THE INTERNAL REGULATIONS /PROCEDURES (R.O.I.) OF THE ETHICS COMMITTEE HOSPITALO–FACULTY SAINT-LUC-UCLouvain (CEHF)

1 INTRODUCTION

The missions and procedures of the Ethics Committee (CEHF) draw inspiration from

- an unwritten tradition of our university institution which was established in 1977 under the name "Medical Ethics Commission" and followed by "UCL Hospital-Faculty Biomedical Ethics Commission" and its R.O.I. of August 21, 1997,
- as well as from the legal texts, including those contained in CEHF-DSQ-054[i].

2 MISSIONS

2.1 Generalities

Ethics Committee exercises the following missions, whether upon request or at its own initiative:

- 1° an advisory function on all experimental protocols on the human being and somatic material (MCHR[1]) and human reproductive material, discussed during the protocol analysis meeting which takes place once a week.
- 2° a mission to assist in decision-making concerning individual ethical cases (link with CADE[2]).
- 3° a mission of support and advice concerning the ethical aspects of the practice of hospital care. This is discussed during plenary meetings which take place in general, once a month and at least once a quarter behind closed doors, but also in working groups when an ethical issue requires it. A working group can also be created on the initiative of the CEHF or one of its members.
- 4° The Ethics Committee takes the initiative to reflect on any subject within its competence ("vigilance" or questioning of current practices)

➔ The request can come from any member of the hospital staff, or from UCLouvain.

➔ The opinions and advice of the CEHF are confidential and not binding, except for matters explicitly required by law. (e.g. review of human experimentation protocols). They are the subject of a reasoned report, sent exclusively to the applicant and reflecting the different points of view of its members.
The Ethics Committee may, by a reasoned decision, not respond to a request.

➔ The opinions issued by the Ethics Committee do not release the applicants from their personal responsibility vis-à-vis their patients, their work team and their institution, just as they cannot be a substitute for the applicant's personal conscience.

2.2 Review of research protocols

As part of its missions, the Ethics Committee gives ethical opinions on research protocols according to the procedures provided for this purpose by Belgian and European laws in force and according to the requirements of national (FAMHP/AFMPS) and international accreditations retained by the Cliniques Universitaires Saint-Luc et l'UCLouvain, such as Accreditation Canada (ACI) and the AAHRPP (Association for the Accreditation of Human Research Protection Program) (cf alsoi CEHF-DSQ-054[ii]).

2.3 Organization of Ethics Decision Support Units (CADE)

The Ethics Committee makes sure that some of its members are on a permanent basis available to organize a CADE. The purpose is to provide ethical information to the doctor(s) and their healthcare team who face ethical difficulties and encourage them to make a decision with regard to a patient.

[1] MCHR : matériel corporel humain résiduel. residual human body material
[2] CADE : Cellule d'Aide à la Décision Ethique

2.4 Study of general ethical questions

The purpose of studying and reflecting on ethical issues is to give a general opinion on the ethics of health care within the various institutions of the Health Care Sector, in particular the Faculty of Medicine of the UCLouvain and the Cliniques universitaires Saint-Luc.
The introduction of new diagnostic or therapeutic approaches, of communication, specific legal or social changes and the media coverage of these questions is also the subject of an appropriate reflection.
This study of ethical issues is be carried out in collaboration with the people and structures of UCLouvain, the Health Care Sector, the Faculty of Medicine and the Cliniques universitaires Saint-Luc which have particular competence in the fields of ethics and health.

3 COMPOSITION OF THE CEHF SAINT-LUC - UCLOUVAIN

3.1 Full members

The Ethics Committee has a minimum of 8 and a maximum of 15 « full », members, as required by law, members whose training varies to allow a complete and adequate analysis of the research conducted by the institution. The Ethics Committee is composed of « full members » with the right to vote and « alternate members » with a consultative voice at plenary meetings of the Committee. This includes representatives of both sexes. The number of alternate members cannot exceed the number of full members.

The Ethics Committee has at least one member who is not affiliated with the institution and who is not a family member of a person affiliated with the organization.

