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

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

* Retrospective studies
* Studies involving only **RHBM** + "label" and/or associated retrospective data
* Dissertations (master - bachelor) :
* Retrospectives
* Non-interventional prospectives
* Interventional prospective consisting only of non-routine questionnaires or surveys
* Only on **RHBM** + "label" and/or associated retrospective data

***Please tick the box(es) corresponding to your type of experimentat in the table on page 2***

1. Definitions
	* **Retrospective** : 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 iys approval.
	* **Prospective:** examination in the future of data that will be newly acquired.
	* **Interventional** *(in the case of studies submitted via this form)*: only questionnaire or survey, if there is an additional visit or telephone call for the questionnaire, or if the questionnaire is completed at home.
	* **Non-interventional (observational)** : observation de données de prise en charge de routine (questionnaire ou enquête lors d’une visite de routine).
	* **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 (not to be confused with memory promoter)
	* **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 or she may be the promoter of the dissertation).
	* **CEHF :** french acronym that stands for ‘*Comité d’Ethique Hospitalo-Facultaire Saint-Luc – UCLouvain*’ (Ethics Committee Saint-Luc Hospital UCLouvain)

***Please tick the box (or boxes) related to your type of experiment in the table below***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of trial** | **Comments**  | **Submission type**  | **Submission document** | **Section to be completed** |
| Prospective interventional |  | Classical | Document 1CEHF-FORM-097[[1]](#footnote-2) |  |
| [ ]  Prospective interventional | Non –routine Questionnaire or survey, as part of a master/bachelor thesis (out of PhD dissertation and end of specialization thesis) | Simplified | Simplified Submission Form - FSS | 2 (2.1, 2.2, 2.3, 2.4)6.1.1, 6.1.2, 6.1.3, 6.1.477 |
| [ ]  Prospective interventionalMedical Device |  | Classical | Document 11CEHF-FORM-097 |  |
| [ ]  Prospective non-interventional | Questionnaire or survey during a routine medical visit or standard of care treatment | Classical | Document 11CEHF-FORM-097 |  |
| [ ]  Prospective non-interventionnelleMedical Device |  | Classical | Document 11CEHF-FORM-097 |  |
| [ ]  Retrospective | Collection of data already available in patient records | Simplified | Simplified Submission Form - FSS | 2 (2.1, 2.2, 2.3, 2.4)3 ;  6.1.2; 7 |
| [ ]  Human Body Material (HBM) | Collected specifically for the trialConsidered as a prospective interventional trial | Classical | Document 11CEHF-FORM-097 |  |
| [ ]  Residual Human Body Material (RHBM)  |  + associated retrospective related data (already available) | Simplified | Simplified Submission Form - FSS | 2 (2.1, 2.2, 2.3, 2.4)3 ; 4 ; 7 |
| [ ]  Residual Human Body Material (RHBM)  | + associated prospective data | Classical | Document 11CEHF-FORM-097 |  |

1. Global Information :

**Study title:**

**Protocol number** (*optional)* :

**Acronym** (*optional)* :

**Medical Field of the clinical trial**

[ ]  Surgery [ ]  Psychiatry [ ]  Intensive care

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

[ ]  Obstetrics/Gynaecology [ ]  Clinical biology [ ]  Nursing care

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

* 1. **Goal and specificity of the trial**

Briefly describe in 10 lines maximum

Click here to enter text

* 1. **Rationale of the trial**

Briefly describe the rationale

Click here to enter text

* 1. **Sponsor** *(cfr definition page 1)*

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

[ ]  University Clinic of Saint-Luc (*CUSL*)

[ ]  Catholic University of Louvain

[ ]  Other:

* Institution:

Name:

Address:

E-mail:

Phone number:

**Commercial Clinical Trial**

Company:

Address:

Contact name:

E-mail:

Phone number:

* 1. **Confidentiality and data protection:**
* Is the confidentiality of study data ensured? [ ]  YES [ ]  NO

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

Click here to enter text

* Is he patient's anonymity guaranteed by the confidentiality of the study records and provided for in the trial protocol?

