Nutrition - GERMANY

Competent authority

Contact Details	**Contact Name 1** Competent federal higher authority ("Bundesoberbehörde- BOB") **Contact Name 2** Federal Institute for Drugs and Medical Devices*: Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) **Phone** +49-228-20730 **Fax** +49-228-2075207 **Email Department** ct@bfarm.de **Address** Kurt-Georg-Kiesinger-Allee 3 **ZIP/City** 53175 Bonn **Country** Germany (DE) **Web address** http://www.bfarm.de/EN **Additional Information** BfArM is the CA for medicinal products and MD!
Trial Authorisation / Registration / Notification	**Regulatory and ethics bodies involved in approval process** Institutional Ethics Committee Agency for data protection **CA - Registration requirements for clinical trials** Registration not mandatory **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

	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** Ethikkommission der Charité-Universitätsmedizin Berlin **Phone** +49 30 450 517 222 **Fax** +49 30 450 517 952 **Address** Charitéplatz 1 **ZIP/City** 10117 Berlin **Country** Germany (DE) **Web address** http://ethikkommission.charite.de/ **Additional Information** Email: http://ethikkommission.charite.de/metas/kontakt/adresse/mickscho/
Ethical Review – General	**Submission for Ethical review mandatory for** – **Submission of study mandatory** No **Submission of study mandatory - Additional information** only required to submit interventional studies and drug trials to the ethics committee. **Submission to CA and EC to be performed in the following order** – **National declaration on Ethical requirements exists** No
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** All local ECs of participating sites Not validated
Submission of Application	**Entitled to study submission** Sponsor Principal Investigator Investigator Physician Dietitian Nutritionist PhD Industry National citizen Not validated **Prerequisites for submission / approval** Application is limited to the institution Not validated
Submission Format	**Standard application form available** No
Language of Submission	**Language(s) of application** Official national language German English **Preferred language of application** – **English accepted** Yes **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)** 3 **Time in weeks from submission to positive approval (maximum)** 8 **Time in weeks from submission to positive approval (average)** 4
Safety Reporting	**Investigator shall report SAE to** Institution

Study specific Requirements

Sponsor	**Sponsor - Definition available in national law** No **Co-sponsorship allowed** Yes

	Contracts with external sponsor No
Investigator	**Entitled to be principal investigator** Physician Dietitian Nutritionist Nurse Pharmacist PhD Each investigator Not validated **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 **Regulations concerning the inclusion or exclusion** not validated **Applicable ethical regulations** –

Study Participants - Compensation & Reimbursement	**Reimbursement for study participants** Optional volunteers may be reimbursed **Compensation is limited to/provided for** Time effort Expenses arising from study participation (e.g. Travel)
Funding	**Trials generally financially supported by industry** No **Name of public company/institution supporting financially** only pharmaceutical trials **Funding is an issue during the approval process** Yes
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 **Insurance fee in € value indicated as** – **Insurance fee in € value indicated as** –
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** Inspections Monitoring Standard Operating Procedures (SOP) Case Report Form (CRF) **Standards concerning quality assurance and quality control exist** No **Regularly performed audits** –
Archiving & Data Management	**Study documents must be kept at least (in years)** – **Legal framework for data management exists** Yes **Legal framework for data management** Only for Berlin (in German): Berliner Datenschutzgesetz (BlnDSG)

National legislation

General Information: Applicable Legislation & Conventions	**Applied regulatory conventions** Declaration of Helsinki ICH-GCP Guidelines Regional regulatory requirements **Applicable national laws** Data protection Act Genetical engineering act Medical device act Nutrition intervention includes different strategies: dietary changes, simply nutritional education, supplements, fortified food, drugs. So, no general answer is possible here **National regulations for volunteers exist for** –
Nutrition	**Nutrition considered as drug** Depends on dose Depends on product **Additional Information** Nutritional treatment includes different strategies including supplements, fortified food, dietary changes ✉ depends on the product and dosage. Whether supplements or fortified food is considered drug/medication depends on many factors including dosage.
Blood & Tissue Samples	**Specific requirements** Yes **Applicable legal framework** no general permission for any type of study exists **Tissue samples permitted** Not specified
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** not validated

Definition

Observational Study	**Definition in national law** No official definition found. Legal definition exists in the German Medicinal Product Act §67 for studies with drugs: (6) The pharmaceutical entrepreneur shall immediately give notice to the Federal Panel Doctors' Association, the Central Federal Association of the health insurance funds, as well as the competent higher federal authority of tests which serve the purpose of gathering knowledge on the application of authorized or registered medicinal products. In this regard, the location, time, purpose and observation plan of the non-interventional study shall be stated and the names of the participating doctors revealed to the Federal Panel Doctors' Association and the Central Federal Association of the health insurance funds. Further, definitions exist in other documents but are not legally binding.
Nutrition Study	**Definition available in national law** No