Nutrition - AUSTRIA

Competent authority

Contact Details	**Contact Name 1** Bundesamt für Sicherheit im Gesundheitswesen BASG/ Federal Office for Safety in Health Care **Contact Name 2** Agentur für Gesundheit und Ernährungssicherheit AGES/ Austrian Medicines and Medical Devices Agency **Phone** 0043 50 555-36111, -36820 **Email Department** clinicaltrials@ages.at **Address** Traisengasse 5 **ZIP/City** 1200 Vienna **Country** Austria (AT) **Web address** http://www.ages.at/ages/geschaeftsfelder/ernaehrungssicherung/
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Medicines Agency Institutional Competent Authority Institutional Ethics Committee **Regulatory and ethics bodies involved - Additional information** Institutional Competent Authority is not financially involved in the approval process **CA - Registration requirements for clinical trials** Registration mandatory Not validated **CA - Submission required to** Institutional CA
Submission Format	**Standard application form available** No
Language of Submission	**Language(s) of application** Official national language German **Preferred language of application** –

	English accepted Yes Case by case Not validated May vary by region **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	**Time to approval CA in weeks (average)** 5
Safety Reporting	**Sponsor must declare reportable events to** –
Additional Information & Specifics	**Additional Information** 35 days by law

Ethics committee

Contact Details	**Contact Name 1** Institutional Ethics Committee **Contact Name 2** Ethics Committee Mecical University of Vienna **Phone** +43 1 40400 21470 **Fax** +43 1 40400 16900 **Address** Borschkegasse 8b/E06 **ZIP/City** 1090 Wien **Country** Austria (AT) **E-Mail** ethik-kom@meduniwien.ac.at **Web address** http://ethikkommission.meduniwien.ac.at/
Ethical Review – General	**Submission for Ethical review mandatory for** – **Submission of study mandatory** No

	Submission of study mandatory - Additional information Submission of study is regulated on institutional level **Submission to CA and EC to be performed in the following order** – **National declaration on Ethical requirements exists** Yes
Single-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) to be obtained from** Institutional EC
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** Single Opinion EC review not required Not validated **Additional Information** each ethics committee has to approve multi center research projects individually when not drug study
Submission of Application	**Entitled to study submission** Sponsor Principal Investigator Investigator Physician Dietitian Nutritionist PhD Industry National citizen **Prerequisites for submission / approval** –
Submission Format	**Standard application form available** Yes **Standard application form** Forum Österreichischer Ethikkommissionen (Network of Austrian Ethics Committees) Forum Österreich (Agreement but not law)
Language of Submission	**Language(s) of application** Official national language German **Preferred language of application** – **English accepted** Yes May vary by region **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)** 12 **Time in weeks from submission to positive approval (average)** 7
Safety Reporting	**Investigator shall report SAE to** Sponsor

Study specific Requirements

Sponsor	**Contracts with external sponsor** Yes
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** –
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** Yes **Accepted format of Informed Consent (IC) form** Oral consent Written consent No consent required Not validated May vary by region **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 **Vulnerable population - Additional information** Elderly people: depends on mental status if or if not they are considered as vulnerable population **Regulations concerning the inclusion or exclusion available** Yes **Applicable ethical regulations** Institutional National International EU directive (2001/20/EC) Not validated
Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional **Compensation is limited to/provided for** Time effort Inconvenience Expenses arising from study participation (e.g. Travel) **Additional Information** compensation only for inconvenience but not for pain
Funding	**Trials generally financially supported by industry** No **Funding is an issue during the approval process** Yes **Additional Information** Only interventional studies There is a standard question in the submission form to the EC and the CA about funding
Study Participants - Recruitment & Trial Outcome	**Regulations on recruitment process exist** No **Recruitment process** Specific for each region **Mandatory to inform participant of clinical trial outcome** No
Insurance	**Liability insurance or alternative arrangements for damages mandatory for** Not mandatory

	Name and contact insurance companies insuring clinical research e.g. Zürich Versicherungen **Insurance fee in € for lowest risk research (minimum)** 17 **Insurance fee in € value indicated as** – **Insurance fee in € value indicated as** – **Additional Information** low risk €17- max. €22 (depending on contract negotiations)
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Monitoring Standard Operating Procedures (SOP) Case Report Form (CRF) Case by Case Regional differences may exist **Standards concerning quality assurance and quality control exist** Yes **Regularly performed audits** –
Archiving & Data Management	**Study documents must be kept at least (in years)** –

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 Other guidelines for good clinical practice (other than ICH-GCP) International regulatory requirements Institutional regulatory requirements **Applicable national laws** Hospital Act Data protection Act Genetical engineering act Medical device act **National regulations for volunteers exist for** Nutrition intervention in healthy people Pharmaceuticals/drug trials Invasive procedures Catheters Isotopes Tissue samples Not validated
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)** – **Additional Information** standard requirements regarding data protection exists
Invasive Catheters	**Invasive catheters permitted** Yes **Additional Information** trial automatically becomes MPG §40 – Medizinproduktegesetz (medical device directive)

Definition

Observational Study	**Definition in national law** Non interventional research is defined in Austrian law according to the European directive in AMG§2a, Paragraph 3: Applies to systematic investigation of drugs if: 1. used according to indication 2. no additional therapeutic or diagnostic interventions, no burden for patients 3. no predefined strategy of treatment, and therapeutic decision unrelated to inclusion. Typically treatment decision must precede inclusion decision. Group comparison is possible.
Nutrition Study	**Definition available in national law** No
Additional Information & Specifics	**Additional Information** Definition only available for pharmaceuticals / drug trials --> Arzneimittelgesetz §1, §2a