3.1.1 Qualification of the CEHF members

In accordance with the **Royal Decree of April 4th, 2014** establishing the measures for implementing the law of May 7, 2004 relating to experiments on the human being, concerning the Ethics Committee (Belgian Moniteur – B.M., May 16th, 2004), the Ethics Committee is composed in accordance with said law and has additionally :

> at least two nurses; a hospital pharmacist; at least one member with expertise in clinical research methodology; a philosopher or representative of the humanities, initiated or trained in medical ethics; for ethics committees which issue the single opinion for phase I trials: an expert with expertise in pharmacology, pharmacotherapy and pharmacokinetics; at least one psychologist; more than half of the members is a medical doctor; at least one general practitioner; a lawyer

In accordance with the **law of May 7th, 2017** relating to clinical trials of drugs for human use, the Ethics Committee is composed of at least:

> an expert in pharmacology, pharmacotherapy and pharmacokinetics; a member with expertise in clinical research methodology; a general practitioner ; a paediatrician; a psychologist ; two nurses; a hospital pharmacist; a philosopher or representative of the humanities, initiated or trained in medical ethics; a lawyer ; a patient representative;

In accordance with the **Royal Decree of October 9th, 2017** implementing the law of May 7, 2017 relating to clinical trials of drugs for human use, the Ethics Committee, to be approved for the evaluation of phase I trials, must have minimum the following members within or in addition to the above mentioned members:

> a member with proven clinical pharmacology expertise; a member with proven expertise in the evaluation or conduct of phase I trials; a representative of healthy volunteers, who must have participated in Phase I clinical trials.

Ultimately, the Ethics Committee must be composed of (cf also CEHF-DSQ-005[iii])

- A majority of medical doctors
- A paediatrician
- A general practitioner
- A psychologist
- Two nurses
- A hospital pharmacist
- An expert with expertise in pharmacology, pharmacotherapy and pharmacokinetics
- A member with expertise in clinical research methodology
- A philosopher or representative of the humanities initiated or trained in medical ethics
- A lawyer
- A patient representative, or, if applicable, his deputy
- An expert with proven expertise in clinical pharmacology (for the evaluation of Phase I clinical trials)
- A member with proven expertise in the evaluation or conduct of Phase I trials (for the evaluation of Phase I clinical trials)
- A healthy volunteer who has participated in at least two clinical studies (for the evaluation of CTR protocols of Phase I on healthy volunteers). The latter cannot be a healthcare professional and cannot participate as a participant in clinical trials evaluated by the Ethics Committee of which he is a member

3.1.2 Nomination / Designation procedure

The selection of candidates is carried out as follows:

- Full members who are medical doctors are proposed among the permanent members of the Cliniques Universitaires Saint-Luc or the Faculty of Medicine of UCLouvain;
- The medical doctors of the Clinics are proposed by the Medical Director of the Clinics with the approval of the Medical Council;
- Doctors representing the Faculty of Medicine are proposed by the Vice-Rector of the Health Sciences Sector or the Dean of the Faculty of Medicine;
- The hospital pharmacist is proposed by the Management of the Pharmacy Department;
- The members of the Nursing Staff are proposed by the Management of the Nursing Department after consultation with the Nursing Council;
- The patient representative is, if necessary, proposed by a federation of patient representative organizations; he may also be chosen from the motivated applications demonstrating the representativeness of the candidate; he shall not be a healthcare professional within the meaning of the law relating to the exercise of healthcare professions, coordinated on May 10, 2015;

Applications are sent to the Chair of CEHF, who ensures the next part of the procedure.
The Chair and Vice-Chair are elected from among the full members of the CEHF. This is validated in plenary meeting.

3.2 Alternate members

In addition to the full members, the number and qualifications are fixed by law, the Ethics Committee may be composed of "alternate" members, the number of invited members may not exceed the number of full members.

They are chosen by the Chair of the CEHF, after consultation with other full members, in view of their expertise and the contribution they can make with regard of their specialty to the CEHF as an expert, whether in the medical field or in other field.

The Alternate members work at the CEHF as consultants, based on their scientific and/or medical and/or institutional expertise for members who are not specifically caregivers but who have a transverse implication in the institution.

They are not considered as deputy members and therefore cannot replace full members.

