

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