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| Cliniques universitaires SAINT-LUC UCL BRUXELLES | **Check list submission commercial experiment to CEHF** |
| N° : AAHRPP-DSQ-102<br>Ennov: REV011 /PaCo: Version 1.0 | N° ENGLISH VERSION : 053 |

***"Please do take into account that this is a translation of the original French version validated in the Quality Management System (QMS) of Cliniques universitaires Saint-Luc through the software Ennov GED. Therefore in case of doubt, differences, inconsistency or discrepancy in this English version, the French version shall prevail"***

## DOCUMENTS TO PROVIDE TO CEHF FOR SUBMISSION OF A NEW CLINICAL RESEARCH PROJECT

## COMMERCIAL EXPERIMENTS

**All documents must be checked by the investigator (version and dates)**

| | Paper copy | Electronic copy | Provided by the sponsor | Provided by the investigator | Signed by the investigator |
|---|---|---|---|---|---|
| Acknowledgement of receipt | X | X | X | | X |
| Document 1(dated and signed) | X | X | | X | X and by the head of service |
| Summary in French (1 page) | X | X | X | | |
| Informed consent form French | X | X | X | | |
| Billing sheet | X | X | X | | |
| Contact information sheet | | X | X | X | |
| Protocol | X | X | X | | X |
| Dated and signed CV of the investigator and sub-investigators Saint-Luc **+ Financial disclosure form investigator/sub-investigators Saint-Luc** | | X | | | X |
| Insurance certificate | | X | X | | |
| Financial agreement (or draft) | | X | X | | X |

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| **FOR DRUG EXPERIMENT :** | | | | | |
| Clinical Trial Application Form | | X | X | | X |
| Pharmacological data (non authorized drug) | | X | X | | |
| Scientific and public leaflets (authorized drug) | | X | X | | |
| Confirmation that drugs will be provided freely | | X | X | | |
| **FOR MEDICAL DEVICE EXPERIMENT :** | | | | | |
| FAMHP submission package (if MD not used in the indication) | | X | X | | |
| Label CE | | X | X | | |
| Investigator's brochure | | X | X | | |
| Scientific leaflet | | X | X | | |