Nutrition - LUXEMBOURG

Competent authority

Contact Details	**Contact Name 1** Ministry of Health **Phone** +352 247-85592 / 96 **Fax** +352 24795615 **Email General** info@ms.etat.lu **Address** Allée Marconi - Villa Louvigny **ZIP/City** 2120 Luxembourg **Country** Luxembourg (LU) **Web address** http://www.ms.etat.lu **Additional Information** CA = Ministry of Health No local / regional CA.
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Ethics committee(s) Agency for data protection **CA - Registration requirements for clinical trials** Registration recommended **CA - Submission required to** not required **Additional Information** The Luxemburg clinical trial law only refers to drug trials. Observational studies must not be submitted to CA but if it is an interventional nutrition study we would recommend to notify the Competent Authorities.
Submission Format	**Standard application form available** No
Language of Submission	**Language(s) of application** National languages: French and German, English **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 the study participant** –
Timelines Authorisation	**Additional Information** not indicated

Ethics committee

Contact Details	**Contact Name 1** Comité National d'Ethique de Recherche (CNER) **Contact Name 2** Dr Georges MICHEL, Président **Address** Rue Thomas Edison 1A **ZIP/City** L-1445 Strassen **Country** Luxembourg (LU) **Additional Information** There is only 1 national EC committee
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** • Deontology code, chap V • Hospital act, article 25
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** National EC
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Central EC (authorised to issue a single opinion)

Submission of Application	**Entitled to study submission** Sponsor Principal Investigator Investigator Industry **Prerequisites for submission / approval** –
Submission Format	**Standard application form available** Yes **Standard application form** Standard application form
Language of Submission	**Language(s) of application** National languages: French and German, 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)** 4 **Time in weeks from submission to positive approval (maximum)** 13 **Time in weeks from submission to positive approval (average)** 8 **Additional Information** Meeting every 2 months, but documents have to be submitted at the latest 3 weeks before the meeting
Safety Reporting	**Investigator shall report SAE to** Sponsor

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes **Sponsorship mandatory - Additional information** There must be a sponsor but not always funding **Co-Sponsor - Definition available in national law** No

	Co-sponsorship allowed Yes **Co-sponsorship allowed - Additional information** Not mentioned in law but co-sponsorship possible **Contracts with external sponsor** Yes
Investigator	**Entitled to be principal investigator** Dietitian Nutritionist 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** – **Additional Information** Not defined in law, but Primary Investigator has to be experienced in the related domain
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 Incapacitated adults Other **Vulnerable population - Additional information** No definition for vulnerable population in law but minors and incapable adults are specifically mentioned **Regulations concerning the inclusion or exclusion available** Yes **Regulations concerning the inclusion or exclusion** only for pharmaceuticals

	Applicable ethical regulations National **Additional Information** Law for CT with drugs (30.05.2005) mention minors and incapable adults
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional **Compensation is limited to/provided for** – **Additional Information** No incentives or financial benefit are allowed except compensation
Funding	**Trials generally financially supported by industry** Yes **Name of industry company/institution supporting financially** Pharma companies **Funding is an issue during the approval process** Yes **Additional Information** only pharmaceutical studies are generally sponsored by industry CA submission: free EC submission (initial submission 500€ for academic studies, 1000€ for commercial trials) EC ensure the Investigator fees and patient compensation are reasonable and are not incentives to join the trial
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** No **Mandatory to inform participant of clinical trial outcome** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Patients/Volunteers Researchers Sponsor **Name and contact insurance companies insuring clinical research** Zurich Global Corporate Benelux Zurich Insurance plc, Belgium branch Avenue Lloyd Georgelaan 7 B-1000 Brussels **Insurance fee in € value indicated as** – **Insurance fee for lowest risk research - Additional Information** not indicated **Insurance fee in € value indicated as** –

	Insurance fee for highest risk research - Additional Information not indicated
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Standard Operating Procedures (SOP) Case Report Form (CRF) **Standards concerning quality assurance and quality control exist** No **Regularly performed audits** – **Additional Information** Regularly performed audits: ISO 9001 certification ongoing at CRP-Santé in pharmaceutical trials
Archiving & Data Management	**Study documents must be kept at least (in years)** – **Legal framework for data management exists** No

National legislation

General Information: Applicable Legislation & Conventions	**Applied regulatory conventions** Declaration of Helsinki ICH-GCP Guidelines **Applicable national laws** Hospital Act Data protection Act **National regulations for volunteers exist for** Do not exist **Network providing information on regulations and ethical requirements in studies** Clinical and Epidemiological Investigation Center, Public Research Center for Health **Network contact person** Nancy De Bremaeker **Personal Email** nancy.debremaeker@crp-sante.lu **Official website providing relevant national legislation** http://www.crp-sante.lu/Competence-centers/Clinical-and-Epidemiological-Investigation-Center-CIEC CLinical Research in Luxembourg: www.luxclin.lu,
Nutrition	**Nutrition considered as drug** No
Blood & Tissue Samples	**Tissue samples permitted** No

Data Protection	**Specific Requirements** Yes **Legal framework (on safeguarding the collection, handling, recording, keeping and/or processing of any clinical trial related data and patient files)** –
Invasive Catheters	**Invasive catheters permitted** Yes **Additional Information** as long as there is a favourable opinion from EC

Definition

Clinical Research	**Definition in national law** The existing law in Luxemburg in clinical trials is the “Grand-Ducal Regulation of 30 May 2005 regarding the implementation of good clinical practice in the conduct of clinical trials with medicinal products for human use”. Therefore the below definitions are related to clinical trials with drugs. There is no definition for “interventional studies” or “observational study”. The law defines “clinical trials and “non-interventional trials”.
Observational Study	**Definition in national law** “non-interventional trial": a study where the medicinal products are prescribed in the usual manner in accordance with the terms of the marketing authorization. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.