

# 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**

–

	<p><b>Submission to CA and EC to be performed in the following order</b></p> <p>–</p>
<p>Multi-Centre Studies - Ethical Review</p>	<p><b>Ethical approval (favourable opinion) required from</b></p> <p>Lead EC (authorised to issue a single opinion)</p> <p><b>Ethical approval in trials including patients obtained from</b></p> <p>–</p> <p><b>Ethical approval in trials including healthy participants obtained from</b></p> <p>–</p> <p><b>Ethical approval in trials including vulnerable population obtained from</b></p> <p>–</p>
<p>Submission of Application</p>	<p><b>Entitled to study submission</b></p> <p>Principal Investigator Investigator Physician Dietitian Nutritionist PhD Industry</p> <p><b>Entitled to submission of trials including patients</b></p> <p>–</p> <p><b>Entitled to submission of trials including healthy participants</b></p> <p>–</p> <p><b>Responsible for submission of trials including vulnerable population</b></p> <p>–</p> <p><b>Prerequisites for submission / approval</b></p> <p>–</p>
<p>Language of Submission</p>	<p><b>Language(s) of application</b></p> <p>Official national language</p> <p><b>Language(s) of application for trials including patients</b></p> <p>–</p> <p><b>Language(s) of application for trials including healthy participants</b></p> <p>–</p> <p><b>Language(s) of application for trials including vulnerable population</b></p> <p>–</p> <p><b>Preferred language of application</b></p> <p>–</p> <p><b>English accepted</b></p> <p>–</p> <p><b>Documents mandatory to be in official national language</b></p> <p>–</p> <p><b>Documents mandatory to be in local language of study site</b></p> <p>–</p>

**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