

Procedure for the end of trial notification to CEHF

N° de référence : [CEHF-SOP-111]

[Commission d'éthique hospitalo-facultaire]

Version : [3.0]

Date d'application : 08/03/2023

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. Responsibilities and Authorities

- The **CEHF¹ administrative secretary** is in charge of encoding the date of end of experiment in the CEHF database.
- The **sponsor** of an experiment is responsible to inform the LEC² 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'Éthique 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) 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 CEHF³ of the end of experiment at the CUSL⁴ 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 ».
- The secretariat of the ethics committee encodes the End of Study date and creates the "End of Study" status on the date of receipt of the notification

Documents to provide to the LEC⁵ for information of the (+ notification of the local EC) end of trial :

	Provided by sponsor	Provided by the CUSL investigator	Signed by investigator
Acknowledgement of receipt	X	X if not provided by the sponsor	X
Notification of end of trial form: document provided by the sponsor or CEHF-FORM-112 ¹	X	X if not provided by the sponsor	X
FOR DRUG EXPERIMENT : DOCUMENTS TO PROVIDE ADDITIONNALLY			
CT End of trial form (CEHF-DOE-118 ¹¹) http://ec.europa.eu/health/files/eudra_lex/vol-10/declaration_end_trial_form.doc	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		

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

See procedure AAHRPP-SOP-011_Notification End of trial to AFMPS^{III} of the Clinical trial Centre.

3.3. Suspension or interdiction of experiment

See CEHF-SOP-127, Procedure for the declaration of a deviation, violation, unexpected event^{IV} (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 LEC⁶ 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 IMP⁷.
- 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

See procedure AAHRPP-SOP-011_Notification End of trial to AFMPS^{III} of the Clinical trial Centre.

3.5. Premature termination or suspension of a trial by the investigator (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

⁶ LEC : leading Ethics Committee

⁷ IMP : Investigational Medicinal Product

- Informs the institution in encoding the termination/suspension of the trial in the Claire database

3.6. Temporary halt, as decided by the sponsor

- The **sponsor** informs the Ethics Committee, 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 LEC⁸ 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

See procedure AAHRPP-SOP-011_Notification End of trial to AFMPS^{III} of the Clinical trial Centre.

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^V

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^{VI} (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 (LEC⁹ if multicentre study) and if competent authorities (FAMHP¹⁰) 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.

⁸ LEC : leading Ethics Committee

⁹ LEC : leading Ethics Committee

¹⁰ FAMHP : Federal Agency for medicines and health products / AFMPS : Agence Fédérale des Médicaments et des Produits de Santé

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4. DISTRIBUTION

This procedure has to be diffused

Publicly

Restricted to the unit/entity/department

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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} AAHRPP-SOP-011_Notification End of trial to AFMPS

^{IV} CEHF-SOP-127, Procedure for the declaration of a deviation, violation, unexpected event

^V CEHF-SOP-109_ Procédure soumission amendement

^{VI} CEHF-DOE-120_Substantial Amendment Notification Form, also available on

https://ec.europa.eu/health/documents/eudralex/vol10_eu