**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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| +32 11 69 96 00Jolanda.Verheezen@rzst.be |  | Kinder Psychiatrisch Centrum Genk+32 89 32 59 59kpc@kpc-genk.be  |

# 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 InvestigatorName + signature + date |  | Co-investigator Name + signature + date |