Nutrition/Interventional - ICELAND

Competent authority

Contact Details	**Contact Name 1** Icelandic Medicines Agency (IMA) **Phone** 520 2100 **Fax** 561 2170 **Email Department** clinical.trials@ima.is **Address** Vínlandsleið 14 **ZIP/City** 113 Reykjavík **Country** Iceland (IS) **Web address** http://www.ima.is **Additional Information** No local CA
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** National Ethics Committee Agency for data protection **Regulatory and ethics bodies involved in approval process for trials including patients** Institutional 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 recommended Not mandatory **Registration requirements for clinical trials including patients** –

	Registration requirements for clinical trials including healthy participants – **Registration requirements for clinical trials including vulnerable population** – **Registration requirements - Additional information** The registration is not mandatory according to our regulations, but we register all nutrition intervention trials, both in healthy people and patients **CA - Submission required to** – **Studies including patients - submission required to** Institutional CA **Studies including healthy participants - submission required to** – **Studies including vulnerable population - submission required to** –
Submission Format	**Standard application form available** No **Additional Information** Only in pharmaceuticals
Language of Submission	**Language(s) of application** Icelandic **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** Partly, not for all documents **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 to approval CA 4-8 weeks (average)

Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Contact Details	**Contact Name 1** The National Bioethics Committee - NBC (Vísindasiðanefnd) **Phone** +354 5517100 **Address** Tryggvagata 17 **ZIP/City** 101 Reykjavík **Country** Iceland (IS) **E-Mail** vsn@vsn.is **Web address** http://www.vsn.is/en **Additional Information** Relevant for most of the nutritional studies
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
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** International EC National EC **Ethical approval (favourable opinion) for trials including patients to be obtained from** Institutional EC **Ethical approval (favourable opinion) for trials including healthy participants to be obtained from** – **Ethical approval (favourable opinion) for trials including vulnerable population to be obtained from** –
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** 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** Uncertain **Entitled to submission of trials including patients** – **Entitled to submission of trials including healthy participants** – **Responsible for submission of trials including vulnerable population** – **Prerequisites for submission / approval** –
Submission Format	**Standard application form available** Yes **Standard application form** Standard application form
Language of Submission	**Language(s) of application** Icelandic **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** Partly, not for all documents **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 study participant** –

Timelines Ethical Review	**Additional Information** Time to approval CA 4-8 weeks (average)
Safety Reporting	**Investigator shall report SAE to** Uncertain **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

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** No **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** Uncertain **Reimbursement for patients** – **Reimbursement for healthy participants** – **Reimbursement for vulnerable population** – **Compensation is limited to/provided for** Not specified **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** Not specified **Funding is an issue during the approval process** Not specified
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** Yes
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

Not specified

Regularly performed methods in trials including patients

–

Regularly performed methods in trials including healthy participants

–

Regularly performed methods in trials including vulnerable population

–

Regularly performed methods - Additional information

Standard Operating Procedures (SOPs) and Case Report Form (CRF) only in pharmaceuticals/drug trials

Standards concerning quality assurance and quality control

Only in pharmaceuticals/drug trials

Regularly performed audits

–

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

Uncertain

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

Declaration of Helsinki
Other ethical principles for medical research (other than Declaration of Helsinki)
National regulatory requirements

Applied regulatory conventions in studies including patients

Institutional regulatory requirements

Applied regulatory conventions in studies including healthy participants

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	Applied regulatory conventions in studies including vulnerable population – **Applicable national laws** – **Applicable national laws for patients** Hospital Act Data protection Act Medical device act Drug act **Applicable national laws for healthy participants** Not specified **Applicable national laws for vulnerable population** – **National regulations for volunteers exist for** –
Nutrition	**Nutrition considered as drug** No
Blood & Tissue Samples	**Tissue samples permitted** Not specified
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** Not specified

Definition

Interventional Study	**Definition in national law** Traditionally the term intervention study is used for clinical trials and randomized trials (for dietary intervention studies meaning changing/providing earlier dietary habits)