

# Submission form Bachelor/Master thesis

N° de référence : CEHF-SOP-145

[Commission d'éthique hospitalo-facultaire]

Version : 2.0

Date d'application : 01/12/2025

## 1. OBJET DE LA PROCÉDURE

The procedure describes the submission to the Ethics Committee of a clinical research project on humans performed by a student, future health professional; study performed at the **Cliniques universitaires Saint-Luc (CUSL), de l'UCLouvain** or elsewhere.

## 2. DOMAINE D'APPLICATION

This procedure is applicable to the members of the CEHF<sup>1</sup> and to the Clinical Trial Center (CTC)

## 3. DESCRIPTION

### 3.1. Responsibilities and authorities

The sponsor of a master/bachelor thesis is responsible for the student he/she supervises.

The principal investigator (also called *PI*) must be a health professional (see list in annex) and is responsible for the conduct of the study.

The sponsor of a master/bachelor thesis may be the principal investigator if he/she is a health professional.

The study sponsor in the legal sense of the term (according to the law of 7 May 2004) is a university, a college or an institution to which the student belongs and is responsible for the management and financing of the study

### 3.2. Description

Any research on the humans aiming to develop knowledge in the field of health care **as described in the Belgian law of May 7, 2004**, carried out **by a student, future health professional**, at the end of the first (BAC) or second cycle (Master) of graduate studies and carried out as part of a bachelor/master thesis **or carried out by paramedical health professionals who have already graduated and provided that they are submitted as part of a master thesis (public health, psychology, ...)**, must be submitted for approval by an Ethics Committee.

Research projects not falling within the scope of the law of May 7, 2004 and not requiring a binding favorable opinion from an ethics committee may also be submitted for ethical approval with a view to publication.

A thesis submitted to the Ethics Committee and which concerns a hospital service must have received the prior **written consent of a health professional<sup>2</sup>** (doctor, nurse, physiotherapist or

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<sup>1</sup> CEHF : Comité d'éthique hospitalo-facultaire

<sup>2</sup> List of health care professionals :

Doctors, dentists, physiotherapists, nurses, midwives, pharmacists, mental health professions and the paramedical professions (pharmacy assistants; audiology; bandaging, orthotics and prostheses; dietetic; occupational therapy; medical laboratory technology; speech therapy; eye care; podiatry; medical imagery; patient transport (excluding the transport of the persons referred to in Article 1 of the law of 8 July 1964 on emergency medical aid); oral care

other, member of the staff of the hospital institution) involved in the project, and who will supervise the study.

The bachelor/master thesis may be:

- either **monocentric** if it is carried out in a single clinical site or if it is carried out on a population outside a clinical site: the ethics committee is then designated as the "unique" Ethics Committee in Belgium;
- or **multicentric** if it is carried out simultaneously in several sites: in this case, the thesis project must be submitted simultaneously to the Ethics Committees of the various sites and the CEHF<sup>3</sup> is designated as the "main" Ethics Committee, the only one empowered to issue the single final opinion, after receiving the opinions of the other Ethics Committees concerned.

**The opinion given by the "main" Ethics Committee is unique and binding. It is a condition for the initiation of any study.**

The thesis submission procedures, simplified compared to standard procedures, vary according to **the type of research carried out:**

In the case of a study **not involving patients from Cliniques universitaires Saint-Luc** or a **prospective interventional dissertation consisting solely of non-routine surveys or questionnaires**, or in the case of a **prospective observational dissertation or a retrospective dissertation involving patients from Cliniques universitaires Saint-Luc**,

→ documents are submitted electronically to the ethics committee at the following address : [commission.ethique-saintluc@uclouvain.be](mailto:commission.ethique-saintluc@uclouvain.be)

In the case of a **prospective interventional study thesis or an RHBM<sup>4</sup> thesis involving patients from Cliniques universitaires Saint-Luc**,

→ The submission is made via the Clinical Trial Center – CTC. Information can be found on their website at the following page : <https://www.saintluc.be/en/student-dissertation>

Based on a complete file, the CEHF will analyse the application and may initially formulate a **provisional opinion** (remarks, request for amendments or request for additional information) and, finally, a **final opinion**.

This opinion will then be sent to the **PI<sup>5</sup>** of the project with a copy to the student within 28 days maximum.

Once the positive opinion of the Ethics Committee has been obtained, any **request for modification** is considered as an amendment, which must also be submitted to the Ethics Committee. Information related to the submission of an amendment is available on the website at the following page : [Comité d'Ethique - Investigations cliniques: suivi | Cliniques universitaires Saint-Luc \(saintluc.be\)](#).

From an administrative point of view, an internal CEHF reference number and a unique Belgian registration number (in the case of prospective studies) will be assigned to the project. These shall be mentioned in all correspondence.

