Nutrition/Interventional - POLAND

Competent authority

Contact Details

Contact Name 1

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products – URPL („The Office“)

Phone

+ 48 22 492 11 00

Fax

+ 48 22 492 11 09

Email General

pl@urpl.gov.pl

Address

Al. Jerozolimskie 181C

ZIP/City

02-222 Warszawa

Country

Poland (PL)

Web address

http://www.urpl.gov.pl

Trial Authorisation / Registration / Notification

Regulatory and ethics bodies involved in approval process

Institutional Ethics Committee
Regional Ethics Committee

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

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

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Regulatory and ethics bodies involved in approval process for trials including vulnerable population

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CA - Registration/ notification without approval required for

–

CA - Registration requirements for clinical trials

Not mandatory

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** 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** Yes **Standard application form** Standard Application Form
Language of Submission	**Language(s) of application** Official national language Polish **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** No **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 of CA in weeks (minimum)** 2 **Time to approval of CA in weeks (maximum)** 6 **Time to approval CA in weeks (average)** 8

Safety Reporting	**Sponsor must declare reportable events to** –

Ethics committee

Contact Details	**Contact Name 1** Local Research Ethics Committees (REC), in Polish „Komisje Bioetyczne“ -„Bioethics Committees“) **Contact Name 2** 50 local independent RECs **Web address** http://www.oil.org.pl/xml/oil/oil68/tematy/komisje/stale/bioetyki/komisje **Additional Information** The local ECs are established at academic institutions (e.g. medical universities), non-university medical research centres and health institutes or at the Regional Chambers of Physicians and Dentists. List of ECs is provided on the website of the Regional Chamber of Physicians and Dentists in Warsaw (Okręgowa Izba Lekarska). There is no central EC.
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** –
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** Lead 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** Principal Investigator Investigator **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 **Standard application form** Standard application form
Language of Submission	**Language(s) of application** Official national language Polish **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** No **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)** 10 **Time in weeks from submission to positive approval (average)** 5

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** Yes
Investigator	**Entitled to be principal investigator** Depends on study population **Entitled to be principal investigator for trials with patients** Physician Dietitian **Entitled to be principal investigator for trials with healthy participants** Physician Dietitian **Entitled to be principal investigator for trials with vulnerable population** Physician
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 **Applicable ethical regulations** Do not exist
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** Adults only Time effort Expenses arising from study participation (e.g. Travel) Phase I trials **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 in patients financially supported by industry** Not specified **Trials in healthy participants financially supported by industry** Not specified **Trials in vulnerable population financially supported by industry** Yes **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 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** Hestia PZU **Insurance fee in € for lowest risk research (minimum)** 5000 **Insurance fee in € for lowest risk research (average)** 10000 **Insurance fee in € value indicated as** Lumpsum **Insurance fee in € value indicated as** –
Quality Assurance/ Quality Control (QA/QC)	**Regularly performed methods** 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** Yes **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 not performed regularly in trials in Poland
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 Regional regulatory requirements Institutional regulatory requirements **Applied regulatory conventions in studies including patients** – **Applied regulatory conventions in studies including healthy participants** – **Applied regulatory conventions in studies including vulnerable population** – **Applicable national laws** Hospital Act Data protection Act Genetical engineering act Medical device act Drug act **Applicable national laws for patients** – **Applicable national laws for healthy participants** – **Applicable national laws for vulnerable population** – **National regulations for volunteers exist for** –
Nutrition	**Nutrition considered as drug** Yes
Blood & Tissue Samples	**Tissue samples permitted** Yes
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

Definition

Nutrition Study	**Definition available in national law** Yes