**Application Form**

**Ethical opinion for an experiment on the human subject**

**For the initial submission, files should be submitted simultaneously to the central ethics committee and the local ethics committees of the participating sites.**

|  |  |  |
| --- | --- | --- |
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| cid:image001.png@01DA0697.30605960  +32 11 80 92 33  [ethisch\_comite@noorderhart.be](mailto:ethisch_comite@noorderhart.be) | +32 475 34 28 17  [ethische.commissie@sfz.be](mailto:ethische.commissie@sfz.be) | +32 12 39 61 11  [CME@azvesalius.be](mailto:CME@azvesalius.be) |
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# General information on the study.

* Study title: ………………………………………………………………………….
* Acronym: (if applicable) ………………………………………………………………………….
* EudraCT Number (if applicable): ………………………………………………………………………….
* Protocol number: (if applicable) ………………………………………………………………………….
* Sponsor (mail + tel. number): ………………………………………………………………………….

Commercial clinical trial

CRO (if applicable) (name + address +mail +tel. number) ………………………………….

Contact facturatie (mail + tel. number)………………………………………………………………………….

Non-commercial clinical trial

Internal sponsor (name site) …………………………………………………………………….

Internal sponsor (name site) + third-party institution without an ethics committee participating in the study (name + address + mail + tel. number) ……………………………………………………………………………………

External sponsor (academic, government, other...)………………………………………….

Thesis/PhD ………………………………….………………………………….………………………….

* Expected start date:
* Expected end date:
* Registration via:

[www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu) (medication trials only)

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)

<http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/>

Other: …………………………………………………………………………………………….

none  
 Reason:

# Financing and fees

## Project funding

FWO

IWF

BOF

EU

Grant

Free medication/device:……………………………………………..

other, nl.………………………………………

NA

## Investigator’s fee:

(draft-) agreements attached

(draft)- agreements NOT attached:

* Reason …………………………………………………………

Not applicable

## Fee participant:

Yes, nl …………………………………………………………………

No

## In case of a contractual study, is there a provision in the contract that can stop the publication of the results or subject them to conditions?

Yes, nl …………………………………………………………………

No

# Ethics committees

## Ethics committees involved

*you can add extra lines*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Name** | **Address** | **phone number** | **e-mail address** | **Admission by amendment** |
| **Leading** |  |  |  |  | Yes/No |
| **Local** |  |  |  |  | Yes/No |
| **Local** |  |  |  |  | Yes/No |

# Other approvals

## Was the study in his current form already approved by:

FDA / EMA  Yes  No  NA

EC other Belgian University  Yes  No  NA

EC other Belgian Hospital  Yes  No  NA

## Has the study already been approved in other countries?

Yes  No  NA

## Has the study already been started in other countries?

Yes  No  NA

Was the study already conducted elsewhere (completely or partially)

No

Yes🡪 Where and with which outcomes?

…………………………………………………………………………………………………………………………………………………………..

# Study structure

Study NOT covered by the law of 07/05/2004

Retrospective

The use of human body material stored in the Biobank for scientific research

Study covered by the law of 07/05/2004 on experiments on the human person

Monocentric

Multicentric

National

European

Global

Prospective non-interventional study (= clinical path does not change) (e.g. observational study)

Prospective interventional

With medication

Date of submission fagg:

Phase 1

Phase 2

Phase 3

Phase 4

With medical device

Without medication

Questionnaire

Interview

……………………………………………..…

Double blinded

Placebo-controlled

Randomized

The study is:

Physiological/physiopathological

Diagnostic

Therapeutic

Epidemiological

Psychological

Other - specify

Type of discipline

Surgery

Internal diseases

Gynaecology and obstetrics

Oncology

Emergency admission

Clinical biology

Intensive Care

Nursing

Paediatrics

Palliative care

Bacteriology/virology (=Microbiology)

Psychiatric

Molecular biology

Rehabilitation sciences and physiotherapy

Mobility

Marketing

Patient safety

Neurology

Cardiology

Other, nl. ……………………………………

# Contact details concerning the researcher(s), collaborators and sites.

*Additional lines can be added at any time*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Name**  **First name** | **Institution + Unit or discipline**  **Faculty and department**  **(name + address)** | **E-mail address** | **phone number** |
| **Coordinating principal investigator** |  |  |  |  |
| **Local principal investigator** |  |  |  |  |
| **Investigator** |  |  |  |  |

