## **Nutrition - ICELAND**

Competent author	rity
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 /	Regulatory and ethics bodies involved in approval process
Registration / Notification	National Ethics Committee Agency for data protection
	CA - Registration requirements for clinical trials
	Registration recommended Not mandatory
	<b>Registration requirements - Additional information</b>
	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
	-

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 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         Safety Reporting         Contact Details         Contact Details         Contact Details         Contact Name 1         The National Bioethics Committee - NBC (Visindasibanefind)         Phone         +354 5517100         Address         Trygguagata 17         ZIP/City         101 Reykjavik         Country         Keland (IS)         E-Mail         Vangwan.is         Web address         http://www.vsn.is/en         Additional Information         Relevant for most of the nutritional studies         Ethcal Review - Generation         Submission of study mandatory		English accepted
-       Documents mandatory to be in local language of study site         -       Documents mandatory to be in language of the study participant         -       Documents mandatory to be in language of the study participant         -       Documents mandatory to be in language of the study participant         -       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 Bloethics Committee - NBC (Visindasiðanefnd)       Phone         + 354 5517100       Address         Tryggvagata 17       ZiP/City         101 Reykjavik       Country         Colation (Is)       E-Mail         Keland (Is)       E-Mail         Kisn@vsn.is       Kelandress         http://www.vsn.is/en       Address         Address       Address         http://www.vsn.is/en       Address         Address       Bubmission for Ethical review mandatory for         -       Submission of study mandatory		Partly, not for all documents
-       Documents mandatory to be in language of the study participant         -       Additional Information         Time to approval CA 4-8 weeks (average)       Sponsor must declare reportable events to         -       -         Ethics committee         Contact Details         Contact Details       Contact Name 1         The National Bioethics Committee - NBC (Visindasiðanefnd)         Phone         +354 5517100         Address         Tryggvagata 17         ZIP/City         101 Reykjavík         Country         keland (IS)         E-Mail         Naveysn.is         Web address         http://www.vsn.is/en         Additional Information         Relevant for most of the nutritional studies         Ethical Review - General         Submission of study mandatory for		Documents mandatory to be in official national language
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E-Mail         vsn@vsn.is         Web address         http://www.vsn.is/en         Additional Information         Relevant for most of the nutritional studies         Submission for Ethical review mandatory for         -         Submission of study mandatory		Country
wsn@vsn.is         Web address         http://www.vsn.is/en         Additional Information         Relevant for most of the nutritional studies         Submission for Ethical review mandatory for         -         Submission of study mandatory		Iceland (IS)
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Relevant for most of the nutritional studies   Ethical Review - General   Submission for Ethical review mandatory for   -   Submission of study mandatory		http://www.vsn.is/en
Ethical Review – General       Submission for Ethical review mandatory for         -       Submission of study mandatory		Additional Information
- Submission of study mandatory		Relevant for most of the nutritional studies
Submission of study mandatory	Ethical Review - General	Submission for Ethical review mandatory for
		-
Vac		Submission of study mandatory
		Yes
Submission to CA and EC to be performed in the following order		Submission to CA and EC to be performed in the following order
—		-
National declaration on Ethical requirements exists		
Yes		Yes

Single-Centre Studies - Ethical Review	Ethical approval (favourable opinion) to be obtained from
	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 Req	uirements
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 for study participants
Reimbursement	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	Regulations on recruitment process exist
Outcome	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

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pha <b>Sta</b> Onl	armaceuticals/drug trials andards concerning quality assurance and quality control ly in pharmaceuticals/drug trials
On	ly in pharmaceuticals/drug trials
Re	gularly performed audits
-	
Re	gularly performed audits - Additional information
Une	certain
Archiving & Data Stu Management –	udy documents must be kept at least (in years)
Le	gal framework for data management exists
Yes	S
National legislation	
Applicable Legislation &	plied regulatory conventions
Oth	claration of Helsinki her ethical principles for medical research (other than Declaration of Isinki) tional regulatory requirements
Ар	plicable national laws
Dat Me	spital Act ta protection Act dical device act ug act
Na	tional regulations for volunteers exist for
Not	t specified
Nutrition <b>Nu</b>	trition considered as drug
No	
Blood & Tissue Samples Tis	ssue samples permitted
Not	t specified
Data Protection Sp	ecific Requirements
Yes	5
red	gal framework (on safeguarding the collection, handling, cording, keeping and/or processing of any clinical trial related data d patient files)
-	
Invasive Catheters	asive catheters permitted
Not	t specified
Definition	
Observational Study De	finition in national law
	aditionally observation studies refers to studies without intervention, i.e. ly observing and recording the current situation.