

# 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

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#### Regulatory and ethics bodies involved in approval process for trials including including healthy participants

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#### Regulatory and ethics bodies involved in approval process for trials including vulnerable population

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#### CA - Registration/ notification without approval required for

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#### 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

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## Ethics committee

### Ethical Review - General

#### Submission for Ethical review mandatory for

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	<p><b>Submission to CA and EC to be performed in the following order</b></p> <p>—</p>
Multi-Centre Studies - Ethical Review	<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>
Submission of Application	<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>
Language of Submission	<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**

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## 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**

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**Entitled to be principal investigator for trials with vulnerable population**

—

Study Participants -  
Vulnerable Population

**Considered as vulnerable population**

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**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**

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Quality Assurance/  
Quality Control (QA/QC)

**Regularly performed methods**

Monitoring

Case Report Form (CRF)

	<p><b>Regularly performed methods in trials including patients</b></p> <p>—</p> <p><b>Regularly performed methods in trials including healthy participants</b></p> <p>—</p> <p><b>Regularly performed methods in trials including vulnerable population</b></p> <p>—</p> <p><b>Regularly performed audits</b></p> <p>—</p> <p><b>Regularly performed audits in trials including patients</b></p> <p>—</p> <p><b>Regularly performed audits in trials including healthy participants</b></p> <p>—</p> <p><b>Regularly performed audits in trials including vulnerable population</b></p> <p>—</p>
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National legislation	
Nutrition	<p><b>Nutrition considered as drug</b></p> <p>Only parenteral nutrition</p>
Blood & Tissue Samples	<p><b>Tissue samples permitted</b></p> <p>Yes</p> <p><b>Tissue samples permitted - Additional information</b></p> <p>not validated</p>
Invasive Catheters	<p><b>Invasive catheters permitted</b></p> <p>Yes</p> <p><b>Additional Information</b></p> <p>not validated</p>