**Ethics Committee Saint-Luc Hospital - UCLouvain - CEHF**

**Submission form to be used in case of interventional and non-interventional prospective studies (master/bachelor thesis excluded)**

***Please tick the box(es) corresponding to your type of experiment in the table***

|  |  |  |
| --- | --- | --- |
| **Type of trial** | **Comments**  | **Submission document** |
| [ ]  Prospective interventional | Non-routine treatment or IMP or device or non-routine procedures Questionnaire or survey during a non-routine visit or completed at home | Document 1CEHF-FORM-097[[1]](#footnote-2) |
| [ ]  Prospective non interventional | Questionnaire or survey during a routine visit / treatment  | Document 1CEHF-FORM-097 |
| Prospective interventional master/bachelor thesis  | Non –routine Questionnaire or survey, as part of a master/bachelor thesis (excl. PhD dissertation and end of specialization thesis)  | MasterSubmission form Bachelor/Master thesisCEHF-FORM-143[[2]](#footnote-3) |
| Retrospective | Collection of data already available in patient medical dossier | Simplified Submission Form – FSSCEHF-FORM-108[[3]](#footnote-4) |
| Residual Human Body Material (RHBM))  | + associated retrospective related data (already available) | Simplified Submission Form – FSSCEHF-FORM-108 |
| Analysis of professional practices | Only concerns nursing staff | Simplified Submission Form – FSSCEHF-FORM-108 |
| Creation of a databases |  | Simplified Submission Form – FSSCEHF-FORM-108 |

1. Definitions
	* **Prospective interventional study**: concerns a clinical drug trial, a study of a medical device or any other study requiring non-routine treatment or follow-up procedures. This study type also includes questionnaires or surveys completed during a non-routine visit or at home.
	* **Prospective non- interventional study (observational)**: concerns questionnaires intended for participants in a study, completed during a consultation or routine follow-up.
	* **Sponsor:** a physical person, a company, an institution or an organization responsible for launching, managing and / or funding an experiment
* **Principal investigator**: A medical doctor or any other person engaged in a position covered by the royal decree n ° 78 of 10 November 1967, related to the exercise of health care professions, qualified to carry out an experiment. The principal investigator is responsible for conducting the experiment on a site.
* **Human Body Material (HBM):** every human biological material, including human tissues and cells, gametes, embryos, and foetuses, as well as the substances extracted therefrom, whatever the degree to which they have been processed; blood, blood components and derivatives; hair and body hair, nails, urine, breast milk, stool, tears and sweats when intended for scientific research without human application. HBM can be for primary use (the donor has specifically given his consent) or for secondary use, i.e. other than that initially planned.
* **Residual Human Body Material (RHBM)**: part of human body material that is removed with a view to diagnosis or treatment of the donor which, after a sufficient and relevant part is stored for making, refining or completing the diagnosis or treatment of the donor on the basis of new scientific information, is superfluous with regard to these purposes and may thus be discarded. The label is part of the sample and contains the minimum identification data: age of the patient, sex, location of the sample and pathology
1. GENERAL INFORMATION:

**Study title:**

**Protocol number / Acronym:**

**EudraCT / EUDAMED number** (if applicable) :

* 1. **Sponsor**

**Non-Commercial Clinical Trial (academic)**

[ ]  University Clinics Saint-Luc (CUSL)

[ ]  Catholic University of Louvain (UCL)

[ ]  Other:

Institution:

Name:

Address:

E-mail:

Telephone:

**Commercial Clinical Trial**

Company:

Address:

Contact name:

E-mail:

Telephone:

* 1. **People involved in the research**
		1. ***CUSL / UCLouvain***

**Principal Investigator (permanent staff members only or resident) :**

Name:

Medical Unit/department:

Contact data (telephone, pager, e-mail):

**Co-investigator :**

Name:

Contact details (telephone, e-mail):

**CRCM**

Name:

Medical Unit/department:

Contact details (telephone, pager, e-mail):

**2.2.2 *Other*** :

**Principal Investigator**:

Institution:

Contact details (telephone, pager, e-mail):

* 1. **Medical Field of the clinical trial:**

[ ]  Surgery [ ]  Psychiatry [ ]  Intensive care [ ]  Psychology

[ ]  Internal medicine [ ]  Oncology/radiotherapy [ ]  Palliative care [ ]  General medicine

[ ]  Obstetrics/Gynaecology [ ]  Clinical biology [ ]  Nurse care [ ]  Public health

[ ]  Paediatrics [ ]  Bacteriology/virology [ ]  Physiotherapy [ ]  Other:

* 1. **Mono - multicentric**

[ ]  Monocentrice

[ ]  Multicentric – CEHF = principal ethics committee

 List of the local ethics committees:

[ ]  Multicentrique – CEHF = local ethics committee

 Name, address and e-mail of the Principal ethics committee

* 1. **Trial location :**

Clinical trial participants will be

 [ ]  outpatient [ ]  hospitalized [ ]  mixt

* 1. **Estimated dates**

Start of the trial : …… /…… / 20…..