# Protocol

## Aim of the study

*Max. 10 lines*

……………………………………………..………………………………………………..………………………………………………..…

## Brief summary of the protocol

……………………………………………..………………………………………………..………………………………………………..…

## Description of study methodology

*Max. 30 lines*

……………………………………………..………………………………………………..………………………………………………..…

## Expected benefits for the participant and/or the science

……………………………………………..………………………………………………..………………………………………………..…

## Scientific foundation

*What are the arguments (theoretical, experimental or otherwise) on the basis of which you expect an advantage of the new method, the new specimen, above the one already used?*

……………………………………………..………………………………………………..………………………………………………..…

## Propose your own evaluation of the risk/benefit balance

*Evaluation of the predictable risks of the treatment and/or procedures of the study (pain, discomfort, invasive procedures, also the means to reduce the risks).*

……………………………………………..………………………………………………..………………………………………………..…

## Evaluation of potential harm to investigators and participants

### Risks for investigators and staff.

No  Yes, defined below

…………………………………………………………………………………………………………………………………………………………..

### Risks for the participants.

No  Yes, defined below

…………………………………………………………………………………………………………………………………………………………..

### Which safety precautions are taken?

…………………………………………………………………………………………………………………………………………………………..

# Characteristics of the pharmacon or medical device (if applicable)

## Pharmacon

Will a chemical substance be administered?  
 Yes  No

If yes:

PO, IV, SC, other? ………………………………………………………………………………………………………………………………………………………….

Generic name of the product:…..

Pharmacologic group (optional ACT code):

If the drug is registered:

* Product name (if available):….
* Company name:……
* In which country was the product registered?...

In case of an investigational drug:

The drug is registered abroad/Europe/USA

The drug is registered in Belgium

Please note any non-approved indication(s) of the drug

………………………………………………………………………………………………………………………………………………………….

Following documents should be enclosed:

information leaflet for the physician/Investigator’s Brochure

Patient information leaflet

## Medical device

Will medical devices be used?

Yes  No

If yes, what type of medical device is involved

………………………………………………………………………………………………………………………………………………………….

Is the device CE certified?

Yes  No

If yes, add the CE certificate

The medical device is:

Premarket (prior to commercialisation)

No CE-certificate

With CE-certificaet

With CE-certificate, used for other indications

Postmarket

Risks for the participant?

………………………………………………………………………………………………………………………………………………………….

Were there problems with the medical device in the past?

………………………………………………………………………………………………………………………………………………………….

Following documents should be added:

CE-certificate

Technical information

Manual

# Information concerning the participants

## Number of expected participants

* + Number of subjects participating in the study : ……………
  + Number of subjects participating at this site : ……………

## Recruiting procedure

………………………………………………………………………………………………………………………………………………………….

## Study population

Patients, disease:……………………………………………………………………

Healthy subjects

Children or adolescents

Dependent persons

Pregnant women

Staff

Students

* Range of age: ………………….………………….………………….………………….
* Gender: ………………….………………….………………….……………………………...

## Are similar studies ongoing at the site at the same time?

No

Yes🡪 Explain the enrolment procedure in the different studies?

…………………………………………………………………………………………………………………………………………………………..

## Medical supervision

Continuous medical supervision during the study?

NA

No

Yes

* By whom: ………………………………………………………………………..……
* contactability: ……………………………………………………………………

Supervision after the working hours? (Intern + extern)

NA

No

Yes

* By whom: ………………………………………………………………………..……
* Contactability: ……………………………………………………………………

## Treatment per study arm.

*Brief description*

|  |  |  |
| --- | --- | --- |
|  | **Description** | **Treatment(s)** |
| **Study arm 1** |  |  |
| **Study arm 2** |  |  |
| **Study arm 3** |  |  |
| **Study arm 4** |  |  |
| **Study arm 5** |  |  |

# Informed Consent Form

## Will the subject be orally informed in an adequate and clear manner?

NA, reason: ………………………………………..…………………………………………….

No, reason: …………………………………………………………………………………….

Yes

## Was the Informed Consent included?

NA, reason: ………………………………………..…………………………………………….

