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

**Simplified submission form to be used in the following cases:**

* **Retrospective studies**
* **Studies involving only RHBM + "label" and/or associated retrospective data**
* **Registries / data collection**
* **Study on the analysis of professional practices**

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

|  |  |  |
| --- | --- | --- |
| **Type of trial** | **Comments** | **Submission document** |
| Prospective interventional | Non-SOC treatment | Document 1  CEHF-FORM-097[[1]](#footnote-2) |
| Prospective interventional | Questionnaire or survey during a routine visit / SOC treatment | Document 1  CEHF-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) | Master  Submission form Bachelor/Master thesis  CEHF-FORM-143[[2]](#footnote-3) |
| Retrospective | Collection of data already available in patient medical dossier | Simplified Submission Form – FSS  CEHF-FORM-108[[3]](#footnote-4) |
| Residual Human Body Material (RHBM)) | + associated retrospective related data (already available) | Simplified Submission Form – FSS  CEHF-FORM-108 |
| Analysis of professional practices | Only concerns nursing staff | Simplified Submission Form – FSS  CEHF-FORM-108 |
| Creation of a databases |  | Simplified Submission Form – FSS  CEHF-FORM-108 |

* 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.
  + **Register** : Creation of a database with or without a specific research goal at the time of its creation
  + **Analysis of professional practices:** Questionnaire / survey concerning only the nursing staff and their practice.
  + **Prospective interventional study**: concerns a clinical drug trial, a study of a medical device or any other study requiring non-routine acts of treatment or follow-up.
  + **Prospective non- interventional study (observational)**: concern 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:**

* 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) :**

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. **Estimated dates**

Study start date :

Study end date :

* 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?

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
  2. Goal and specificity of the trial
* Briefly describe the goal and specificity of the experiment:

Click here to enter text

* 1. Rationale of the trial

Briefly describe the rationale:

Click here to enter text

* 1. Retrospective trial

**4.1 Data Collection**

* Period during which data were collected from patients (source data)
  + From .….. /….… /20…… to .….. /….… /20……
* Period during which the data will be analysed by the investigator
  + From .….. /….… /20…… to .….. /….… /20……

**4.2 Confidentiality and data protection**

* Is the confidentiality of study data ensured?  YES  NO

Describe the patient's pseudonymisation process*:*

Click here to enter text

**4.3 Transfer of data**

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

**4.4 Methodology and statistical methods used**

Click here to enter text

* 1. Study involving Human Body Material (secondary use of HBM/residual HBM - RHBM)

**5.1 Associated clinical data (excluding data on the RHBM label)**

No associated data

Associated retrospective data *(i.e. already available at the time of the CEHF final agreement)*

If associated prospective data *(i.e. data to be collected after CEHF agreement)*

***-> Submission via document 1***

**5.2 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

**5.3 Transfer of RHBM**

Is there a transfer of RHBM 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

* 1. CREATION OF A DATABASE / REGISTER

***This database must be submitted in advance to the Academic Desk - CTC to determine the type of study***

**6.1 Target population**

* Number of subjects foreseen:
* Minimum age: Maximum age:
* Sex :  Male  Female

Adults able to consent  Emergencies

Persons with **impaired capacity** that affect their ability to consent    Dementia

Paediatrics  Unconsciousness

Pregnant or breastfeeding women  Embryos

**6.2 Financial conditions**

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

**6.3 Transfer of data**

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

**6.4 Objectives of the database**

Gather data

Answer a specific research question

Other (please specify):

* 1. Analysis of professional practices

Target population :

Recruitment process:

*Please provide the summary of the study and the questionnaire*

* 1. signatures Page

« I declare that I take full responsibility for the experiment described above and certify that the information provided corresponds to reality, based on current knowledge. »

**Signature of the Principal Investigator**

Date:

Last name and First name:

Signature

**In case of a retrospective trial**

**Signature of the head of medical department/unit responsible for patients:**

Date:

Last name and First name:

Signature:

**In case of a study on (residual) human body material ((R)HBM)**

**Signature of the Biobank Manager:**

Date:

Last name and 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 study**

**Study on residual human body material**

**Creation of a database / register**

**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:

Simplified submission form

Information and Consent Document (DIC)

Summary of the experiment

Protocol

Questionnaire - survey

CV of the principal investigator (First – last name ………………………………… …………)

Financial conditions /transfer conditions

Questionnaire 1 GDPR (General Data Protection Regulation)

Other: …………………………………………………………………………………………………………………..

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**The CEHF's opinion is**

Favourable: the project can be initiated

Under no circumstances is contact with patients permitted once the ethics committee has given its approval

Unfavourable: the project cannot be initiated

justification:

Date and signature :

Professeur J.M. MALOTEAUX

Chairman CEHF

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)