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<sup>3</sup> CEHF : Comité d'éthique hospitalo-facultaire

<sup>4</sup> RHBM : residual human body material

<sup>5</sup> PI : principal investigator

### 3.3. Documents to be submitted to the Ethics Committee

Type of thesis	Documents to be provided
<b>Prospective interventionnal study</b> (excluding thesis relating only to questionnaires)	<ul style="list-style-type: none"> <li>• Submission form Bachelor/Master thesis CEHF-FORM-143<sup>1</sup></li> <li>• Protocol</li> <li>• Research Summary in French (1 page)</li> <li>• Informed consent Form (CEHF-FORM-129<sup>II</sup>)</li> <li>• Dated and signed CV of student</li> <li>• Dated and signed CV of PI<sup>6</sup></li> <li>• Insurance Certificat</li> <li>• Budget</li> <li>• Questionnaire 1 GDPR<sup>7</sup> (AAHRPP-FORM-082<sup>III</sup>)</li> </ul>
<b>Prospective interventionnal study</b> relating only to questionnaires or surveys	<ul style="list-style-type: none"> <li>• Submission form Bachelor/Master thesis CEHF-FORM-143</li> <li>• Protocol</li> <li>• Research Summary in French (1 page)</li> <li>• Informed consent Form (CEHF-FORM-129)</li> <li>• Questionnaire or interview guide</li> <li>• Dated and signed CV of student</li> <li>• Dated and signed CV of PI<sup>6</sup></li> <li>• Insurance Certificat</li> <li>• Budget</li> <li>• Questionnaire 1 GDPR (AAHRPP-FORM-082)</li> </ul>
Retrospective study, based on analysis of records and <b>pre-existing data</b>	<ul style="list-style-type: none"> <li>• Submission form Bachelor/Master thesis CEHF-FORM-143</li> <li>• Protocol/Research Summary</li> <li>• Dated and signed CV of student</li> <li>• Dated and signed CV of PI<sup>6</sup></li> <li>• Budget</li> <li>• Questionnaire 1 GDPR (AAHRPP-FORM-082)</li> </ul>
<b>Residual human body material</b> without data other than material identification data <sup>8</sup>	<ul style="list-style-type: none"> <li>• Submission form Bachelor/Master thesis CEHF-FORM-143</li> <li>• Protocol/Research Summary</li> <li>• Dated and signed CV of student</li> <li>• Dated and signed CV of PI<sup>6</sup></li> <li>• Budget</li> <li>• Questionnaire 1 GDPR (AAHRPP-FORM-082)</li> </ul>
Analysis of professional practices (only concerns nursing staff)	<ul style="list-style-type: none"> <li>• Submission form Bachelor/Master thesis CEHF-FORM-143</li> <li>• Protocol/Research Summary</li> <li>• Dated and signed CV of student</li> <li>• Dated and signed CV of PI<sup>6</sup></li> <li>• Budget</li> <li>• Questionnaire 1 GDPR (AAHRPP-FORM-082)</li> </ul>

<sup>6</sup> PI : principal investigator

<sup>7</sup> GDPR : General Data Protection Regulation

<sup>8</sup> RHBM : Residual human body material : the part of body material collected for donor diagnosis or treatment which, after a sufficient and relevant part has been retained to establish, perfect or complete the donor's diagnosis or treatment on the basis of new scientific data, is redundant with respect to these objectives and could therefore be discarded

- ✓ **Submission form Bachelor/Master thesis** : must be dated and signed by the PI after verification of its contents ;
- ✓ **Research Summary** : 1 to 2 pages maximum, written in French, and must include the title of the project, the objectives, the methodology, the target population (participants), the method of recruitment of participants and the measures taken to ensure the confidentiality of the data ;
- ✓ **Protocol** : the templates can be found on the website at the following page : [Comité d'Ethique - Investigation clinique: soumission initiale | Cliniques universitaires Saint-Luc \(saintluc.be\)](#) ;
- ✓ **Informed consent form** : the templates can be found on the website at the following page : [Comité d'Ethique - Investigation clinique: soumission initiale | Cliniques universitaires Saint-Luc \(saintluc.be\)](#) ;
- ✓ **Insurance certificate** : is a certificate from the sponsor's (institution's) insurance company certifying that the policy complies with the law of 7 May 2004 (no-fault insurance); it can be obtained from the insurance department of the university, college or other institution
- ✓ **Budget** : defines the financial conditions if costs are incurred

**The conformity of the version numbers and dates of the different documents must be checked by the PI<sup>9</sup> before submission**

**NB** : Ethics Committee meetings are held every Monday (except during school holidays).

#### 4. DISTRIBUTION

This procedure is broadcast public ☒  
Restricted to the unit/entity/department ☐

#### 5. RÉFÉRENCES

[CEHF-DSQ-054\\_ Liste des Lois, Arrêtés Royaux, Directives Européennes et normes de qualité en vigueur](#)

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<sup>I</sup> CEHF-FORM-143\_ Formulaire de soumission Mémoire Bac / Master - Submission form Bachelor/Master thesis

<sup>II</sup> CEHF-FORM-129\_ Format DIC : ICF - étudiants et paramédicaux - Information au patient ou participant

<sup>III</sup> AAHRPP-FORM-082\_ questionnaire 1 GDPR

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<sup>9</sup> PI : principal investigator