3.3 Non-member Experts / Consultants

An expert / consultant who is not a member can be consulted for a specific evaluation in a specific area (cf. CEHF-SOP-017 § 3.4[iv]) provided that:

- None of the CEHF member has this expertise
- The confidentiality agreement Form CEHF-FORM-052_Engagement de confidentialité[v] is signed
- The declaration of absence of conflict of interest form (CEHF-FORM-032[vi] ; see CEHF-SOP-031[vii]) is signed
- A signed and dated CV is received by us.

When the expert/consultant is invited as part of the protocol analysis, he may attend the protocol review meeting to present his analysis and comments, but he can and shall not vote.

Experts/consultants may also be invited to give their opinion to the working groups which may be set up by the CEHF in order to prepare an opinion or give advice within their area of expertise.

Non-member experts/consultants are called upon for advisory purposes only.

3.4 Incompatibilities

In accordance with the law of May 7th, 2017 relating to clinical trials of drugs for human use, membership in an Ethics Committee is incompatible with the following functions:

- Hospital director;
- Medical director;
- Chair of the Medical Council of a hospital;
- Head of the nursing department of a hospital;
- Manager, member of management, managing director or member of the board of directors of a marketing authorization holder within the meaning of article 6 § 1 of the law of March 25th, 1964 on medicinal products, of a manufacturing authorization holder, within the meaning of article 12bis of the same law or of a wholesale distribution authorization holder, within the meaning of article 12ter of the same law.

In accordance with the Royal Decree of October 9, 2017 implementing the law of May 7th, 2017 relating to clinical trials of drugs for human use (B.M., November 10th, 2017), the representative of healthy volunteers cannot:

- be a healthcare professional within the meaning of the law relating to the exercise of healthcare professions, coordinated on May 10th, 2015;
- participate as a participant in clinical trials evaluated by the Ethics Committee of which he is a member.

3.5 Requirements and training

3.5.1 CEHF members complete and sign at the start of each mandate and at each renewal of their mandate:

- A conflict of interest declaration form (CEHF-SOP-031)[viii]
- A confidentiality agreement (CEHF-FORM-052)[ix]
- A functional description (CEHF-FORM-116)[x]
- A curriculum vitae (CV) up to date
- The training Plan (CEHF-FORM-137)[xi]

The CEHF member who participates, in any capacity, in a submitted protocol may not sit on the Ethics committee during the protocol review or in the decision. He may however be heard as an investigator if the CEHF deems it necessary.

3.5.2 Good Clinical Practices (BPC/GCP) training : A BPC / GCP certificate is required for investigators and their research teams at the Cliniques Universitaires Saint-Luc. It is also required for the CEHF members involved in protocol analysis. The certificate shall be renewed every 3 years and be provided to the CEHF secretariat.

3.5.3 Members: The CEHF encourages continuing education in the area of ethics for the members. Medical doctors attend every year accredited meetings in ethics (legal requirement to be an "INAMI accredited" medical doctor). Various training courses are organized by the Cliniques universitaires Saint-Luc and CEHF members are invited to participate in these training courses. The list of training courses taken during the year will be provided to the CEHF secretariat at the time of the annual evaluation of the members. On this occasion, the CEHF members can also express their desire to follow a training in a specific discipline.

3.5.4 A yearly review is performed to make sure all CEHF member documents are up to date (conflict of interest, GCP certificate, CV, …)

3.5.5 New members: Basic training in ethics is an asset and should be encouraged. New members must send their dated and signed CV to the CEHF secretariat to document their qualifications.

If new members wish to participate in the analysis of clinical research protocols, they will be trained by more experienced members. The first protocols will be analysed in tandem and new members are invited to participate in the protocol review meetings as part of their training in this particular context.

3.5.6 At the time of the annual evaluation (CEHF-SOP-10[xii]), the Chair and/or Vice-Chair will ask CEHF members for their opinion on the training courses they have taken or would like to take. If the Chair and/or Vice-Chair consider that the CEHF member does not meet the requirements in terms of continuing education, he will be notified at the time of his annual evaluation. The CEHF member must then follow the necessary training sessions during the year. This will be assessed at the time of the next evaluation. If the CEHF member has not been able to follow the required training or if a problem is identified, CEHF members will meet to discuss this particular situation and the Chair will send a letter to the member concerned, specifying the actions taken or to be taken.

