>English accepted</p> <p>Yes Partly, not for all documents depending on EC if or if not patient documents need to be in Finnish</p> <p>Documents mandatory to be in official national language</p> <p>Information material, Documents and Forms intended for study participants and patient information</p> <p>Documents mandatory to be in local language of study site</p> <p>—</p> <p>Documents mandatory to be in language of study participant</p> <p>—</p>
Timelines Ethical Review	<p>Time in weeks from submission to positive approval (minimum)</p> <p>2</p> <p>Time in weeks from submission to positive approval (maximum)</p> <p>8</p> <p>Time in weeks from submission to positive approval (average)</p> <p>4</p>
Safety Reporting	<p>Investigator shall report SAE to</p> <p>Institution</p> <p>Investigator shall report SAE in trials with patients to</p> <p>—</p> <p>Investigator shall report SAE in trials with healthy participants to</p> <p>—</p> <p>Investigator shall report SAE in trials with volunteers to</p> <p>—</p>

Study specific Requirements

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

	<p>Entitled to be principal investigator for trials with vulnerable population</p> <p>Physician</p>
Study Participants - Informed Consent (IC)	<p>Standard IC form (ICF) available</p> <p>Yes</p> <p>Accepted format of Informed Consent (IC) form</p> <p>Written consent</p> <p>Accepted format of IC form for studies including patients</p> <p>—</p> <p>Accepted format of IC form for studies including healthy participants</p> <p>—</p> <p>Accepted format of IC form for studies including vulnerable population</p> <p>—</p>
Study Participants - Vulnerable Population	<p>Considered as vulnerable population</p> <p>Children Elderly Pregnant women (Pregnancy) Lactating women Unconscious Persons Incapacitated adults People with psychiatric disorder People with dementia Prisoners</p> <p>Regulations concerning the inclusion or exclusion available</p> <p>Yes</p> <p>Applicable ethical regulations</p> <p>Institutional National International EU directive (2001/20/EC)</p>
Study Participants - Compensation & Reimbursement	<p>Reimbursement for study participants</p> <p>Optional</p> <p>Reimbursement for patients</p> <p>—</p> <p>Reimbursement for healthy participants</p> <p>—</p> <p>Reimbursement for vulnerable population</p> <p>—</p> <p>Compensation is limited to/provided for</p> <p>Time effort Expenses arising from study participation (e.g. Travel)</p> <p>Compensation for patients is limited to/provided for</p> <p>—</p> <p>Compensation for healthy participants is limited to/provided for</p> <p>—</p>

	<p>Compensation for vulnerable population is limited to/provided for</p> <p>—</p>
Funding	<p>Trials generally financially supported by industry</p> <p>No</p> <p>Funding is an issue during the approval process</p> <p>Yes</p> <p>Additional Information</p> <p>only pharmaceuticals/drug trials are generally sponsored by industry</p>
Study Participants - Recruitment & Trial Outcome	<p>Regulations on recruitment process exist</p> <p>Yes</p> <p>Mandatory to inform participant of clinical trial outcome</p> <p>No</p>
Insurance	<p>Liability insurance or alternative arrangements for damages mandatory for</p> <p>Patients/Volunteers Researchers</p> <p>Obligation to contract a liability insurance for trials including patients for</p> <p>—</p> <p>Obligation to contract a liability insurance for trials including healthy participants for</p> <p>—</p> <p>Obligation to contract a liability insurance for trials including vulnerable population for</p> <p>—</p> <p>Insurance fee in € value indicated as</p> <p>—</p> <p>Insurance fee in € value indicated as</p> <p>—</p>
Quality Assurance/ Quality Control (QA/QC)	<p>Regularly performed methods</p> <p>—</p> <p>Regularly performed methods in trials including patients</p> <p>—</p> <p>Regularly performed methods in trials including healthy participants</p> <p>—</p> <p>Regularly performed methods in trials including vulnerable population</p> <p>—</p> <p>Standards concerning quality assurance and quality control exist</p> <p>Yes</p> <p>Regularly performed audits</p> <p>—</p>

	Regularly performed audits in trials including patients
	—
	Regularly performed audits in trials including healthy participants
	—
	Regularly performed audits in trials including vulnerable population
	—
	Regularly performed audits - Additional information
	Audit, Inspections, Monitoring, SOPs, Audit trails, CRFs are not regularly performed methods for quality assurance and quality control.
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
	Applied regulatory conventions in studies including patients
	—
	Applied regulatory conventions in studies including healthy participants
	—
	Applied regulatory conventions in studies including vulnerable population
	—
	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
	—
	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.
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