Nutrition/Interventional - ISRAEL

Competent authority

Contact Details

Contact Name 1

Ministry of Health

Phone

Contacts by department: http://www.health.gov.il/English/About/phonebook/Pages/PhoneBook.aspx

Address

39 Yirmiyahu St. P.O.Box 1176

ZIP/City

Jerusalem 9101002

Country

Israel (IL)

Web address

http://www.health.gov.il/English/MinistryUnits/HealthDivision/PublicHealth/nutrition/Pages/default.aspx

Additional Information

Contact nutrition department:
http://www.health.gov.il/English/MinistryUnits/HealthDivision/PublicHealth/nutrition/Pages/default.aspx
Phone: nutrition department: 02-5080407
Fax nutrition department: 02-6747840

A research department also exists but no contact details found.

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Ministry of Health
Institutional Competent Authority

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

–

CA - Registration/ notification without approval required for

–

CA - Registration requirements for clinical trials

Depends on study population

Registration requirements for clinical trials including patients

Registration mandatory

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

Sponsor
Principal Investigator
Investigator
Physician

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

Proof of GCP Training of applicant

Language of Submission

Language(s) of application

Official national language
English

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

Yes

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

Physician

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

–

National legislation

General Information: Applicable Legislation & Conventions

Applied regulatory conventions

–

Applied regulatory conventions in studies including patients

–

Applied regulatory conventions in studies including healthy participants

–

Applied regulatory conventions in studies including vulnerable population

–

Applicable national laws

Hospital Act
Data protection Act
Genetical engineering act
Medical device act
Drug act

Applicable national laws for patients

–

Applicable national laws for healthy participants

–

Applicable national laws for vulnerable population

–

National regulations for volunteers exist for

–

Nutrition

Nutrition considered as drug

No

Blood & Tissue Samples

Tissue samples permitted in trials including patients

Yes

Tissue samples permitted in trials including healthy participants

No

	Tissue samples permitted in trials including vulnerable population No
Invasive Catheters	**Invasive catheters permitted for trials including patients** Yes **Invasive catheters permitted for trials including healthy participants** No **Invasive catheters permitted for trials including vulnerable population** No