4 PROCESS OF WORKING

4.1 The duration of the members' mandate

The duration of the mandate is four years and is renewable. If a member of the CEHF wishes to resign from his position during his term of office, he informs the Ethics Committee, which is responsible for taking note of the request, recording it and informing the other members of the Ethics Committee.

4.2 The Bureau.

The Bureau is composed of the chair or a vice-chair and a scientific coordinator (CEHF-DSQ-005[xiii]).
The role of the Bureau is to ensure, under the aegis of the Chair, the general good functioning of the CEHF and the execution of the tasks entrusted by the CEHF.
The Bureau also assesses files subject to an « accelerated procedure ».
This accelerated protocol review procedure concerns retrospective studies and a few other protocols that obviously do not pose any risk to humans, such as certain questionnaires or surveys. In case of questioning or a negative opinion, the protocol is automatically submitted to the usual procedure, before the investigator is informed of any decision.

4.3 Meetings.

There are three types of meetings:

- plenary meetings
- protocol review meetings
- and ad hoc meetings for CADEs[3].
  (see also CEHF-SOP-015[xiv])

4.3.1 Quorum for plenary and protocol meetings

The Ethics Committee validly deliberates when:

- the number of members present is greater than half the number of effective members;
- both professional healthcare members within the meaning of the law for healthcare professions coordinated on May 10th, 2015, including at least two medical doctors, and members who do not have this quality are present; and
- the patient representative, or, where appropriate, his deputy

When the Ethics Committee is called upon to give an opinion on a phase I clinical trial on healthy volunteers, it only deliberates validly when, in addition to the above-mentioned members, the following members are also present:

- a member with proven expertise in clinical pharmacology;
- a member with proven expertise in the evaluation or conduct of phase I trials;
- and a representative of healthy volunteers.

Opinions are issued by consensus or, failing that, by a majority of the votes of the members present. In the event of parity of votes, the chair's vote is decisive.

[3] CADE : Cellule d'Aide à la Décision Ethique

- The member who cannot be present at the CEHF meeting but who has submitted his report or opinion in writing to the secretariat before the meeting is counted in the attendance and voting quorums (in accordance with the AR dated 09/10/2017, see also CEHF-SOP-019[xv]).
- When the attendance quorum is not reached, the meeting is generally postponed and a new meeting is scheduled.
- Exceptionally, the study could still be evaluated, and the justification will be documented on the study voting sheet as well as in the attendance list and the actions to be taken to accept the voting will be described in the minutes.
- When the quorum is not reached, the Ethics Committee may also decide to use a written procedure in order to give an opinion. The Chair fixes, in this case, the deadline within which the members must give their opinion.

The above-mentioned points of Quorum and vote are mainly applicable for protocol meetings, during which clinical study protocols are evaluated, and opinions are given.

During plenary meetings, it is extremely rare that votes are taking place. If this is nevertheless necessary, the following quorum applies: a number of members greater than half of the number of effective members must be present. Which means at least 8 members. Voting is then by majority. In the event of a parity of votes, the one of the president is preponderant.

4.3.2 Plenary meeting

- The CEHF meets in plenary session, in general, once a month and at least once a quarter, behind closed doors, according to the calendar established at the end of the academic year.
- The invitation together with the agenda and its appendices is sent in due time.
- At plenary meetings, opinions can be discussed, drafted and voted according to the quorum described above.
- Members are invited to participate regularly to the scheduled meetings. The members will not participate in decisions on subjects or projects for which a conflict of interest could arise on their behalf.
- The decisions are recorded in the minutes drawn up by the secretary of the meeting, and submitted for approval to all the members at the next meeting. In the absence of a decision by consensus, the minutes will mention the result of the votes as well as any minority scores (cfr CEHF-SOP-019 [xvi]). The minutes are kept at the CEHF headquarters.

The study of ethical issues/questions

- When studying these questions, the CEHF may also call upon, in an advisory capacity, experts in the various fields of medicine, nursing, biomedical ethics or the humanities concerned. Working groups or expert groups can be set up to prepare an opinion.

