Procédure for the end of trial notification

Commission d'éthique hospitalo-facultaire	**N° de référence :** CEHF-SOP-111
	Version : 1.0
	Date d'application : 03/09/2019

1. OBJET DE LA PROCÉDURE

The objective of this procedure is to determine the end of approval of a clinical experiment and to specify the modalities to inform the Ethics Committee, the institution, the investigator and the competent authorities.

2. DOMAINE D'APPLICATION

All persons involved in clinical research.

3. DESCRIPTION

3.1. Responsabilities and Authorities

- The **CEHF**[1] **administrative secretary** is in charge of encoding the date of end of experiment in the CEHF database. The information is provided by the sponsor of the experiment or the investigator at time of initial submission. If no amendment has been submitted requesting for prolongation of the experiment, the date of end of experiment will be the one mentioned in the initial submission package.
- The **sponsor** of an experiment is responsible to inform the LEC[2] of the end of study, suspension, early termination or temporary halt.
- The **investigator** of an experiment is responsible to transmit the documents provided by the sponsor to the CEHF in case of end of study, suspension, early termination or temporary halt. He/she is responsible the record these events in the database Claire. He/is also responsible to ensure the participants 'safety.
- **Validity of the positive opinion:** the positive opinion of the LEC is applicable for the declared duration of the experiment, as defined at time of submission of the research project to the Ethics Committee. The approval is therefore applicable from approval date to the presumed termination of the experiment as mentioned in Document 1. However, the renewal of the validity of the approval depends on the continuing review of the CEHF and of the analysis of the annual report, provided by the investigator each year after the date of the initial approval.

Please Note:
Should any inconsistency or discrepancy occur between the French and the English version of this document, the French version shall prevail.

[1] CEHF : Comité d'Ethique Hospitalo-facultaire
[2] LEC : leading Ethics Committee

3.2.End of experiment

3.2.1. *Information of the EC for each clinical research*

- The **sponsor** informs the EC (the competent EC for monocenter study, and the leading EC for multicenter study) by **mail/email** within **90 days** after the end of the experiment.
    - The 90 days timing is shortened to 15 days when the end of experiment must be anticipated. Notifications will detail clearly the reasons of anticipated stop.
    - A report (http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E3/E3_Guideline.pdf) of end of experiment must be sent within the year following the notification of end of experiment for non-paediatric clinical trials. For paediatric clinical trials, the timing is shortened to 6 months (2009/C168/02).
- The **investigator** informs by **email** the CEHF[3] of the end of experiment at the CUSL[4] as notified by the sponsor.
    - He/she records the center closure date in Claire
    - He creates the submission « déclaration de fin d'étude » or « déclaration de clôture de site ».

Documents to provide to the LEC[5] for information of the (+ notification of the local EC) end of trial :

	Paper copy (1)	Electronic copy	Provided by sponsor	Provided by the CUSL investigator	Signed by investigator
Acknowledgement of receipt	X	X	X	X if not provided by the sponsor	X
Notification of end of trial form: document provided by the sponsor or CEHF-FORM-112[I]		X	X	X if not provided by the sponsor	X
FOR DRUG EXPERIMENT : DOCUMENTS TO PROVIDE ADDITIONNALLY					
CT End of trial form (CEHF-DOE-118[II]) http://ec.europa.eu/health/files/eudralex/vol-10/declaration_end_trial_form.doc		X	X		
Summary of experiment report (according to Eudralex Volume 10 : Detailed guidance on the application format and documentation to be submitted in an application for an Ethics Committee opinion))		X	X		

[3] CEHF : Comité d'Ethique Hospitalo-Facultaire
[4] CUSL : Cliniques universitaires Saint-Luc
[5] LEC : leading Ethics Committee

3.2.2. *Information of the competent authorities for clinical trials with medicinal product only*

- The **sponsor** informs the competent authorities of each country concerned by the trial by **mail** within **90 days** after the end of the experiment.
  CT End of trial form http://ec.europa.eu/health/files/eudralex/vol-10/declaration_end_trial_form.doc[III] (CEHF-DOE-118[IV])
  - The 90 days timing is shortened to 15 days when the end of experiment must be anticipated. Notifications will detail clearly the reasons of anticipated stop.

