In order to register a new study at the CTU, the principal investigator (at ZOL) completes this application form after receiving the study number. The fully completed and signed application form has to be sent to ctu@zol.be. *If the application form is not submitted by the principal investigator himself, the principal investigator should be in copy of the submission e-mail.*

ACRONYM:

STUDY NUMBER:

PRINCIPAL INVESTIGATOR (at ZOL):

1. **General information about the study**

Title:

Protocol number:

Medical department / research department where the study will be conducted:

Expected total number of participants in the study, as described in the protocol:

Expected number of participants at the ZOL site, if different from the total number:

Expected start date (first patient included in ZOL):

Expected stop date (last patient last visit in ZOL):

1. **Sponsor of the study**

*Sponsor: An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or funding of a clinical trial (definition 1.53 in ICH-GCP E6(R2)). The sponsor is not necessarily the funder of the study. Attention: The sponsor of the study is responsible for the insurance as stated by the Belgian law dated 7th May 2004 related to experiments on humans.*

*Non-commercial study (Art. 2, 15°): a study in which*

*• The sponsor is (Art. 2, 15°, a):*

* *a Belgian university or a Belgian hospital; or*
* *the FWO or the FNRS, or a research fund depending on one of both; or*
* *a recognized centre of expertise in a hospital; or*
* *a non-profit organisation with a main focus on scientific research (Art.31);*

*• AND the patent holder of a medicine or a registered trademark of a medical device is directly nor indirectly the sponsor of the study (Art. 2, 15°, b)*

*• AND the sponsor owns the intellectual property of the concept of, the conduction of and the scientific data generated by the study (Art. 2, 15°, c)*

*Commercial study: each study that is not non-commercial (Art.2, 24°)*

[ ]  Medical need or Compassionate use programme; Company:

[ ]  Commercial study; company name or name of external sponsor:

[ ]  Non-commercial study

Sponsor:

[ ]  ZOL

[ ]  UHasselt

[ ]  Other, e.g. university, hospital, FWO (please specify):

Study in the framework of (multiple answers possible):

[ ]  Limburg Clinical Research Center

[ ]  Ziekenhuis Oost-Limburg Future Health

[ ]  Collaboration TRACE

[ ]  Doctoral thesis

University:

[ ]  Master/bachelor thesis or school assignment

Institution (e.g. UHasselt, UCLL):

Grade (e.g. Bachelor 2, Master 1):

Educational program (medicine, science, nursing):

[ ]  Investigation of quality aspects

[ ]  Other (please specify):

1. **Sponsor contact information**

Company or other external sponsor:

Company name:

Address:

[ ]  Sponsor contact person for the study (CRA or start-up specialist) :

Name:

Telephone:       E-mail:

[ ]  Contact person for invoicing (if known and different from contact person above) :

Name:

Telephone:       E-mail:

[ ]  Contact person for clinical trial agreement (if known and different from contact person above):

Name:

Telephone:       E-mail:

1. **ZOL Principal investigator contact information**

*The principal investigator is a person responsible for the conduct of the clinical trial at a trial site. The principal investigator is a medical doctor or any other health professional recognized by royal degree 78 dated 10th November 1967 and is qualified to conduct experiments (good clinical practice certificate). The principal investigator is responsible for performing the study at a specific trial site. If a study is conducted by a team of individuals at a trial site, the principal investigator is the responsible leader of the team.*

Principal investigator at ZOL

Name:

Telephone:       E-mail:

Contact person at the ZOL department of the principal investigator (if applicable)
(e.g. study coordinator employed by ZOL or doctoral student/postdoc/research scientist)

Name:

Telephone:       E-mail:

External contact person of the principal investigator [only external persons of Uhasselt or KULeuven who are part of the study team and involved in data collection]

Name:       Department:

Telephone:       E-mail:

1. **Clinical Research Organization (CRO)** (if applicable)

Company name:

Address:

Contact person for the study:

Telephone:

E-mail:

Role in the study:

1. **Ethical committee ZOL**

If the study is already registered at the CTU of ZOL, several sections of the EC ZOL application form should not be completed to avoid double information collection. It concerns the following sections;

