Nutrition - 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

Above: Contact nutrition department:

Phone: 02-5080407 Fax: 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

CA - Registration requirements for clinical trials

Not mandatory

CA - Submission required to

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Ethics committee

Ethical Review – General Submission for Ethical review mandatory for

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Submission to CA and EC to be performed in the following order

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Multi-Centre Studies -Ethical Review Ethical approval (favourable opinion) required from

Lead EC (authorised to issue a single opinion)

Submission of Application **Entitled to study submission**

Sponsor Principal Investigator Investigator Physician

Prerequisites for submission / approval

Proof of GCP Training of applicant

Language of Submission

Language(s) of application

Official national language

English

Preferred language of application

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English accepted

Yes

Documents mandatory to be in local language of study site

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Documents mandatory to be in language of study participant

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Study specific Requirements

Investigator Entitled to be principal investigator

Physician

Entitled to be principal investigator for trials with patients

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Entitled to be principal investigator for trials with healthy participants

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Entitled to be principal investigator for trials with vulnerable population

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Study Participants -Compensation

Reimbursement

Reimbursement for study participants

Are not reimbursed

Compensation is limited to/provided for

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National legislation

General Information: Applicable Legislation & Conventions **Applied regulatory conventions**

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Applicable national laws

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

National regulations for volunteers exist for

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Nutrition Nutrition considered as drug

No

Blood & Tissue Samples Tissue samples permitted

No

Tissue samples permitted - Additional information

only in interventional trials including patients

Invasive Catheters Invasive catheters permitted

No

Additional Information

only in interventional trials including patients