Nutrition/Interventional - GREECE

Competent authority

Contact Details	**Contact Name 1** National Drug Organisation **Web address** http://www.eof.gr
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Institutional Ethics Committee **Regulatory and ethics bodies involved in approval process for trials including patients** – **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** 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** – **CA - Submission required to** – **Studies including patients - submission required to** – **Studies including healthy participants - submission required to** – **Studies including vulnerable population - submission required to** –

Ethics committee

Ethical Review – General	**Submission for Ethical review mandatory for** –

	Submission to CA and EC to be performed in the following order –
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Lead EC (authorised to issue a 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** Principal Investigator Investigator Physician Dietitian Nutritionist PhD Industry **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** –
Language of Submission	**Language(s) of application** Official national language **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** – **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

–

Study specific Requirements

Investigator

Entitled to be principal investigator

Each investigator

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 - Vulnerable Population

Considered as vulnerable population

–

Regulations concerning the inclusion or exclusion available

No

Regulations concerning the inclusion or exclusion

not validated

Applicable ethical regulations

–

Study Participants - Compensation & Reimbursement

Reimbursement for study participants

Optional
Not validated

Reimbursement for patients

–

Reimbursement for healthy participants

–

Reimbursement for vulnerable population

–

Compensation is limited to/provided for

–

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

–

Quality Assurance/ Quality Control (QA/QC)

Regularly performed methods

Monitoring
Case Report Form (CRF)

	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 audits** – **Regularly performed audits in trials including patients** – **Regularly performed audits in trials including healthy participants** – **Regularly performed audits in trials including vulnerable population** –

National legislation

Nutrition	**Nutrition considered as drug** Only parenteral nutrition
Blood & Tissue Samples	**Tissue samples permitted** Yes **Tissue samples permitted - Additional information** not validated
Invasive Catheters	**Invasive catheters permitted** Yes **Additional Information** not validated