 [ ]  YES [ ]  NO

* If NO to any of the questions, how will you keep the patient's medical record confidential during the study and / or during any subsequent check-ups?
1. Retrospective trial

**Principal Investigator** (*permanent staff member if St Luc or UCLouvain study*)

Last name / First name:

Medical Unit/department:

E-mail :

Telephone :

Institution :

 **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……

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

 **Methodology**

Statistical methods used:

Click here to enter text

Don't forget to sign the document on page 10

1. Study involving Residual Human body material (RHBM)

**Principal Investigator** (*permanent staff member if St Luc or UCLouvain study*)

Last name / First name:

Medical Unit/department:

E-mail :

Telephone :

Institution :

 **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***

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

Don't forget to sign the document on page 10

1. Study involving secondary use of Human Body Material (HBM)

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

1. Master/Bachelor thesis

 *!! Do not complete the dissertation part if thesis, MACCS, intervention other than questionnaire, drugs, medical devices* ***-> submission via Document 1***

[ ]  Medicine [ ]  Nursing care [ ]  Nutrition

[ ]  Physiotherapy [ ]  Psychology [ ]  Other :

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

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

:

* 1. **Prospective thesis** *(data collection after CEHF approval)*

[ ]  **Non interventional** (including Questionnaire or survey during a routine medical visit)

If **interventional**: *Questionnaire or survey* *(if there is an additional visit or telephone call for the questionnaire, or if the questionnaire is completed at home)*

* ***submission via document 1*** *(CEHF-FORM-097)*
	+ 1. Mono - Multicentric

[ ]  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 :

* + 1. Trial location :

Click here to enter text

Clinical trial participants will be?

 [ ]  outpatient [ ]  hospitalized [ ]  mixt

* + 1. Target population

* Healthy participants [ ]  Yes [ ]  NO
* Patients [ ]  Yes [ ]  NO

If yes, which disease?

* Number of subjects foreseen:
* Minimum age : Maximum age :
* See : [ ]  Male [ ]  Female

[ ]  Adults able to consent

[ ]  Emergencies / Acute medical conditions

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

[ ]  Dementia

[ ]  Unconsciousness

[ ]  Minors

[ ]  Pregnant or breastfeeding women

[ ]  Embryos

[ ]  Other :

* + 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. Financial Compensations

Who bears the costs of the experiment? (grant, clinical account, ...)

Don't forget to sign the document on page 10

* 1. **Retrospective thesis** *(Collection of data already available at the time of the CEHF approval)*
* Place of 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……

 **Methodology**

Statistical methods used:

Click here to enter text

 Don't forget to sign the document on page 10

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 (RHBM)**

 **Signature of the Biobank Manager:**

Date:

Last name and First name:

Signature:

[ ]  **In case of a thesis,**

 **Signature of the promoter:**

Date:

Last name and First name:

Signature:

**Signature of the head of medical department/unit, for agreement and information:**

Date:

Last name and First name:

Signature:

 **CEHF OPINION**

**Please check the corresponding box(es).**

[ ]  **Retrospective study**

[ ]  **Study on residual human body material**

[ ]  **Prospective non-interventional (observational) thesis**

[ ]  Prospective **interventional thesis consisting only of a questionnaire or non-routine survey**

**Title of the experiment:**

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 Student

[ ]  CV of the principal investigator

[ ]  Certificate of no-fault insurance

[ ]  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**:**

CEHF reference: ………………………………….…………. *(to be mentioned in all subsequent correspondence)*

Belgian registration number: B 403………………………………….……

Date and signature:

Professeur J.M. MALOTEAUX

Chairman CEHF

1. CEHF-FORM-097\_Soumission - Document 1 [↑](#footnote-ref-2)