Nutrition/Interventional - 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** National Ethics Committee; Agency for Data Protection; **Regulatory and ethics bodies involved in approval process for trials including patients** – **Regulatory and ethics bodies involved in approval process for trials including including healthy participants** – **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** Registration recommended **Registration requirements for clinical trials including patients** –

	Registration requirements for clinical trials including healthy participants – **Registration requirements for clinical trials including vulnerable population** – **CA - Submission required to** not required **Studies including patients - submission required to** – **Studies including healthy participants - submission required to** – **Studies including vulnerable population - submission required to** – **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** Yes **Standard application form** Standard application form
Language of Submission	**Language(s) of application** National languages: French and German, 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** – **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** –

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)
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 **Ethical approval (favourable opinion) for trials including patients to be obtained from** – **Ethical approval (favourable opinion) for trials including healthy participants to be obtained from** – **Ethical approval (favourable opinion) for trials including vulnerable population to be obtained from** – **Additional Information** only one Ethics Committee exists in Luxembourg
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Central 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 Industry **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** –
Submission Format	**Standard application form available** Yes
Language of Submission	**Language(s) of application** National languages: French and German, 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** – **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** –
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 **Investigator shall report SAE in trials with patients to** – **Investigator shall report SAE in trials with healthy participants to** – **Investigator shall report SAE in trials with volunteers to** –

Study specific Requirements

Sponsor	**Sponsorship mandatory** Yes **Sponsorship mandatory - Additional information** There must be a sponsor but not always funding **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 **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** exist 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 **Reimbursement for patients** – **Reimbursement for healthy participants** – **Reimbursement for vulnerable population** – **Compensation is limited to/provided for** No incentives or financial benefit are allowed except compensation **Compensation for patients is limited to/provided for** – **Compensation for healthy participants is limited to/provided for** – **Compensation for vulnerable population is limited to/provided for** –
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 trials are usually sponsored by industry Funding during the approval process: 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	**Mandatory to inform participant of clinical trial outcome** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Patients/Volunteers Researchers Sponsor **Obligation to contract a liability insurance for trials including patients for** – **Obligation to contract a liability insurance for trials including healthy participants for** – **Obligation to contract a liability insurance for trials including vulnerable population for** – **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** Not specified **Insurance fee in € value indicated as** – **Additional Information** No information about usual insurance fees available up to now: As an example, the insurance for a recent (2014) interventional study in nutrition with healthy people has cost 1000 EUR for 30 participants (study including several blood draws)
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Standard Operating Procedures (SOP) Case Report Form (CRF) **Regularly performed methods in trials including patients** – **Regularly performed methods in trials including healthy participants** –

Regularly performed methods in trials including vulnerable population

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Standards concerning quality assurance and quality control exist

No

Standards concerning quality assurance and quality control

No specific standards exist

Regularly performed audits

–

Regularly performed audits in trials including patients

–

Regularly performed audits in trials including healthy participants

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Regularly performed audits in trials including vulnerable population

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Additional Information

Regularly performed audits: only in pharmaceutical trials: ISO 9001 certification ongoing at CRP-Santé

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

Applied regulatory conventions in studies including patients

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Applied regulatory conventions in studies including healthy participants

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Applied regulatory conventions in studies including vulnerable population

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Applicable national laws

Hospital Act
Data protection Act

Applicable national laws for patients

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Applicable national laws for healthy participants

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	Applicable national laws for vulnerable population – **National regulations for volunteers exist for** – **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 **Additional Information** Contact details: Clinical and Epidemiological Investigation Center, Public Research Center for Health http://www.crp-sante.lu/Competence-centers/Clinical-and-Epidemiological-Investigation-Center-CIEC Nancy De Bremaeker Tel: +352 26 970 804 further network "Clinical Research in Luxembourg: www.luxclin.lu
Nutrition	**Nutrition considered as drug** No
Blood & Tissue Samples	**Tissue samples permitted** Yes **Additional Information** as long as there is a favourable opinion from EC
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”.

Interventional Study	**Definition in national law** “clinical trial": any investigation in human persons intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy. This includes clinical trials performed in a single site or multiple sites in Luxembourg or in other countries.
Nutrition Study	**Definition available in national law** Yes
Additional Information & Specifics	**Additional Information** "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" is only relevant for pharmaceutical studies, not specifically for nutrition studies