* Part 1: except for the study number (assigned by the CTU) and the question concerning the registration of the study in a public database. [the study number Z-202xxx will also become the EC-reference number]
* Part 2: except for question 2.3 and 2.4
* Part 5
* Part 9, only question 9.1 can be left blank

[ ]  ZOL is central ethical committee

[ ]  ZOL is local ethical committee

Central ethical committee is:

[ ]  Clinical Trial College *(CTR pilot; only for clinical trials on medicinal products)* Pilot number:

[ ]  Ethical approval is not required because:

Which EC will provide approval for:

 [ ]  the collection and storage of human bodily material in a tissue bank collection:

 [ ]  the use of existing tissue bank collection of human bodily material :

 [ ]  the collection, storage and use of human bodily material of a tissue bank collection:

1. **Study characteristics**

*The Belgian law dated 7th May 2004 related to experiments on humans covers interventional and non-interventional studies, with the exception of retrospective studies.*

*Interventional studies cover all experiments on humans that hold a deviation of the standard clinical care (e.g. an additional blood collection, additional RX, medication in different dose, randomisation of participants, administration of questionnaires …)*

*Non-interventional studies cover studies in which medication is prescribed in accordance to standard clinical procedures. The allocation of participants to a therapeutic strategy is not determined in advance by the study protocol, but is part of the common clinical practice and the decision to prescribe medication is independent of the decision to include a patient in the study. The patient is not required to undergo additional diagnostic or check procedures and epidemiological methods are applied for the analyses of the obtained data.*

[ ]  The study is conducted solely in Belgium (national)

[ ]  Mono centric [ ]  Multi centric

[ ]  The study is conducted internationally

 [ ]  Europe [ ]  World wide

 ZOL is the single participating Belgian centre [ ]  yes [ ]  no

[ ]  Study is not within the scope of the Belgian law dated 7the May 2004 related to experiments on humans

[ ]  Retrospective

[ ]  Medical need program

[ ]  Compassionate use

[ ]  Collection + storage and/or usage of human bodily material (HBM) for scientific research purposes (Human Tissue Act Belgium)

Human bodily material concerns every biological material from the human body, as well as substances extracted there from, whatever the degree to which they have been processed (i.e. cerebrospinal fluid, embryos, foetuses, gametes, breast milk, nails, organs, faeces, teeth, tears, urine, tissues and cells, sweat). The tissue bank is responsible for registration, the coding and disposal of the material (traceability). For the collection and as well for the usage of human bodily material, an approval of an ethical committee is required. The project can be submitted to the EC for simultaneous approval for the collection and usage of the human material.

Removal and collection of HBM

[ ]  it concerns an existing human tissue collection located in (an abroad) tissue bank(s):       [name and location of tissue bank]

[ ]  to set up a new tissue bank collection for future research purposes

[ ]  is performed for a specific study and used in this study. The HBM will only be used for this study to answer the research questions and objectives within the time period defined in the study protocol. This concerns a prospective interventional study.

Storage of HBM

[ ]  Direct analysis and destruction after the analyses.

[ ]  Short term storage; the HBM is not immediately analysed, but will be used in for the defined study within the time period defined in the study protocol. No future research purposes.

[ ]  Long term storage; the HBM will be stored after the closure of the study until       [calendar year] for future research purposes

Disposal and usage of HBM

[ ]  Primary use (when the HBM is used for the purpose for which is has been collected. The donor has consented for the removal and use to the HBM)

[ ]  Secondary use (any other use of the HBM than consented to by donor at time of procurement. It concerns remaining material from primary use)

[ ]  Residuary material (HBM procured for diagnostic or treatment purposes that is no longer necessary and therefore can be destroyed, provided a sufficient sample is kept for setting, finetuning or finalizing the diagnosis or treatment)

[ ]  By an end user outside Belgium (export of HBM to abroad)

With regards to the HBM, will there also be personal and health data collected?