4.3.3 Protocol meetings

- The CEHF generally meets once a week to discuss the Study Protocols together. Amendments and the safety review are also discussed. (cf CEHF-SOP-019[xvii])
- The CEHF provides investigators with the documents to give them an opinion based on compliance with the criteria and deadlines set by law.
- The administrative secretariat provides members with a list of projects submitted to CEHF.
- All members are invited to regularly participate in the analysis of the protocols according to their experience and expertise.
- The review of paediatric protocols (minor participants) must be done by paediatricians.
- The review of protocols with a general practitioner as principal investigator should preferably be reviewed by a general practitioner.
- The dossiers and annexed documents are made available electronically to the CEHF members via a dedicated platform located on a secure server belonging to UCLouvain (Sharepoint).
- The final opinion is given by the CEHF (cf also CEHF-SOP-020[xviii]). During the meeting, discussions and comments are noted for each protocol and a vote on the conclusion of the discussion is held. The conclusion of the discussion can be accepted, refused or a review can be requested. Abstention is also possible. After the exchange necessary to obtain a consensus, a provisional or final opinion is provided to the investigator explaining this.
- Any investigator can be called in to explain his project. Similarly, he can request to be heard, in any case if a negative opinion is given.
- The opinions are transmitted to the investigators according to legal regulations. The CEHF opinions are binding. The final opinions are therefore only written when the investigator has replied to all the observations made by the CEHF. Without a final approval, the study cannot be initiated.
- A copy of the final opinions is sent to the Chair of the FAMHP/AFMPS for drug studies by mail.
- Any specific request to UCLouvain which does not fall within the missions or competences of the CEHF or of another ethics committee to whom it can be redirected, will be addressed to the Research Council of UCLouvain (requested by the UCLouvain Academic Council).

Particular Case 1 : CTR (Clinical Trial Regulation) studies (Belgian law of May 07th, 2017)

The CEHF obtained specific FAMHP accreditation to evaluate studies under the law of May 07th, 2017 (CTR[4]), including Phase I studies (Cf also CEHF-SOP-017 and CEHF-SOP-020 [xix]).

Each study is analysed by the FAMHP/AFMPS[5] and a unique Evaluating Ethics Committee in Belgium, which is independent of the participating centers. The CEHF is therefore evaluating the CTR studies that will take place in centers other than ours. On the other hand, CTR studies taking place in our center are evaluated by other Ethics Committees independent of the CEHF, but these Ethics Committees also hold the specific FAMHP accreditation required for the evaluation of this type of study. (This concerns the initial submissions as well as the amendments and the "safety review").

These 2 entities (FAMHP and the evaluating Ethics Committee) must give their agreement so that the study can start. If there is a refusal by one of these two entities, the CTR study cannot start.

Since January 31, 2022, the reception of the applications is obligatorily done via CTIS (Clinical Trials Information System) by the FAMHP (unique desk for Belgium). After confirmation that the file is complete, the documents are sent by the CT College via the CTIS system to the CEHF.

- The studies are evaluated by the different European countries and our country is either RMS (Reporting Member State) or CMS (Concerned Member State). The RMS is the country, which coordinates the actions with the CMSs, and which is responsible for the statistical analysis.
- If the file is complete, it is sent by the CTIS system for evaluation by the designated Ethics Committee.

  The evaluation of these types of studies is done during protocol meetings (cfr §4.3.3).
- The CEHF must then submit in due time the "assessment reports Part I & Part II" in CTIS, including the considerations formulated.
- After receipt of the sponsor's answers, the CEHF must examine the answers to the questions, and provide the final opinion on the study (see also CEHF-SOP-020), also in CTIS.

Particular Case 2 : MDR/IVDR Studies - MDR (Medical Device Regulation) / IVDR (In Vitro Diagnostics Regulation) : (Belgian law of December 22d, 2020)

The analysis of the MDR (applicable since 05/26/2021) and IVDR (applicable since 05/26/2022) studies is done in a similar way as for the CTR. Nevertheless, these studies are submitted via a specific Sharepoint, as the "Eudamed" system is not yet functional.
There are "assessment reports Part I and Part II" specific to the MDR/IVDR, which are different from the CTR.

