Nutrition/Interventional - 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)

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ZIP/City

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Country

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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

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Regulatory and ethics bodies involved in approval process for trials including patients

Institutional Competent Authority
Institutional Ethics Committee
Regional Ethics Committee
Agency for data protection
Not validated

Regulatory and ethics bodies involved in approval process for trials including including healthy participants

Institutional Ethics Committee
Agency for data protection
Not validated

	Regulatory and ethics bodies involved in approval process for trials including vulnerable population Institutional Competent Authority Regional Competent Authorities Institutional Ethics Committee Regional Ethics Committee Agency for data protection Not validated **CA - Registration/ notification without approval required for** – **CA - Registration requirements for clinical trials** – **Registration requirements for clinical trials including patients** Not mandatory **Registration requirements for clinical trials including healthy participants** Not mandatory **Registration requirements for clinical trials including vulnerable population** Registration mandatory Not validated **CA - Submission required to** Institutional CA **Studies including patients - submission required to** – **Studies including healthy participants - submission required to** – **Studies including vulnerable population - submission required to** –
Submission Format	**Standard application form available** No
Language of Submission	**Language(s) of application** Official national language 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

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

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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

Yes

Submission to CA and EC to be performed in the following order

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National declaration on Ethical requirements exists

No

Single-Centre Studies - Ethical Review

Ethical approval (favourable opinion) to be obtained from

Institutional 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** –
Multi-Centre Studies - Ethical Review	**Ethical approval (favourable opinion) required from** All local ECs of participating sites Not validated **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 Physician Dietitian Nutritionist PhD Industry National citizen **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** Proof of GCP Training of applicant Application is limited to the institution Not validated
Submission Format	**Standard application form available** No **Standard application form** only for pharmaceuticla trials
Language of Submission	**Language(s) of application** 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** 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 study participant** –
Safety Reporting	**Investigator shall report SAE to** Institution **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** No **Co-sponsorship allowed** Yes **Contracts with external sponsor** No **Additional Information** Contracts with external sponsors are only set up in case of pharmaceutical studies
Investigator	**Entitled to be principal investigator** Physician Dietitian Nutritionist Nurse Pharmacist PhD Each investigator Depends on study population

	Entitled to be principal investigator for trials with patients Physician PhD **Entitled to be principal investigator for trials with healthy participants** Physician Dietitian Nutritionist Nurse Pharmacist PhD Each investigator Not validated **Entitled to be principal investigator for trials with vulnerable population** Physician PhD
Study Participants - Informed Consent (IC)	**Standard IC form (ICF) available** No **Standard IC form (ICF)** Only in pharmaceuticals /drug trials available **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** Written consent Consent by proxy
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 **Reimbursement for patients** – **Reimbursement for healthy participants** – **Reimbursement for vulnerable population** – **Compensation is limited to/provided for** Time effort Expenses arising from study participation (e.g. Travel) **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** – **Additional Information** volunteers may be reimbursed
Funding	**Trials generally financially supported by industry** No **Name of public company/institution supporting financially** DGF **Name of private company/institution supporting financially** a number of foundations **Name of industry company/institution supporting financially** nutrition studies, Baxter, Fresenius, Pfrimmer, nutriticia, Braun **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 **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** – **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) **Regularly performed methods in trials including patients** – **Regularly performed methods in trials including healthy participants** – **Regularly performed methods in trials including vulnerable population** – **Standards concerning quality assurance and quality control exist** No **Standards concerning quality assurance and quality control** only in pharmaceuticals/ drug trials **Regularly performed audits** – **Regularly performed audits in trials including patients** – **Regularly performed audits in trials including healthy participants** – **Regularly performed audits in trials including vulnerable population** – **Regularly performed audits - Additional information** Internal and External audits are generally performed in pharmaceuticals/drug trials
Archiving & Data Management	**Study documents must be kept at least (in years)** – **Legal framework for data management exists** Yes

Legal framework for data management

For Berlin (in German): Berliner Datenschutzgesetz (BlnDSG)
For Germany in general (in German): Bundesdatenschutzgesetz

National legislation

General Information: Applicable Legislation & Conventions

Applied regulatory conventions

Declaration of Helsinki
ICH-GCP Guidelines
Regional regulatory requirements

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

Data protection Act
Medical device 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

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Nutrition

Nutrition considered as drug

Depends on dose
Depends on product

Additional Information

Nutritional treatment includes different strategies including supplements, fortified food, dietary changes --> thus it 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

No

Applicable legal framework

no general permission for any kind of study

Tissue samples permitted

Not specified

Tissue samples permitted in trials including patients

Not specified

	Tissue samples permitted in trials including healthy participants Not specified **Tissue samples permitted in trials including vulnerable population** 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

Interventional Study	**Definition in national law** Legal definition exists in the German Medicinal Product Act §4 for clinical studies with drugs: (23) A clinical trial on human beings is any investigation on human subjects intended to investigate or verify the clinical or pharmacological effects of medicinal products, or to identify side-effects or to study the absorption, distribution, metabolisation or excretion, with the aim of ascertaining the safety or efficacy of the medicinal product. Sentence 1 does not apply to non-interventional trials. A non-interventional trial is a study, in the context of which findings resulting from persons' treatment with medicinal products are analyzed using epidemiological methods; the treatment, including the diagnosis and monitoring, shall not follow a predetermined trial protocol but shall result exclusively from current medical practice; in so far as a medicinal product requiring a marketing authorization or a medicinal product requiring an authorization pursuant to Section 21a sub-section 1 is concerned, this shall be conducted, moreover, according to the specifications regarding its use contained in the marketing authorization or authorization. Further definitions exist in other documents but are not legally binding. Quasi-experimental long term trial, which evaluates the effects on the health in a certain population (e.g. effectiveness of a preventive measure) - through change (or the elimination) of apparently pathogenetic factors (1 Pschyrembel, 257. Edition)
Nutrition Study	**Definition available in national law** No
Additional Information & Specifics	**Additional Information** If nutrition intervention includes intervention with drugs containing nutrients èlegal definition exists in the German Medicinal Product Act.