    Document: « Declaration of the End of Trial Form » : *Eudralex- Volume 10 Clinical Trials guidelines*
  - An end of experiment report (CT End of trial form http://ec.europa.eu/health/files/eudralex/vol-10/declaration_end_trial_form.doc , (CEHF-DOE-118) must be sent within the year following the notification of end of experiment for non-paediatric clinical trials. For paediatric clinical trials, the timing is shortened to 6 months (2009/C168/02).
  - FORM for Belgium : to be sent by registered mail:

    Agence Fédérale des Médicaments et des Produits de Santé
    Responsable de la Division Recherche et Développement
    Bâtiment Eurostation, 8ème étage
    Place Victor Horta 40, boîte 40
    B-1060 Bruxelles

3.3. Suspension or interdiction of experiment (Law 7 May 2004)

See AHRPP-SOP-040, procedure for the declaration of non-compliance, deviation, violation, unexpected events occurring during an experiment[V] (GCP 4.12.3)

3.4. Early termination of experiment decided by the sponsor

3.4.1. *Information of the Ethics Committee in case of early termination of any experiment*

The **sponsor**:

- Informs the LEC[6] by regular mail or e-mail within 15 days following the termination.
- Details clearly the reasons of early termination
- Communicates the specific measures taken to guarantee the safety of participants, if applicable.
- Uses the standard European document (« Declaration of the End of Trial Form »: Eudralex- Volume 10 Clinical Trials guidelines) for clinical trials with IMP[7].
- Uses his own template for any other study type
- Inform the investigator who will inform the institution by encoding the information in the Claire database (GCP 4.12.2)

3.4.2. *Information of the competent authorities in case of early termination of a clinical trial with IMP*

The **sponsor**:

- Informs the competent authorities of each country concerned by the trial by registered mail within 15 days after the early termination of the experiment.
- Details clearly the reasons of early termination
- Communicates the specific measures taken to guarantee the safety of participants, if applicable.
- Uses the standard European document (« Declaration of the End of Trial Form »: Eudralex- Volume 10 Clinical Trials guidelines) for clinical trials with IMP

3.5. Premature termination or suspension of a trial (GCP 4.12.1)

The investigator who stops or prematurely suspends his participation in the study without the prior consent of the sponsor:

- Informs the sponsor immediately and provides in writing a detailed explanation for his decision
- Informs the Ethics Committee immediately and provides a detailed explanation for his decision
- Informs the institution in encoding the termination/suspension of the trial in the Claire database

[6] LEC : leading Ethics Committee
[7] IMP : Investigational Medicinal Product

3.6. Temporary halt, as decided by the sponsor

- The **sponsor** informs the Ethics Committee by mail, within 15 calendar days after the temporary halt of a study for safety reasons.
- The sponsor informs directly the principal investigator who will inform the institution in encoding the halt in the Claire database (GCP 4.12.2)

3.6.1. Information of the Ethics Committee in case of temporary halt of any prospective experiment for safety reasons

The **sponsor**:

- Informs the LEC[8] by regular mail or e-mail within 15 days following the temporary halt.
- Details clearly the reasons of temporary halt
- Communicates the specific measures taken to guarantee the safety of participants, if applicable.

3.6.2. Information of the competent authorities in case of temporary halt of a clinical trial with IMP[9]

The **sponsor**:

- Informs the ethics committees (LEC) of each country concerned by the trial by registered mail within 15 days after temporary halt of the experiment.
- Details clearly the reasons of temporary halt
- Communicates the specific measures taken to guarantee the safety of participants, if applicable.

3.6.3. Temporary halt

Any temporary halt decided by the sponsor for any non-safety reason will be included in a substantial amendment and submitted to the Ethics Committee and to the Competent Authorities according to the procedure CEHF-SOP-109[VI]

[8] LEC : leading Ethics Committee
[9] IMP : Investigational Medicinal Product

3.7. Restart of experiment

The sponsor submits a request of restart, formulated as a substantial amendment (with the form " Substantial amendment notification form", CEHF-DOE-120[VII] (cfr also CEHF-SOP-109).

The grounds related to safety justifying the restart of the experiment must be detailed.

The experiment will restart only after approval of the Ethics Committee (LEC[10] if multicentre study) and if competent authorities (FAMHP[11]) didn't raise any motivated objections.

If the sponsor decides to not restart the experiment, he must inform the Ethics Committee and competent authorities within 15 days, as described in section early termination.

4. DISTRIBUTION

Cette procédure est à diffusion

Publique	☒
Restreinte à l'unité/entité/département	☐

5. RÉFÉRENCES

CEHF-DSQ-045_Liste des Lois, Arrêtés Royaux, Directives Européennes et normes de qualité en vigueur

[I] CEHF-FORM-112_ Fin étude - Formulaire de notification de fin étude
[II] CEHF-DOE-118_ Declaration of the end of trial form - Clinical Trial on Medicinal product
[III] CT End of trial form http://ec.europa.eu/health/files/eudralex/vol-10/declaration_end_trial_form.doc
[IV] CEHF-DOE-118_ Declaration of the end of trial form - Clinical Trial on Medicinal product
[V] AHRPP-SOP-040_Conduite étude – suivi – Procédure déclaration déviation, violation, événement inattendu.
[VI] CEHF-SOP-109_ Procédure soumission amendement
[VII] CEHF-DOE-120_Substantial Amendment Notification Form, available on _https://ec.europa.eu/health/documents/eudralex/vol10_eu

[10] LEC : leading Ethics Committee
[11] FAMHP : Federal Agency for medicines and health products / AFMPS : Agence Fédérale des Médicaments et des Produits de Santé