End of the trial : …… /…… / 20…..

* 1. **Financial conditions**

Who bears, even partially, the costs associated with the experiment? (grant, clinical account, ...)

* 1. **Target population**

[ ]  Healthy participants

[ ]  Patients

If yes, which disease?

[ ]  Adults able to consent

[ ]  Pregnant or breastfeeding women

If pregnant women or women of potential reproductive age are included in the study, please indicate why or specify the protective measures that will be applied:

[ ]  Embryos

[ ]  Minors (< 18 years old)

* + Developmental disorders [ ]  YES [ ]  NO

[ ]  Adults with **impaired capacity** that affect their ability to consent

[ ]  Acute medical conditions

[ ]  Psychiatric disorders

[ ]  Neurological disorders

[ ]  Behavioural disorders

[ ]  Dementia

* Able to consent
* Unable to consent:

[ ]  Temporarily due to [ ]  Emergencies

 [ ]  Acute medical conditions

 [ ]  Unconsciousness

[ ]  Definitively

[ ]  Fluctuating / decreasing capacity during the study

Number of subjects foreseen locally (on this site) :

 Globally:

Minimum age :       Maximum age :

Sex : [ ]  Male [ ]  Female

* 1. **Recruitment process**

 What media will be used? (*Posters and / or advertisement to be provided to us)*

1. Goal and rationale of the trial

3.1 Goal and specificity of the trial

* Briefly describe the goal and specificity of the experiment:

Click here to enter text

* Is this study immediately beneficial to the subject? [ ]  YES [ ]  NO

3.2 Rationale of the trial

* Briefly describe the rationale:

Click here to enter text

Has a similar experiment been carried out (in whole or in part) on humans?

 [ ]  YES [ ]  NO

If YES, why do you plan to start it over? Please describe the previous results as well as the new information that this trial is expected to bring:

Click here to enter text

If a new drug/medical device is compared to another product, please specify how this new product could be preferable to the comparator:

Click here to enter text

1. Actual experimentation

**4.1 DRUG RELATED STUDY**

[ ]  Not applicable

[ ]  Phase 1 : [ ]  first-in-human [ ]  dose escalation [ ]  dose expansion

[ ]  Phase 2 [ ]  Phase 3 [ ]  Phase 4

[ ]  IND (FDA) number :

**4.1.1 Administered substance(s) – IMP** *(Investigational Medicinal Product)*

* Will one or more substances be administered? [ ]  YES [ ]  NO

 If YES, specify for each of them:

* Generic name / international non-proprietary name (INN) :
* Route of administration:
* Is it registered in Belgium (even if not yet marketed)? [ ]  YES [ ]  NO
* Is it a new one? [ ]  YES [ ]  NO

 If yes, has the experimenter read the toxicological and

 Pharmacological record? [ ]  YES [ ]  NO

* Will drugs, other than that the one or those being tested, be provided/paid for by the firm / promoter? [ ]  YES [ ]  NO

If not, please justify.

**4.1.2 Risks related to the use of one or more substances**

* Please specify the important toxicological aspects:

Click here to enter text

* Adverse events likely to be induced by the target dose administered in the most sensitive subjects :

Click here to enter text

* Is there a safety margin between the dose mentioned in the protocol and the dose causing toxic effects?

 [ ]  YES [ ]  NO

* Is there a risk for the partner and/or other persons? [ ]  YES [ ]  NO

**4.1.3 Placebo**

* Will a placebo be used? [ ]  YES [ ]  NO
* Does the use of placebo result in therapeutic abstention?

 [ ]  YES [ ]  NO

 If YES, why prefer placebo ?

 Please also specify the duration of this abstention and the potential risks related to it :

Click here to enter text

**4.2 Medical device / implant**

[ ]  Not applicable

Does the device have the CE mark?

[ ]  Yes -> Is the device used as indicated by the manufacturer?

