Nutrition - MACEDONIA

Competent authority

Contact Details	**Contact Name 1** Food and Veterinary Agency **Contact Name 2** Suzana Popovska **Phone** +38922457895 **Email General** spopovska@fva.gov.mk **Address** III Makedonska brigada No 20 Macedonia Tabak building **ZIP/City** 1000 Skopje **Country** Macedonia (MK) **Web address** http://www.fva.gov.mk
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Institutional Competent Authority 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** moh.gov.mk --> http://zdravstvo.gov.mk/klinichki-pateki/
Language of Submission	**Language(s) of application** – **Preferred language of application** Official national language **English accepted** No **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** –
Safety Reporting	**Sponsor must declare reportable events to** National CA Sponsor Trial Coordinator

Ethics committee

Contact Details	**Contact Name 1** Medical Ethics Committee **Contact Name 2** Medical Faculty Skopje **Address** 50 Divizija 6 **ZIP/City** 1000 Skopje **Country** Macedonia (MK)
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** www.moh.gov.mk
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** Sponsor **Prerequisites for submission / approval** Proof of GCP Training of applicant
Submission Format	**Standard application form available** Yes

	Standard application form Standard application form
Language of Submission	**Language(s) of application** Official national language **Preferred language of application** Official national language **English accepted** No **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)** 2 **Time in weeks from submission to positive approval (maximum)** 6 **Time in weeks from submission to positive approval (average)** 5
Safety Reporting	**Investigator shall report SAE to** National CA Sponsor Trial Coordinator

Study specific Requirements

Sponsor	**Sponsorship mandatory** No **Co-sponsorship allowed** Yes **Contracts with external sponsor** No
Investigator	**Entitled to be principal investigator** Physician **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** Yes

	Standard IC form (ICF) www.moh.gov.mk **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 People with psychiatric disorder **Applicable ethical regulations** National
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional **Compensation is limited to/provided for** –
Funding	**Trials generally financially supported by industry** No **Funding is an issue during the approval process** Yes
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** No **Mandatory to inform participant of clinical trial outcome** Yes
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Not mandatory **Insurance fee in € value indicated as** – **Insurance fee in € value indicated as** –
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Monitoring Case Report Form (CRF)

	Standards concerning quality assurance and quality control exist No **Regularly performed audits** – **Regularly performed audits - Additional information** internal and external audits regularly performed
Archiving & Data Management	**Study documents must be kept at least (in years)** – **Legal framework for data management exists** No

National legislation

General Information: Applicable Legislation & Conventions	**Applied regulatory conventions** Declaration of Helsinki ICH-GCP Guidelines Other guidelines for good clinical practice (other than ICH-GCP) International regulatory requirements National regulatory requirements **Applicable national laws** Hospital Act Data protection Act Medical device act Drug act **National regulations for volunteers exist for** Nutrition intervention in healthy people Pharmaceuticals/drug trials **Network providing information on regulations and ethical requirements in studies** National Drug Investigation Centre **Official website providing relevant national legislation available** Yes **Official website providing relevant national legislation** www.reglek.com.mk
Nutrition	**Nutrition considered as drug** Not specified
Blood & Tissue Samples	**Tissue samples permitted** No
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

Nutrition Study	**Definition available in national law** Yes