Nutrition - LITHUANIA

Competent authority

Contact Details	**Contact Name 1** State Medicines Control Agency **Phone** +370 5 263 9264 **Fax** +370 5 263 9265 **Email General** vvkt@vvkt.lt **Address** Žirmūnų g. 139A **ZIP/City** 09120 Vilnius **Country** Lithuania (LT) **Web address** http://www.vvkt.lt/
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** National Competent Authorities Regional Ethics Committee National Ethics Committee Agency for data protection **CA - Registration requirements for clinical trials** Registration mandatory **CA - Submission required to** National CA
Submission Format	**Standard application form available** Yes **Standard application form** http://bioetika.sam.lt/
Language of Submission	**Language(s) of application** Official national language English **Preferred language of application** – **English accepted** –

	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	**Time to approval of CA in weeks (minimum)** 8 **Time to approval of CA in weeks (maximum)** 12 **Time to approval CA in weeks (average)** 8
Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Contact Details	**Contact Name 1** Lithuanian Bioethics Committee **Contact Name 2** Lietuvos bioetikos komitetas **Phone** (+370 5) 212 45 65 **Fax** (+370 5) 260 86 40 **Address** Vilniaus str. 16 **ZIP/City** LT-01402,Vilnius **Country** Lithuania (LT) **E-Mail** lbek@sam.lt **Web address** http://bioetika.sam.lt/index.php?3221858831 **Additional Information** Kaunas Regional Biomedical Research Ethics Committee: LUHS Kaunas Region Biomedical Research Ethics Committee
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 **National declaration** http://bioetika.sam.lt/
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 Multiple Opinion
Submission of Application	**Entitled to study submission** Sponsor Investigator **Prerequisites for submission / approval** –
Language of Submission	**Language(s) of application** Official national language English **Preferred language of application** – **English accepted** – **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)** 8 **Time in weeks from submission to positive approval (maximum)** 12 **Time in weeks from submission to positive approval (average)** 8
Safety Reporting	**Investigator shall report SAE to** National CA Sponsor

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes

Investigator	**Entitled to be principal investigator** Physician Dietitian PhD **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 **Regulations concerning the inclusion or exclusion** Law on Biomedical research **Applicable ethical regulations** Institutional National International EU directive (2001/20/EC)
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Not specified **Compensation is limited to/provided for** Expenses arising from study participation (e.g. Travel) Phase I trials

Funding	**Trials generally financially supported by industry** No **Name of public company/institution supporting financially** Medical university or university hospital **Name of industry company/institution supporting financially** Pharma and biotech companies **Funding is an issue during the approval process** No
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Patients/Volunteers Researchers Sponsor **Insurance fee in € value indicated as** – **Insurance fee in € value indicated as** –
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Audits Inspections Monitoring Standard Operating Procedures (SOP) Audit Trail Case Report Form (CRF) **Standards concerning quality assurance and quality control exist** Yes **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) ICH-GCP Guidelines Other guidelines for good clinical practice (other than ICH-GCP) International regulatory requirements European regulatory requirements - European Directive 2001/20/EC, 2005/28/EC National regulatory requirements Regional regulatory requirements Institutional regulatory requirements **Applicable national laws** Data protection Act Drug act **National regulations for volunteers exist for** Not specified **Network providing information on regulations and ethical requirements in studies** Medicines Control Agency of Lithuania **Network Email** vvkt@vvkt.lt **Official website providing relevant national legislation available** Yes **Official website providing relevant national legislation** http://www.vvkt.lt/lit/English **Additional Information** http://bioetika.sam.lt/
Nutrition	**Nutrition considered as drug** No
Blood & Tissue Samples	**Tissue samples permitted** Yes
Invasive Catheters	**Invasive catheters permitted** Yes