[ ]  No, only minimal data required for tissue bank registration purposes is used

[ ]  Yes, it concerns personal and health data which is already recorded in the

electronic medical record of the participants 🡪 considered as a retrospective study

[ ]  Yes, it concerns personal and health data which will be collected prospectively (i.e. future disease status or development, outcomes) 🡪 considered as a prospective study which is in the scope of of the Belgian law dated 7the May 2004 related to experiments on humans

[ ]  Other (please specify):

[ ]  Study within the scope of the Belgian law dated 7the May 2004 related to experiments on humans

[ ]  Prospective non-interventional = observational

[ ]  Prospective interventional study

[ ]  involving drugs / medicinal products

EudraCT number:

Date of FAMHP application:

 Placebo controlled: [ ]  yes [ ]  no

[ ]  involving medical device / prosthesis

[ ]  with CE label and in accepted indication

[ ]  with CE label but in deviant indication

date FAMHP application:

[ ]  without CE label

date FAMHP application:

 Placebo controlled: [ ]  yes [ ]  no

[ ] other:

[ ]  Diagnostic study

[ ]  Epidemiological study

[ ]  Physiology / Physiopathology

[ ]  Psychological study

[ ]  Sociological study

[ ]  Questionnaire

[ ]  Other (please specify):

Randomized study:

[ ]  Yes

[ ]  Open study *(everyone knows which intervention is allocated)*

[ ]  Single-blind *(the participant does not know which intervention is allocated)*

[ ]  Double-blind *(neither the participant nor the investigator knows which intervention is allocated)*

[ ]  No

1. **Study phase** (only applicable for drug trials)

*Clinical trials involving drugs are classified into four phases.
Phase 1: first-in-human trials, testing occurs within a small group of people (typically 20–80) to evaluate safety*

*Phase 2: Establishing the preliminary efficacy of the drug, usually against a placebo - Testing with a larger group of people (typically 100–300) to determine efficacy and to further evaluate its safety.*

*Phase 3: Final confirmation of safety and efficacy - Testing within large groups of people (typically 1,000–3,000) to confirm its efficacy, evaluate its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow it to be used safely.*

*Phase 4: Post-marketing studies for long-term effects. These studies delineate risks, benefits, and optimal use. As such, they are ongoing during the drug's lifetime of active medical use.*

[ ]  Preclinical

[ ]  Phase 1

[ ]  Phase 2

[ ]  Phase 3

[ ]  Phase 4

[ ]  Not applicable

1. **Supportive departments of the hospital**

If the study protocol requires study specific assessments that are not part of routine clinical care, then the supportive departments are involved. The application form of the concerning supportive department has to be submitted along with the rest of documents necessary for initial application at the CTU (ctu@zol.be). By doing so, the supportive departments is able to avoid that costs are charged to the participant or RIZIV (public health insurance).

[ ]  Not applicable: the study is only conducted at the medical department of the principal investigator who is responsible himself for arranging that the study related assessments are not invoiced to participants or RIZIV.

[ ]  Anatomy-pathology

[ ]  Pharmacy

[ ]  Biobank UBiLim\*

[ ]  Cardiology

[ ]  Laboratory clinical biology (also involved if only the lab certificate and normal values required)

[ ]  Medical imaging

[ ]  Nuclear medicine

[ ]  Ophthalmology

[ ]  Other (please specify):

*\* According to the biobank law all human body material that is collected for scientific research purposes has to be registered in a biobank. There is an exception for clinical trials that are submitted to the FAMHP (Federal Agency for Medicines and Health Products). However, if in the clinical trials additional blood samples are collected for future research, these samples should be registered at a biobank.*

*The use of human body material for the optimisation/validation of medical devices does not have to be registered at a biobank. However, if you aspire to publish the results of a device validation, the FAMHP advices to work solely with human body material obtained via a biobank.*

*The biobank registration form is available on the ZOL CTU website. The University Biobank Limburg can be contacted at* *Kimberly.Vanhees@jessazh.be*

1. **Agreements and contracts**

FINANCIAL

The study performed at Ziekenhuis Oost-Limburg as participating site is funded by:

[ ]  Non-commercial sponsor by means of:

[ ]  Public resources – project grant

Name of funder (e.g. FWO, H2020):

Project type (e.g. TBM):

Project title:

Grant is provide to:

[ ]  ZOL

[ ]  UHasselt

[ ]  Other (please specify):

 [ ]  Unconditional grant by grant giver:       to

[ ]  ZOL or medical doctor at ZOL

[ ]  UHasselt

 [ ]  Study agreement (financial compensation for the services related to study/research)

[ ]  ZOL or medical doctor at ZOL

[ ]  UHasselt

[ ]  Study medication / medical device is provided free of charge by [company]

[ ]  ZOL or medical doctor at ZOL

[ ]  UHasselt

[ ]  Commercial sponsor of company by means of:

[ ]  Study agreement (financial compensation for the services related to study/research) with

[ ]  ZOL or medical doctor at ZOL

[ ]  UHasselt

[ ]  Other (please specify):

[ ]  Not applicable/no funding

GDPR

[ ]  Data transfer agreement (DTA) for

[ ]  a retrospective study

[ ]  a ZOL-sponsored study which requires transfer of data to a 3rd party for study purposes such as statistical analysis

[ ]  Data processing agreement (DPA)

[ ]  as part of the main contract

[ ]  as stand-alone agreement

HUMAN BODILY MATERIAL (i.e. Human Tissue act)

[ ]  Material transfer agreement (MTA)

1. **Conflict of interest**

*Definitions based on the position paper 8891 of the Superior Health Council, dated 7th November 2012*

*Interest: the direct or indirect relationship between the principal investigator or study employee and the sponsor or other involved institution of which the products, procedures, services or strategy apply to participating to the study (e.g. reimbursement, reward in kind, direct or indirect interests on voluntary basis, financial interests, expert reports and consultancy, organizing and/or attending conferences, …)*

*Conflict of interest:*

*Conflict of interest: the situation in which the interests of the principal investigator or study employee are of that nature that the decision to participate in the study can be influenced in order to receive benefit, financial or not (e.g. scientific fame), directly or indirectly (e.g. reimbursements that are not market conform, participation in the profit), also to family or any other person he/she is related to. It is also possible that advantages are destined for the organisation (e.g. scholar ships, payment of employees, professorship). Even if no fault is made, an interest can indicate a sense of interference which can undermine the trust in the ability of a person to take his responsibility.*

[ ]  As principal investigator, I declare that I and all study employees, during the course of the study, have no conflicts of interest for the conduction of the study.

[ ]  As principal investigator, I declare for myself or a study employee, during the course of the study, the following conflicts of interest for the conduction of the study:

1. **Obligatory documents**

The filled-out application form has to be submitted along with the rest of the documents necessary for initial application at the CTU:

|  |  |
| --- | --- |
| **For studies with ZOL or UHasselt as sponsor:** | **For studies with an external sponsor:** |
| (Draft) contract | (Draft) contract + confirmation of commercial sponsor to reimburse the legal review fee |
| (Draft) Protocol and Informed Consent, with protocol number, version number and version date | (Draft) Protocol, with protocol number |
| Request forms support services, if applicable | Request forms support services, if applicable |
| GCP certificate of the principal investigator, maximally 2 years old (only required if document is not available in the CTU database. CTU will request the document if not available or not longer valid ) | GCP certificate of the principal investigator, maximally 2 years old (only required if document is not available in the CTU database. CTU will request the document if not available or not longer valid ) |
| Signed and dated CV of the principal investigator which demonstrates the affiliation with ZOL and is maximally 2 years old(only required if document is not available in the CTU database. CTU will request the document if not available or not longer valid ) | Signed and dated CV of the principal investigator which demonstrates the affiliation with ZOL and is maximally 2 years old (only required if document is not available in the CTU database. CTU will request the document if not available or not longer valid ) |
| GDPR questionnaire  | GDPR questionnaire |

**13. Signature**

**Name of the Principal Investigator Signature Date**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_ / \_\_\_ / \_\_\_\_\_\_\_