[ ]  Yes 🡪 CEHF only

[ ]  NO 🡪 FAMHP only

 [ ]  NO

[ ]  custom-made device and the data from the study are used to obtain the CE label 🡪 FAMHP submission only

[ ]  custom-made device and the data from the study are not used to obtain the CE label 🡪 FAMHP + CEHF submission

[ ]  home-made device 🡪 FAMHP + CEHF submission

[ ]  other device 🡪 FAMHP submission only

Will the costs of the medical device studied be covered by the company? [ ]  YES [ ]  NO

If not, please justify

**4.2.1 Expected adverse events related to the Medical device / Implant**

Please explain: Click here to enter text

**4.3 Other studies** (not relating to a medical device or a drug)

[ ]  Epidemiological study

[ ]  Diagnostic study [ ]  Other, specify:

[ ]  Physiology-physiopathology

[ ]  Psychological study

**4.4 Additional investigation (i.e. other than the standard medical care)**

* Does the trial involve the following :

 - Additional medical visits? [ ]  YES [ ]  NO

 - Additional investigations? (questionnaires, imaging, surveys, …) [ ]  YES [ ]  NO

 - Additional hospitalizations? [ ]  YES [ ]  NO

 If YES to any of the questions, please specify:

Click here to enter text

* Samples of tissues or biological products (biopsy, etc.) [ ]  YES [ ]  NO

 If YES, specify the sampling area… :

 Click here to enter text

* Genetic or genomic analyses [ ]  YES [ ]  NO

 If YES,

* Has the patient received a specific information and consent form? [ ]  YES [ ]  NO
* Is it specified that the analyses will remain within the framework of the pathology concerned? [ ]  YES [ ]  NO
* Will these additional requirements involve extra financial cost for the patient because of:

 - The investigation itself and/or its follow-up [ ]  YES [ ]  NO

 - Travel expenses [ ]  YES [ ]  NO

* Will these additional investigations involve extra financial cost for Social Security or any private insurance? [ ]  YES [ ]  NO
* How will additional medical visits and investigations be funded?

 [ ]  Financial contract for commercial trial (to be provided in appendix)

 [ ]  Funding from clinical account / principal investigator's grant (please provide a copy of the notification e-mail to the CoFi)

**4.5 HBM/RHBM[[4]](#footnote-5)**

* + 1. **Collecting HBM/RHBM**

Will human body material be collected during the study? [ ]  YES [ ]  NO

 If yes   [ ]  it is a diagnostic sample (RHBM)

 [ ]  it is a research sample (HBM)

* + 1. **Use of HBM/RHBM**

Will previously collected human body material be used in the study? [ ]  YES [ ]  NO

If YES, was it collected during a previous study? [ ]  YES [ ]  NO

If YES, did the patient consent to future research at the time of the (primary) collection of the HBM ? [ ]  YES [ ]  NO

If YES, is a copy of this consent available to the CEHF? [ ]  YES [ ]  NO

Provide the CEHF reference: Click here to enter text

Provide a copy of the ICF

* + 1. **Transfert de MCHR**

Is there a transfer of residual material between different legal entities? (i.e. between CUSL and UCL, or between CUSL and any spin-off from UCL, or between UCL and any spin-off from UCL, or between CUSL and a pharmaceutical industry) ?

[ ]  YES -> a draft of the contract/agreement shall be provided to the CEHF

[ ]  NO

**4.6 Risks related to the trial**

* Based on the data currently available, do you consider that the trial is likely to entail a risk? [ ]  YES [ ]  NO

If YES,

* Please describe the risk(s): Click here to enter text
* Please assess the severity of the risk: [ ]  not significant [ ]  significant [ ]  unpredictable
* Please assess the expected frequency :[ ]  not significant [ ]  significant [ ]  unpredictable
* Is the risk acceptable :

 For patients? [ ]  YES [ ]  NO

 For healthy participants? [ ]  YES [ ]  NO

* Are there any standard treatment(s) in this pathology? [ ] YES [ ]  NO [ ]  NA

If YES, compared to current/standard treatments, does the risk appear to be:

[ ]  Higher [ ]  Identical [ ]  Lower

* Does the protocol include the interruption of previous treatments? [ ]  YES [ ]  NO [ ]  NA

If YES, does this interruption constitute a risk? [ ]  YES [ ]  NO

 If YES, the risk is: [ ]  non-significant

 [ ]  Significant

 [ ]  Unpredictable

* During this trial, will the participants be given appropriate medical surveillance?