No, reason: …………………………………………………………………………………….

Yes

The information is written in a legible and understandable language

A short summary is included.

The ICF is a correct and complete representation of the protocol:

## The participant is unable to give consent him/herself/itself

No

Yes

The participant is a minor

Actions taken?

………………………………………………………………………………………….

Motivation to include these subjects?

………………………………………………………………………………………….

Adult but unable to give consent

Actions taken?

………………………………………………………………………………………….

Motivation to include these subjects?

………………………………………………………………………………………….

Study design requires exception based on high urgency

Actions taken to obtain consent?

………………………………………………………………………………………….

Motivation to include these subjects?

………………………………………………………………………………………….

## The following aspects should be defined in the ICF \*(cfr. The law of 07/05/2004 experiments on the human subject):

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| the aim of the study |  |  |
| the reason why the subject is asked |  |  |
| the relevance of the study |  |  |
| assessments |  |  |
| benefits for the subjects |  |  |
| the load on the subjects |  |  |
| the risks for the subjects |  |  |
| the load and/or risks described in the ICF correspond to protocol/Investigator Brochure |  |  |
| actions taken to reduce the risks |  |  |
| fee for the subjects, if applicable |  |  |
| the insurance information |  |  |
| the privacy of the data |  |  |
| participation in the study is entirely voluntary |  |  |
| the right to withdraw from participation (without consequences for the treatment) |  |  |
| the right to withdraw at any time |  |  |
| who is responsible of the care when the subject stops participating in the study? |  |  |
| contact information and the contactability of the investigator(s) |  |  |
| the ability to ask questions |  |  |
| the ability to consult family and relatives |  |  |
| the rationale for recruiting participants from vulnerable groups (if applicable) |  |  |
| a copy of the Informed Consent Form will be given to the participant |  |  |

**The study will be disapproved if one of the above questions is answered with no.**

# Research parameter(s)/Involved entities/Specific study measures

## Laboratory

No

Yes

study-specific ……………………………………………………………………

non-study specific ……………………………………………………………

the analyses are performed in a reference laboratory only

the analyses are performed partly/completely in the local laboratory

## Imaging

No

Yes

study-specific ……………………………………………………………………

non-study specific ……………………………………………………………

## Pharmacy

No

Yes

study-specific ……………………………………………………………………

non-study specific ……………………………………………………………

## Pathological Dissection

No

Yes

study-specific ……………………………………………………………………

non-study specific ……………………………………………………………

## Nuclear Medicine

No

Yes

study-specific ……………………………………………………………………

non-study specific ……………………………………………………………

## Centre for human genetics

No

Yes

study-specific ……………………………………………………………………

non-study specific ……………………………………………………………

## Biobank

No

Yes (add the approval)

## Specific invasive and non-invasive examinations

No

Yes

study-specific ……………………………………………………………………

non-study specific ………………………………………………………………

## clinical measurements

No

Yes, define below

study-specific ……………………………………………………………………

non-study specific ……………………………………………………………

## Additional study specific assessments

No

Yes, define below

study-specific ……………………………………………………………………

non-study specific ……………………………………………………………

## Arrangements to block the RIZIV billing for study specific measurements

No

Yes, Which procedure:……………………………………………………………………  
Not applicable

## Are the different departments of the study site informed about the study?

No

Yes, add copy

Not applicable

## Specific facilities needed to conduct the clinical trial.

No

Yes: …………………………………………………………………………………………………..

# Insurance

*The Sponsor is responsible for providing the insurance. The follow-up of this is done by the investigator. The investigators and their participants should be adequately insured for the entire duration of the study.*

BAREC, the Belgian Association of Research Ethics Committees, firmly recommends that the minimum insurance amounts below are respected:

* 500.000 EUR/participant
* 2.500.000 EUR/incident
* 5.000.000 EUR/experiment or in aggregate

Has the insurance been arranged in accordance with the Belgian Law of 7/5/2004?

No, reason: ……………………………………………………………….

Yes

**I declare to take full responsibility of the above mentioned project and confirm that to the best of my current knowledge, the information corresponds to reality.**

|  |  |  |
| --- | --- | --- |
| Principal Investigator  Name + signature + date |  | Co-investigator  Name + signature + date |