Nutrition - NETHERLANDS

Competent authority

Contact Details	**Contact Name 1** Central Committee for Research Involving Human Subjects/ Centrale Commissie Mensgebonden Onderzoek (CCMO) **Contact Name 2** F.a.o. Competent authority (CA) **Phone** + 31 70 340 6700 **Email General** ccmo@ccmo.nl **Email Department** bi@ccmo.nl **Address** PO Box 16302 **ZIP/City** 2500 BH The Hague **Country** Netherlands (NL) **Web address** http://www.ccmo-online.nl **Additional Information** NB! Email if CCMO acts as CA: bi@ccmo.nl
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Institutional Competent Authority Institutional Ethics Committee Regional Ethics Committee **CA - Registration requirements for clinical trials** Registration mandatory **CA - Submission required to** National CA Institutional CA International CA
Submission Format	**Standard application form available** No
Language of Submission	**Language(s) of application** English **Preferred language of application** –

	English accepted – **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 the study participant** –
Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Contact Details	**Contact Name 1** Medical Research Ethics Committees MRECs/METCs **Web address** http://www.ccmo.nl/en/accredited-mrecs **Additional Information** Links to the 24 accredited MRECs/METCs and their contact data are provided on the CCMO website (see provided web address)
Ethical Review – General	**Submission for Ethical review mandatory for** – **Submission of study mandatory** Yes **Submission to CA and EC to be performed in the following order** – **National declaration on Ethical requirements exists** Yes **National declaration** available via regional ethics committees
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** International EC National EC Institutional EC
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Single Opinion
Submission of Application	**Entitled to study submission** Sponsor Principal Investigator Physician Dietitian Nutritionist PhD Industry National citizen

	Prerequisites for submission / approval –
Submission Format	**Standard application form available** Yes **Standard application form** available via Regional Ethics Committees
Language of Submission	**Language(s) of application** English **Preferred language of application** – **English accepted** – **Documents mandatory to be in local language of study site** – **Documents mandatory to be in language of study participant** –
Timelines Ethical Review	**Time in weeks from submission to positive approval (minimum)** 6 **Time in weeks from submission to positive approval (maximum)** 12 **Time in weeks from submission to positive approval (average)** 8
Safety Reporting	**Investigator shall report SAE to** National CA Institution Sponsor Trial Coordinator Other

Study specific Requirements

Sponsor	**Contracts with external sponsor** Yes
Investigator	**Entitled to be principal investigator** Physician Dietitian Nutritionist Pharmacist PhD **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 - Informed Consent (IC)	**Standard IC form (ICF) available** No **Accepted format of Informed Consent (IC) form** Written consent **Accepted format of IC form for studies including patients** – **Accepted format of IC form for studies including healthy participants** – **Accepted format of IC form for studies including vulnerable population** –
Study Participants - Vulnerable Population	**Considered as vulnerable population** Children Elderly Pregnant women (Pregnancy) Lactating women Unconscious Persons Incapacitated adults People with psychiatric disorder People with dementia Prisoners **Regulations concerning the inclusion or exclusion available** Yes **Applicable ethical regulations** Not specified
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional **Compensation is limited to/provided for** Compensation optional not mandatory
Funding	**Trials generally financially supported by industry** Yes **Funding is an issue during the approval process** Yes
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Patients/Volunteers Researchers **Specific insurance companies - Additional information** There are no specific insurance companies **Insurance fee in € value indicated as** –

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Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Audits Inspections Monitoring Standard Operating Procedures (SOP) Case Report Form (CRF) **Standards concerning quality assurance and quality control exist** Yes **Regularly performed audits** – **Regularly performed audits - Additional information** Internal and external audits may be performed
Archiving & Data Management	**Study documents must be kept at least (in years)** – **Legal framework for data management exists** Not specified

National legislation

General Information: Applicable Legislation & Conventions	**Applied regulatory conventions** Declaration of Helsinki Other ethical principles for medical research (other than Declaration of Helsinki) ICH-GCP Guidelines **Applicable national laws** Hospital Act Data protection Act Medical device act Drug act **National regulations for volunteers exist for** Nutrition intervention in healthy people Pharmaceuticals/drug trials Invasive procedures Catheters Isotopes Tissue samples
Nutrition	**Nutrition considered as drug** No
Blood & Tissue Samples	**Tissue samples permitted** No
Invasive Catheters	**Invasive catheters permitted** Yes