[ ]  YES [ ]  NO

1. Insurance
* In conformity with the law of 7 May 2004, the Sponsor must take out liability insurance, even without fault, to cover any risks the patient or healthy volunteer might encounter.
* Who is the holder of the insurance?
1. Information and Consent
* If the trial involves minors, the information for minors must be adapted to their level of understanding (Chapter IV of the Law of 7 May 2004). Please provide and tick the following items:

[ ]  Specific information

[ ]  For minors (three age groups are usually considered: 6-11, 12-15, 16-17 years)

[ ]  For the parents or legal representative of the minor

[ ]  Specific consent

[ ]  For minors (referred to as "assent", rather than "consent")

[ ]  For parents (must be signed **by both parents**) and/or the legal representative

* If participants are unable to express their consent because of their condition or because of the emergency, the procedure must be adequate (Chapters V and VI of the law of 7 May 2004). Please provide and tick the following elements when applicable:

[ ]  Specific information

[ ]  Presence of a legal representative

[ ]  The legal representative is involved in the process of obtaining consent

[ ]  The consent process involves obtaining **written consent:**

[ ]  as soon as the participant recovers his or her capacity to consent

[ ]  as soon as the participant emerges from the emergency

[ ]  as soon as the participant emerges from acute medical condition

1. Financial Compensations for the participants

Please specify the financial compensation foreseen for the participants:

Click here to enter text

1. Confidentiality and protection of privacy

Will the confidentiality and anonymization of the study data be ensured and mentioned in the information and consent form (law of 30 July 2018 on the protection of privacy, law of 22 August 2002 on the rights of the patient and GDPR (General Data Protection Regulation**)**)?

 [ ]  YES [ ]  NO

Describe the patient's pseudonymization process *(neutral identifier: do not use CUSL's administrative number, date of birth, or a combination of initials and date of birth*):

Click here to enter text

1. Contacts

**9.1 In the event of problem or question, will participants have the opportunity at any time to contact:**

* The study investigator? [ ]  YES [ ]  NO
* The DPO of the site? [ ]  YES [ ]  NO
* The patient's rights ombudsman? [ ]  YES [ ]  NO

**9.2 Will the patient’s general practitioner be informed of the patient's participation in the study, in agreement with the patient?**  [ ]  YES [ ]  NO

|  |
| --- |
| **Investigator statement** |
| I confirm that the information provided in this Document 1 is correct.I confirm that I have declared possible conflicts of interest that could arise from the relationship that I or someone close to me has with the firm involved in the trial that is the subject of this application. I believe that this study can be carried out in accordance with the protocol and the principles of the "Declaration of Helsinki", the "Good Clinical Practice" and the Belgian legislation on the protection of the privacy of participants and on experiments on embryos / on the human person / on human body material. I am committed to my responsibilities as principal investigator for this trial. I have taken steps to ensure that the privacy of the participants recruited in this trial is protected. This means that :* no identifying data will leave the institution
* no combination of data (such as initials combined with the date of birth expressed in dd/mm/yyyy and sex) that could possibly allow the re-identification of the participant will leave the institution,
* the data and/or biological samples submitted to the sponsor of this study will be coded.
	+ I and my collaborators will be the only owner of the database associating the identification code in the trial and the participant's file.
	+ This database will be kept in a safe place (closed cabinet / password protection if electronic database) and destroyed after the legal archiving period..
* any access to the source data and the patient's medical file by third parties will be under my direct supervision or that of one of my collaborators..
* the computer files hosting the collected data will be protected from misuse.

I commit myself to transmit to the Ethics Committee * milestones for the progress of the study (first participant in, end of recruitment period, end of the trial),
* any severe and unexpected adverse event in any of the participants I recruit,
* an **annual** report together with my assessment of the risk/benefit balance for trial’s participants, **to be sent within the required timeframe (i.e. 365 days after the positive opinion of the principal EC). This is mandatory and I understand that the renewal of the agreement’s validity depends on the receipt of this document (see CEHF-FORM-110).**
* the end of trial report.
 |
| **Date** : | Name, First name, Title of Principal Investigator :Signature : |
| **Date :** | Name, First name, Title of Department header :Signature for agreement and information |
| **In case of a UCLouvain trial, signature the promoter's representative**:Date :First name and last name:Signature : |
| **In case of a study on human body material (HBM / RHBM), signature of the Biobank Manager :**Date : First name and last name :Signature : |

1. CEHF-FORM-097\_Soumission - Document 1 [↑](#footnote-ref-2)
2. CEHF-FORM-143\_Master Submission form Bachelor/Master thesis [↑](#footnote-ref-3)
3. CEHF-FORM-108\_Formulaire de Soumission Simplifiée FSS [↑](#footnote-ref-4)
4. HBM/RHBM : human body material/residual human body material [↑](#footnote-ref-5)