[4] CTR : Clinical Trial Regulation
[5] FAMHP/AFMPS : Federal Agency for Medicines and Health Products / Agence fédérale de médicaments et des produits de santé

4.3.4 Meetings for Ethical Decision Support Units (CADE)

- These meetings take place punctually, in order to respond to the CADE's requests. They can be organized within 24 to 48 hours following the request
- Some of the CEHF members are at all times availability for organising a CADE[6]. The purpose of this is to provide an ethical clarification to the medical doctor (s) and their healthcare team facing ethical difficulties and led to taking a decision with regard to a patient.
- CADE in principle includes at least one medical doctor, who chairs it, and another member of the CEHF.
- The informed opinion is based on a meeting, a common reflection and if needed the collection of the expert opinions. It constitutes a non-binding opinion on the ethical aspect of the question asked and on the compliance with legal requirements. The final decision is the responsibility of the physician requesting the CADE meeting. A report is written by a scientific coordinator present at the meeting. It is submitted to the applicant for approval and inserted in the patient's medical file, according to the medical doctor's judgment.
- The CEHF will transmit in its annual report to the national competent authorities the frequency of consultation, the list of areas concerned and general reflections on the aid provided, via CCB encoding done (Belgian Bioethics Advisory Committee).

4.4 Regulatory aspects

Regulatory aspects (Belgian laws mentioned on CEHF-DSQ-054[xx])

- Deadlines for analysing requests and protocols (according to the Belgian Law of May 7th, 2004):
    - mono-centric phase I: a maximum delay of 15 calendar days,
    - for phase II to IV : a period of 28 calendar days. This period can be extended to 30 days in the case of trials with gene therapy products, somatic cell therapy or drugs containing genetically modified organisms. The extension may extend to 90 days if the Biosafety Council must be consulted.

To obtain full accreditation (Principal Ethics Committee), the CEHF respects the following conditions:

- The CEHF has an internal quality system

- The CEHF manages and records the conflicts of interest of its members.

- The CEHF analyses each year:

    - at least 25 multicentric protocols as the principal Ethics Committee

or

    - at least 40 multicentric protocols as the main or local Ethics Committee.

- Particular case 1 : CTR studies:
  The analysis times are governed by European regulation 2014-536 and by the Belgian law of May 07, 2017, relating to clinical trials of medicinal products for human use.

- Particular case 2 : MDR studies:
  Depending on the type of medical device, three different file analysis flows exist, and the respective deadlines are governed by European regulation 2017-745 and the Belgian law of December 22, 2020 relating to medical devices.

[6] CADE : Cellules d'Aide à la Décision Ethique

- Particular case 3: IVDR studies:
  Depending on the type of in vitro diagnostic medical device, three different file analysis flows exist, and the respective deadlines are governed by European regulation 2017-746 and the Belgian law of June 15, 2022, relating to in vitro diagnostic medical devices.

5 RESOURCES AVAILABLE TO THE ETHICS COMMITTEE

5.1 Carrying out the missions

Carrying out the missions of the Ethics Committee as required by law with regard to the examination of research projects or requests for opinions by authorities and staff of the Cliniques universitaires Saint-Luc involves the organisation of an administrative secretariat, a scientific coordination, IT logistics and adequate and sufficient premises.

5.2 The staff

Staff members:

Administrative secretaries and scientific coordinators who

- Have the specific tasks of monitoring procedures relating to experimentation on the human beings, to the ethical decision support cells and to opinions on general questions. (see also CEHF-SOP-017[xxi])
- Prepare the research projects dossiers, ensure the contact with universities and federal public services, as well as the specific follow-up of re-submissions and amendments and other necessary tasks such as, for example, keeping the CEHF website up to date.
- Prepare the invoices for services to the pharmaceutical industry who apply for an opinion on research protocols according to ministerial specifications, (see also CEHF-SOP-038[xxii])
- Prepare the Ethics Committee's reports, for the Belgian Bioethics Advisory Committee (CCB) and for the authorities of Cliniques universitaires Saint-Luc and UCLouvain.
- Assure the archiving for a legally binding period of 25 years. (see also CEHF-SOP-034[xxiii])

5.3 Premises and equipment

The premises are made available to the CEHF include

- the staff offices (administrative secretariat and scientific coordination),
- an office for the chair, the vice-chairs and/or the secretary,
- a meeting room.

