

Nutrition - GREECE

Competent authority

Contact Details	Contact Name 1 National Organisation for Medicines Web address http://www.eof.gr
Trial Authorisation / Registration / Notification	Regulatory and ethics bodies involved in approval process Institutional Ethics Committee CA - Registration requirements for clinical trials Not mandatory Not validated CA - 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 EC review not required Not validated
Submission of Application	Entitled to study submission Principal Investigator Investigator Dietitian Nutritionist PhD Prerequisites for submission / approval —
Language of Submission	Language(s) of application Official national language Preferred language of application — English accepted No Documents mandatory to be in local language of study site — Documents mandatory to be in language of study participant —

Study specific Requirements

Investigator	<p>Entitled to be principal investigator</p> <p>Each investigator</p> <p>Entitled to be principal investigator for trials with patients</p> <p>—</p> <p>Entitled to be principal investigator for trials with healthy participants</p> <p>—</p> <p>Entitled to be principal investigator for trials with vulnerable population</p> <p>—</p>
Study Participants - Vulnerable Population	<p>Considered as vulnerable population</p> <p>—</p> <p>Regulations concerning the inclusion or exclusion available</p> <p>No</p> <p>Regulations concerning the inclusion or exclusion</p> <p>not validated</p> <p>Applicable ethical regulations</p> <p>—</p>
Quality Assurance/ Quality Control (QA/QC)	<p>Regularly performed methods</p> <p>Monitoring Case Report Form (CRF) Not validated</p> <p>Regularly performed audits</p> <p>—</p>
National legislation	
Nutrition	<p>Nutrition considered as drug</p> <p>Only parenteral nutrition</p>