The fully completed application form has to be sent to ctu@zol.be. If the application form is not submitted by the principal investigator himself/herself, the principal investigator should be in copy of the submission e-mail. Instructions for completing this application form can be found at the end of this document.

|  |  |
| --- | --- |
| **Acronym** |       |
| **Study number**  | Z-       |
| **Principal Investigator**  |       |

1. **GENERAL STUDY INFORMATION**

|  |
| --- |
| **Study information** |
| **Title** |       |
| **Protocol number** |       |
| **Medical department/research department**  |       |
| **Expected total number of participants (as described in the protocol)**  |       |
| **Expected number of participants at the ZOL (if different from the total number)** |       |
| **Expected start date** |       |
| **Expected stop date** |       |

1. **STUDY SPONSOR**

|  |
| --- |
| **Is the sponsor of this study a commercial or non-commercial sponsor?**  |
| [ ]  Commercial sponsor |
| [ ]  Non-commercial sponsor |

|  |
| --- |
| **Who is the sponsor?** |
| [Name sponsor]*NaamNaam* |

|  |
| --- |
| **In case it concerns a non-commercial sponsor, what is the context of this study?**  |
| [ ]  LCRC |
| [ ]  Future Health |
| [ ]  TRACE |
| [ ]  Doctoraatsonderzoek |
| [ ]  Eindwerk of schoolopdracht |
| [ ]  Kwaliteitsonderzoek |
| [ ]  Andere:       |

1. **CONTACT DETAILS OF THE STUDY TEAM**

|  |
| --- |
| **Who is the contact person/study coordinator at the department of the principal investigator in ZOL?** |
| [Name] |
| [Telephone] |
| [E-mail] |

|  |
| --- |
| **Who is the external contact person of the principal investigator? (if applicable)**  |
| [Name] |
| [Telephone] |
| [E-mail] |

1. **CONTACT DETAILS SPONSOR/CRO**

|  |
| --- |
| **Who is the contact person of the sponsor for this study?** |
| [Name] |
| [Telephone] |
| [E-mail] |

|  |
| --- |
| **Who is the contact person of the sponsor for invoicing? (if different from above)** |
| [Name] |
| [Telephone] |
| [E-mail] |

|  |
| --- |
| **Who is the contact person of the sponsor for the clinical trial agreement? (if different from above)** |
| [Name] |
| [Telephone] |
| [E-mail] |

|  |
| --- |
| **Who is the contact person of the CRO? (if applicable)** |
| [Company name] |
| [Name contact person] |
| [Telephone] |
| [E-mail] |
| [Role in study] |

1. **STUDY CHARACTERISTICS**

|  |
| --- |
| **Will this study be executed in Belgium only or also in other countries?**  |
| [ ]  National |
| [ ]  International |

|  |
| --- |
| **Will this study be performed in one centre in Belgium or in multiple centres?**  |
| [ ]  Monocentric |
| [ ]  Multicentric |

|  |
| --- |
| **What type of study is this?**  |
| [ ]  Prospective interventional study with a medicine or medical device |
| ⮡ Review by CT college (according to CTR/MDR legislation)? [ ]  Yes [ ]  No |
| [ ]  Prospective interventional – other |
| [ ]  Prospective non-interventional |
| [ ]  Retrospective |
| [ ]  Secondary use of human body material |

1. **SUPPORTING DEPARTMENTS**

In case the protocol requires study specific assessments that are not standard of care, the supporting departments where these assessments are performed need to be contacted. Please complete the supporting departments’ request forms and send them together with the CTU submission package to ctu@zol.be. By doing so, the supportive departments are able to avoid that costs are wrongfully charged to the participant and/or RIZIV (public health insurance). **Please note** thatthe Clinical laboratory is also involved when only the lab certificate and reference ranges are required. In case of doubt regarding the involvement of the Biobank, please consult [this link](https://msazurezol.sharepoint.com/sites/ZOLnet_FH/SitePages/Biobank.aspx?ga=1) (only for ZOL employees).

**Involved supporting departments**

[ ]  Pathology [ ]  Cardiology [ ]  Nuclear medicine [ ]  None

[ ]  Pharmacy [ ]  Clinical laboratory [ ]  Ophthalmology

[ ]  Biobank [ ]  Radiology [ ]  Other:

1. **AGREEMENTS AND FINANCING**

|  |
| --- |
| **Is there a master agreement or overarching agreement available for this study?** |
| [ ]  Yes – Please add the master agreement or overarching agreement to the CTU submission package |
| [ ]  No |

|  |
| --- |
| **How will this study be financed in ZOL?**  |
| [ ]  Study agreement  |
| [ ]  Public resources (project grant) provided to       |
| * Name funder:
 |
| * Name project:
 |
| * Project type:
 |
| [ ]  Unconditional Grant from        |
| [ ]  Medication/medical device is provided free of charge by        |
| [ ]  Not applicable: no funding |
| [ ]  Other:       |

1. **CONFLICT OF INTEREST**

|  |
| --- |
| **Is there a conflict of interest for the conduction of this study?** |
| [ ]  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 a 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:       |

**APPENDIX A: MANDATORY DOCUMENTS**

The completed CTU application form has to be submitted along with the below documents:

|  |  |
| --- | --- |
| **ZOL Sponsor** | **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** for the **supporting departments**, if applicable  | **Request forms** for the **supporting departments**, if applicable |
| **GCP** certificate of the principal investigator, max. 2 years old | **GCP** certificate of the principal investigator, max. 2 years old |
| Signed and dated **CV** of the principal investigator which demonstrates the affiliation with ZOL, max. 2 years old | Signed and dated **CV** of the principal investigator which demonstrates the affiliation with ZOL, max. 2 years old |

**APPENDIX B: INSTRUCTIES**

Below you can find definitions and more information that could be useful when completing the CTU application form.

**Section – General study 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.

The expected start and stop date: the period in which data will be collected and/or participants will be included. These dates indicate how long the study will last (when the study starts and when the study will end). These dates cannot be in the past.

**Section – Study sponsor**

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: a study in which

* the sponsor is a Belgian university or a Belgian hospital; or
* the sponsor is the FWO or the FNRS, or a research fund depending on one of both; or
* the European sponsor is a university, a hospital or a non-commercial institution; and
* the patent holder of a medicine or a registered trademark of a medical device is directly nor indirectly the sponsor of the study; and
* the sponsor owns the intellectual property of the concept of, the conduction of and the scientific data generated by the study

Commercial study: each study that does not meet the requirements of a non-commercial

**Section – Study characteristics**

Interventional research: every experiment in humans that hold a deviation of the standard clinical care. For example: an additional blood collection, an additional RX, administration of a medicine in a different dose or formulation, randomisation of participants, …

Non-interventional research: every study 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.

Human bodily material: 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. With scientific research, every use of human body material is meant with a view to the development of knowledge specific to the exercise of the health care professions as referred to in Royal Decree No. 78 of 10 November 1967 on the exercise of the health professions. In case already collected data is being used that is linked to the human bodily material, the study is considered a retrospective study. In case new data is being collected in the patient file that is linked to the human bodily material, the study is considered a prospective study.

**Section – Conflict of interest**

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: 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.