Follow-up - Annual report submission procedure

N° de référence :	CEHF-SOP-126
Commission d'éthique hospitalo-facultaire	**Version :** 3.0
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1. OBJET DE LA PROCÉDURE

This procedure describes the submission of an annual report to the Ethics Committee (CEHF) by an investigator and a sponsor of an INTERVENTIONAL PROSPECTIVE EXPERIMENTATION.
Clinical trials with drug taking place on CUSL patients are governed by the authorities under European Regulation 2014-536_Clinical Trials-CTR

2. DOMAINE D'APPLICATION

This procedure is applicable to investigators et sponsors of an INTERVENTIONAL PROSPECTIVE EXPERIMENTATION and to the members of the CEHF[1].

3. DESCRIPTION

3.1. Responsibilities and authorities

3.1.1. *Responsibilities of the commercial or non-commercial sponsor of a clinical drug trial*

- Continuously assessment of the benefit / risk ratio of the experiment.
- Inform the investigator of any new element that may influence the safety of participants during or after the end of the experiment.

3.1.2. *Responsibilities of the investigator of any prospective interventional experimentation*

- Send the annual report form of the experiment to the CEHF (whether local or principal committee) before the annual evaluation date of the protocol determined by the CEHF. This form is prepared, signed and submitted by the investigator to the CEHF
- Provide explanations to the CEHF as required.
- Stop all research-related activities if the CEHF requires so.
- Inform the promoter of the decision issued by the CEHF.
- Inform the participant of any new element that may influence his safety during or after the end of the experiment.

[1] CEHF : Comité d'éthique hospitalo-facultaire

3.1.3. Responsibilities of the CEHF[2]

- Have the authority to stop an experiment carried out at the CUSLs when the evaluation of the benefit / risk balance becomes unfavourable.
- Have the authority to temporarily stop an experiment carried out at the CUSLs when the annual report is not provided within the time limits.
- Provide a renewal of the favourable opinion to the investigator to allow him to continue the clinical research.

3.2.Preamble

3.2.1. Duration of the Ethics Committee agreement

The agreement of the principal ethics committee is valid for the entire duration of the experiment. The date of approval corresponds to the date on which all the conditions for granting the agreement were fulfilled.

- However, with regard to **prospective interventional** experiments (excluding dissertations/BAC/Master), the sustainability of the agreement depends on the evaluation of the annual report provided by the investigator to the CEHF.
- The CEHF may request that the investigator sends a monitoring report at a higher frequency. The types of research projects subject to such a requirement are those which present an increased risk to the participants (i.e., certain protocols with innovative therapies or certain specific medical devices). This more frequent request for review is made by the CEHF on a case-by-case basis after discussion during the initial evaluation of the protocol. This will be clearly notified to the investigator in the initial opinion letter.
- The CEHF agreement is valid for the entire study without any conditions whatsoever for retrospective or prospective non-interventional studies (involving no more than the minimum risk).

3.2.2. Annual report submission date

The annual evaluation date corresponds to one year (365 calendar days) after the approval of the protocol by the Ethics Committee or by the Ethics Committee responsible for issuing the single opinion in the case of multicentre studies.

Eleven and twelve months after the CEP agreement date, an email will be automatically generated and sent to the principal investigator and to the principal CRCM[3] to remind them of the sending of this annual report.

The review of the annual report by the CEHF must be carried out within 365+ maximum 60 days (= 14 months) following the initial or previous agreement. The extension of the agreement therefore begins the day after that date. The annual report must therefore reach the CEHF a maximum of 15 days before the end of this 365 + 60 day period (= 14 months) in order to allow the CEHF to assess the information received within the set deadlines.

[2] CEHF : Comité d'éthique hospitalo-facultaire
[3] CRCM = COORDINATEUR DE RECHERCHE CLINIQUE MEDICALE

3.3. Documents to be submitted by the investigator to the ethics committee of the CUSL

3.3.1. *The annuel report template*

The principal investigator will complete and sign the annual report template (CEHF-FORM-110[I]) in all cases even if another document is provided by the sponsor.

3.4. Evaluation by the Ethics Committee

3.4.1. *Annual report received before the annual evaluation date (within the prescribed deadline: 365 + 45 days))*

3.4.1.1. After *receipt by the CEHF* and analysis of the annual report during the protocol analysis meeting, if no objection is made regarding the continuation of the study, the investigator will be informed by mail that he can continue the experiment. The investigator will forward this notice to the sponsor.

3.4.1.2. Otherwise, the CEHF will send a letter to the principal investigator asking him to provide the necessary details. The investigator is required to answer these questions.

3.4.1.3. If the CEHF considers that the conditions of the agreement are no longer fulfilled, a temporary cessation of recruitment or an early termination of the study may be required.

- The investigator will be notified by letter and will immediately inform the sponsor. The investigator always has the opportunity to respond in person or by mail.
- The CEHF informs the Medical Director and CEO of the CTC[4], he Belgian authorities, the PEC/CEP and the FDA if applicable. In addition, the letters are also available (depending on authorized access) in the Claire database.

3.4.2. *Annual report not received within 365 + 45 days*

- If the CEHF does not receive the annual report within the required deadlines:
  - an email will be sent by the CEHF to the principal investigator informing him that the study will be placed on the agenda of the CEHF meeting held 14 days later.

3.4.3. *Annual report received after the annual evaluation date (365 + 60 days)*

- If the annual evaluation date is reached before the CEHF agreement is reviewed and approved:
  - No further inclusion of participants can be made at the CUSLs until the extension of the agreement has been obtained.
  - All research activities related to this protocol must be stopped.
  - All interventions on participants during the study must be stopped, unless the CEHF considers that ethical or safety considerations imply that it is in the interest of the participants to continue their participation in the study. In this case, the investigator will also justify the ethical and safety reasons to the

[4] CTC : Clinical Trial Centre

CEHF. Therefore, participants during the study will be guaranteed to be kept in the experiment until they withdraw from the study.

- The investigator will be informed by mail and will inform the sponsor immediately.
- The CEHF informs the Medical Director and CEO of the CTC[5], he Belgian authorities, the PEC/CEP and the FDA if applicable. In addition, the letters are also available (depending on authorized access) in the Claire database.

4. DISTRIBUTION

This procedure has to be diffused

Publicly	☒
Restricted to unit/entity/departement	☐

5. RÉFÉRENCES

AAHRPP\DOMAIN 2 : INSTITUTIONAL REVIEW BOARD OR ETHICS COMMITTEE\Standard II-2: The IRB or EC evaluates each research protocol or plan to ensure the protection of participants.\Element II.2.D. The IRB or Ethics Committee has and follows written policies and procedures to conduct reviews by the convened IRB or Ethics Committee. 1. Element II.2.D.1. â€“ Initial review 2. Ele...

ICH GCP 1996 –Directives 2001/20/CE et 2001/83/CE – Loi relative aux expérimentations sur la personne humaine 7/5/2004

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/09/WC500097061.pdf

http://ec.europa.eu/health/files/eudralex/vol-10/2011_c172_01/2011_c172_01_en.pdf

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf

http://www.fagg-afmps.be/fr/humain/medicaments/medicaments_a_base_de_plantes/recherche_developpement/essais_cliniques/ : Circular 586

http://www.fagg-afmps.be/fr/binaries/Circulaire-593-2012-12_tcm291-208387.pdf

[I] CEHF-FORM-110_Suivi - Template rapport annuel

[5] CTC : Clinical Trial Centre