Ethics Committee Saint-Luc Hospital - UCLouvain - CEHF

Submission form to be used in case of master/bachelor thesis:

- Thesis :
  - ☐ Retrospective
  - ☐ Prospective non-interventional
  - ☐ Prospective interventional
  - ☐ Relating only to RHBM +"label" and/or associated retrospective related data

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

1. Definitions

- **Retrospective study** : examination of the past using already available data and provided that no new data is acquired in any way, no contact with patients is allowed once the EC has given his approval.
- **Prospective study** : examinations in the future, data that will be newly acquired.
- **Prospective interventional study**: *in case the study was submitted with this document)* : uniquement questionnaire ou enquête, si visite supplémentaire ou appel téléphonique pour le questionnaire, ou si le questionnaire est rempli à domicile.
- **Prospective non- interventional study (observational)**: concern questionnaires intended for participants in a study, completed during a consultation or routine follow-up.
- **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.
- **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 (he can be the promoter of the dissertation).
- **Register / Creation of a database** with or without a specific research goal at the time of its creation ...! **This must be submitted in advance to the Academic Desk - CTC to determine the type of study**

2. GENERAL INFORMATION:

Thesis title:

Protocol number (*facultative)*:
Acronym (*facultative)*:

☐ Medecine ☐ Nurse care ☐ Nutrition

☐ Physiotherapy ☐ Psychology ☐ Public health ☐ Other :

Name and contact details (e-mail, phone number, institution, year of the study) of the student :

Name and contact details (Medical Unit/department, e-mail, phone number) of the thesis promoter :

2.1 Mono – Multicentric study

☐ Monocentric

☐ Multicentric – CEHF = principal ethics committee

List of the local ethics committees (name, address and e-mail of the committees):

☐ Multicentric – CEHF = local ethics committee

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

2.2 Sponsor : a person, company, institution or body responsible for launching, managing and / or financing an experiment experimentation

Non-commercial study (academic)

☐ UCLouvain

☐ Other:

↳ Institution :

Name:

Address:

E-mail:

Telephone:

2.3 Goal and specificity of the trial

Briefly describe the goal and specificity of the experiment (maximum 10 lines):

Click here to enter text

2.4 Rationale of the trial

Briefly describe the rationale:

Click here to enter text

2.5 Financial conditions

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

3. RETROSPECTIVE THESIS

- Place of data collection:
- Period during which data was collected from patients (source data)

  From ..... /..... /20..... To ..... /..... /20.....
- Period during which the data will be analyzed by the investigator

  From ..... /..... /20..... To ..... /..... /20.....

3.1 Confidentialité et protection des données

- Will the confidentiality of the study data be ensured? ☐ Yes ☐ No

Describe the patient's pseudonymization process:

Click here to enter text

- Is there a transfer of data between different legal entities (e.g. between the CUSL and the UCL, or between the CUSL and a spin-off of the UCL, or between the UCL and a spin-off of the UCL, or between the CUSLs and a pharmaceutical company)?

  ☐ Yes -> Provide the CEHF with the draft contract or convention/contract

  ☐ No

3.2 Methodology

Statistical methods used:

Click here to enter text

Don't forget to sign the document on the last page

4. PROSPECTIVE THESIS *(DATA ACQUISITION AFTER CEHF APPROVAL)*

☐ **Non interventional** (including questionnaire or survey during a routine visit)

☐ **Interventional**

☐ Epidemiological study
☐ Diagnostic study
☐ Physiology-physiopathology
☐ Psychological study
☐ Other, specify:

4.1 Trial location where the experiment will be carried out

Click here to enter text

Clinical trial participants will be ?

☐ outpatient ☐ hospitalized ☐ mixt

4.2 Target Population

- Healthy participants ☐ Yes ☐ No
- Patients ☐ Yes ☐ No
  If yes, which disease?

- Number of subjects foreseen:
- Minimum age : Maximum age :

- Sex : ☐ Male ☐ Female

☐ Adults able to consent
☐ Persons with **impaired capacity** that affect their ability to consent
☐ Paediatrics
☐ Pregnant or breastfeeding women
☐ Other (special population)
☐ Emergencies
☐ Dementia
☐ Unconsciousness
☐ Embryos

4.3 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

4.4 MCH/MCHR

4.4.1 Collecting MCH/MCHR

Will MCH / MCHR be collected during the study? ☐ YES ☐ NO

If yes ☐ is this a diagnostic sample?

☐ is this a research sample?

4.4.2 Use of MCH from another experiment:

In the case of secondary use of HBM, did the patient consent to future research at the time of the (primary) collection of the HBM ☐ YES ☐ NO

Initially taken during a CEHF study -> provide the CEHF reference:

Initially taken during a study outside CEHF -> provide a copy of the ICF

4.4.3 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

4.5 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

  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

  If YES, does this interruption constitute a risk? ☐ YES ☐ NO

  If YES, the risk is : ☐ not significant ☐ significant ☐unpredictable

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

  ☐ YES ☐ NO

4.6 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??

4.7 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

4.8 Financial Compensations for the participants

Please specify the financial compensation foreseen for the participants:

Click here to enter text

5. THESIS CONSISTING OF AN ANALYSIS OF PROFESSIONAL PRACTICES

Target population:

Recruitment process:

Please provide the summary of the study and the questionnaire

6. PAGE DE SIGNATURES

« I hereby declare that I assume full responsibility for the research whose concept is described below and certify that the information provided reflects the reality taking into account the current scientific knowledge. »

Signature of the principal investigator

Date:

Last name / First name:

Signature:

☐ **In case of retrospective thesis**

Signature of Head of the service responsible of patients:

Date:

Last name / First name:

Signature:

☐ **In case of prospective thesis**

Signature of Head of the service responsible of patients:

Date:

Last name / First name:

Signature:

☐ **In case of study on Residual Human Body Material (HBM/RHBM)**

Signature of the Biobank Manager:

Date:

Last name / First name:

Signature:

☐ **Signature the promoter of the thesis**

Date:

Last name / First name:

Signature:

CEHF OPINION

Title of the experiment:

CEHF reference: …… ***(To be mentioned in all subsequent correspondence)***
Belgian registration number: B 403……
Responsible Investigator: ……

☐ **Retrospective thesis/TFE**
☐ **Prospective non interventional (observational) thesis/TFE**
☐ P**rospective interventional thesis/TFE**
☐ **Thesis consisting of an analysis of professional practices**

Saint-Luc- UCLouvain's Hospital-Faculty Ethics Committee has received and examined all the documents relating to the above-mentioned research project:

- ☐ BAC/Master thesis submission form
- ☐ Information and Consent Document (ICF/DIC)
- ☐ Summary of the experiment
- ☐ Protocol
- ☐ Questionnaire - survey
- ☐ CV of the student (First – last name …… ……)
- ☐ CV of the principal investigator (First – last name …… ……)
- ☐ Insurance certificate
- ☐ Questionnaire 1 GDPR (General Data Protection Regulation)
- ☐ Other: …….

The CEHF's opinion is

☐ ***Favourable****: the project can be initiated*

In the event of a retrospective study : Under no circumstances is contact with patients permitted

☐ ***Unfavourable****: the project cannot be initiated*

justification:

Date and signature :
Professeur J.M. MALOTEAUX
Chairman CEHF