Nutrition - 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 **CA - Registration requirements for clinical trials** Registration recommended Not mandatory **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** Institutional CA
Submission Format	**Standard application form available** No **Additional Information** Only in pharmaceuticals
Language of Submission	**Language(s) of application** Icelandic **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
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Single Opinion
Submission of Application	**Entitled to study submission** Uncertain **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 **Preferred language of application** – **English accepted** Partly, not for all documents **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

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 **Compensation is limited to/provided for** Not specified
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** Uncertain **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 - 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 - 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 **Applicable national laws** Hospital Act Data protection Act Medical device act Drug act **National regulations for volunteers exist for** Not specified
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

Observational Study	**Definition in national law** Traditionally observation studies refers to studies without intervention, i.e. only observing and recording the current situation.