Communication equipment, computer hardware and software and copying equipment must be kept up to date.

5.4 Confidentiality

CEHF members and administrative staff are subject to professional secrecy and must respect the confidentiality of all information communicated to them. When they start their mandate or renew their mandate, they all sign CEHF-FORM-052_Engagement de confidentialité.[xxiv] The signed documents are saved in digital format in the personal file of the CEHF member.

Any external expert invited to give an opinion to the CEHF on a particular research project must in the same way, respect the confidential nature of the information and must also sign the Confidentiality agreement which will be saved in digital format in the computers of the CEHF.
Exceptionally, and for the sole purpose of enriching ethical reflection and responding to our university teaching mission, a student in the health field may participate in a CEHF meeting, upon written and motivated request from him/her, after having been expressly authorized by the President. The President's decision is discretionary. This student must respect the confidential nature of the information and must also sign the Confidentiality agreement, as well as a conflict-of-interest declaration document. Those both signed documents are saved in digital format in the computers of the CEHF.

In order for the deliberations and conclusions of the CEHF to remain confidential, they take place behind closed doors in the presence of only the members (full members and/or where applicable invited members) to the exclusion of any other person (expert, student, etc.).

Failure to respect confidentiality is considered a serious breach and may result in the suspension or exclusion of this member of CEHF (cfr CEHF-SOP-010_Evaluation annuelle des membres du CEHF[xxv]). At first, there is an oral reminder is given by the Chair to the member. In the event of a new fact, within the purview of the CEHF, the member will be notified in writing of his exclusion.

The archives (paper and electronic) are confidential. Access or consulting these archives is restricted to CEHF members and for auditors in the presence of a CEHF member, if applicable. To give access to non-members, the Chair and/or a Vice-Chair must give his agreement in writing to an administrative secretary. (cf CEHF-SOP-034_Archivage des dossiers du CEHF[xxvi])

5.5 Funding of the Ethics Committee

The funding of the CEHF is defined by the Belgian law of May 7 , 2004 relating to experiments on the human beings, as well as in accordance with the Belgian law of May 7 , 2017 relating to clinical trials of medicinal products for human use, the Belgian law of December 22 , 2020 relating to medical devices and the law of June 15, 2022 relating to the in vitro diagnostic medical devices.

A faculty account and a hospital account are opened for this purpose in the name of the CEHF.

6 QUALITY SYSTEM

6.1 Quality Management

6.1.1 Document Management

The procedures, forms and other documents of the quality system SyGeDoc[7] are written according to procedure CEHF-SOP-053_ Gestion des Documents du Système Qualité - CEHF[xxvii].

The SyGeDoc includes all the documents and procedures related to the CEHF.

6.1.2 Elements of the Quality System

The main elements of the quality system are:

- Control of the organisation: organisational chart, functions, responsibilities
- Control of competencies: evaluations, training
- Control of data and records: integrity, confidentiality, conservation, sustainability
- Control of the quality system
- Control of installations (included but not limited to: document storage, security, fire protection, long-term archiving)
- Availability, knowledge and application of written procedures
- Complaint management
- Internal Audits

6.2 Evaluation of the quality system

6.2.1 Internal Audits

The audits are planned and carried out periodically as described in procedure CEHF-SOP-014_Audit du CEHF[xxviii], performed by the CEHF quality assurance manager.
The results of the audits are documented in an audit report. The personnel concerned define the corrective and preventive action plans and implements them. The state of progress of the audit program, the corresponding actions, and their effectiveness are evaluated.

6.2.2 External Audits and Inspections

The 'logistics' of the external audit or the inspection by the Authorities (FAMHP,AFMPS[8], AHHRPP[9], etc.) are carried out by the Chair of the CEHF or his delegate together with the quality assurance manager of the CEHF.

- A confidentiality agreement is signed[xxix] before the opening meeting of the external audit/inspection.
- The external auditor//inspector (s) explain (s) the objectives of the audit
- The Chairof the CEHF or his delegate describes the organisational chart and the activities linked to the application field of audit as well as the practical organisation of the audit.

