Protocol:

Title:

Reference number CEHF :

Name of principal investigator:

Date of approval: ……., by Ethics Committee ……., designated as leading EC

1. Current status:

☐ The experiment didn't start yet because: ……

☐ The experiment started on ……. (date of 1st "screening")

2. Monitoring of the experiment from the beginning/from the last status (date: ……):

☐ The experiment is performed according to the expected design : ☐ YES ☐ NO

- Expected patients number: …….
- Screened patients number: ……..
- Enrolled patients number: ……..
- "Drop-out"/withdrawal (+ reasons if known) patients number:……..
- Number of patients having terminated the experiment according to the protocol:……..

Please provide a summary of complaints received about the research (if applicable).

☐ The experiment is temporary stopped: ☐ YES ☐ NO. If yes, because of:

☐ adverse events (please specify):

☐ technical or practical issues (please specify):

☐ other (please specify) :

☐ The experiment is terminated: ☐ YES ☐ NO. If yes, because of:

☐ adverse events (please specify):

☐ other (please specify) :

☐ limited number of recruited patients

☐ according to the study design

Are the observed adverse events and their severity in accordance with the information provided at time of initial submission?

☐ YES

☐ NO (please specify)

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

3. Additional information to be provided to CEHF

3.1. If the information is not available on the CUSL database CLAIRE, please provide a summary of amendments and modifications submitted since last report (+ date of approval).

3.2 If this information has not been submitted to the CEHF since the approval of the LEC (if < 1 year) or since the last updated annual report, please communicate any relevant recent literature or interim findings that could impact safety of participants).

3.3 For St-Luc or UCL sponsored clinical trial (with IMP) only : please provide a DSUR.

TO BE COMPLETED IN ALL CASES: Is the risk/benefit balance, based on study results, still positive for the participants (according to principal investigator's opinion)?

☐ YES

☐ NO (please specify)

Date :

Name of principal investigator :

Signature of principal investigator :

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