[7] SyGeDoc : système de gestion de documents
[8] FAMHP/AFMPS: Federal Agency for Medicines and Health Products / Agence Fédérale des Médicaments et des Produits de Santé
[9] AHHRPP: The Association for the Accreditation of Human Research Protection Programs

- Internal and external audit/inspection reports and their content will not be shown or distributed except by an explicit request by the auditor (s)/inspector (s).

The quality assurance manager compiles all the remarks made during the audit but not necessarily repeated during the closing meeting, in order to have a list of all the remarks which will be discussed later with the persons concerned. The external audit/inspection report is communicated to the persons concerned by the Chair of the CEHF or his delegate or the quality assurance manager. Corrective actions are defined and approved by the persons concerned before the Chair of the CEHF or his delegate or the quality assurance manager sends them to the auditor/inspector within the predefined time limits.

All documentation relating to the external audit/inspection is transferred to the external audit/inspection file.

6.2.3 Complaint Management

Complaints will be inventoried electronically by the CEHF. Each written complaint will be answered and will be managed CEHF-SOP-090_Gestion des plaintes[xxx].

6.2.4 Improvement of the quality system

Improvements made to the quality system have their origins in staff suggestions and in the initiatives of the Chair of CEHF. Corrective and preventive actions implemented to respond to audit (internal and external) and inspection findings also contribute to a gradually improvement of the efficiency of the quality system.

Références :

[i] CEHF-DSQ-054_Liste des Lois, Arrêtés Royaux, Directives Européennes et normes de qualité en vigueur
[ii] CEHF-DSQ-054_Liste des Lois, Arrêtés Royaux, Directives Européennes et normes de qualité en vigueur
[iii] CEHF-DSQ-005_Description fonctionnement CEHF
[iv] CEHF-SOP-017_Gestion administrative des dossiers de recherche
[v] CEHF-FORM-052_Engagement de confidentialité
[vi] CEHF-FORM-032_Formulaire conflit d'intérêt
[vii] CEHF-SOP-031_Conflit d'intérêt CEHF
[viii] CEHF-SOP-031_Conflit d'intérêt CEHF
[ix] CEHF-FORM-052_Document d'engagement de confidentialité
[x] CEHF-FORM-116_Description de fonction – Membre CEHF
[xi] CEHF-FORM-137_Plan de formation – Formation experts
[xii] CEHF-SOP-010_Evaluation annuelle des membres du CEHF
[xiii] CEHF-DSQ-005_Description fonctionnement CEHF
[xiv] CEHF-SOP-015_Organisation des réunions du CEHF
[xv] CEHF-SOP-019_Conduite des réunions d'examen des protocoles du CEHF
[xvi] CEHF-SOP-019_Conduite des réunions d'examen des protocoles du CEHF
[xvii] CEHF-SOP-019_Conduite des réunions d'examen des protocoles du CEHF
[xviii] CEHF-SOP-020_ Examen des protocoles et amendements par le CEHF
[xix] CEHF-SOP-017_Gestion administrative des dossiers de recherche, CEHF-SOP-020_ Examen des protocoles et amendements par le CEHF
[xx] CEHF-DSQ-054_Liste des Lois, Arrêtés Royaux, Directives Européennes et normes de qualité en vigueur
[xxi] CEHF-SOP-017_Gestion administrative des dossiers de recherche
[xxii] CEHF-SOP-038_Facturation des études par le CEHF
[xxiii] CEHF-SOP-034_Archivage des dossiers du CEHF
[xxiv] CEHF-FORM-052_Engagement de confidentialité
[xxv] CEHF-SOP-010_Evaluation annuelle des membres du CEHF
[xxvi] CEHF-SOP-034_ Archivage des dossiers du CEHF
[xxvii] CEHF-SOP-053_Gestion des Documents du Système Qualité - CEHF
[xxviii] CEHF-SOP-014_Audit du CEHF
[xxix] CEHF-FORM-052_Engagement de Confidentialité - CEHF
[xxx] CEHF-SOP-090_Gestion des plaintes