Cliniques universitaires SAINT-LUC UCL BRUXELLES	**POLICY - Checklist of submission documents for a clinical investigation with a medical device**
N° : AAHRPP-DSQ-008 / REV002	N° ENGLISH VERSION : 217

"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 SharePoint PaCo GED. Therefore in case of doubt, differences, inconsistency or discrepancy in this English version, the French version shall prevail"

1 DOCUMENTS TO BE PROVIDED TO THE REGULATORY AUTHORITIES FOR THE SUBMISSION OF A CLINICAL INVESTIGATION WITH MEDICAL DEVICE

Submissions to the regulatory authorities (FAMHP) are made via the CESP portal pending the implementation of the Eudamed portal.

The initial submission file will be sent to the FAMHP by the Cliniques universitaires Saint-Luc (CUSL) central academic office.
Substantial amendment submission dossiers will be forwarded to the FAMHP by the CUSL staff member acting as the non-commercial sponsor of the clinical investigation on behalf of CUSL.

The submission procedure is detailed in AAHRPP-SOP-008.

All documents must be submitted electronically in PDF format, except for the "List of submitted document" which must remain in WORD format.

In the submission package:
- PDF format must allow for "copy/paste" and search within the document
- the layout of the documents must be clear, if possible including a detailed table of contents
- documents should not be password protected
- each document in the submission package should be a separate file

Certificates, licenses, authorizations and other documents with signatures can be scanned (OCR). Digital signatures are accepted.

A supplemental document will be attached to the initial submission package (regardless of type) in case of:
- more than one investigational device in the clinical investigation - Annex A
- more than one comparator in the protocol - Annex B
- addition of other sites - Annex C

The document Clinical investigations - Guidance on Dossier Content provides a complete description of the content of each document required for submission to the FAMHP for a clinical investigation with a medical device.

1.1 Regulatory pathway: Validation FAMHP and opinion CE

➔ **Medical device CE marked, PMCF investigation involving burdensome and/or invasive procedures**

Initial submission				
Title	**Template**	**CUSL Document**	**FAMHP Document**	**Signed by**
Cover letter	AAHRPP-FORM-001	✓		Sponsor
List of submitted documents – **WORD** format	List of submitted document for initial application		✓	
Application Form	Initial application form		✓	
Synopsis (English and French)				
Clinical Investigation Plan (Protocol)	AAHRPP-DSQ-007	✓		Sponsor
CE Certificate and CE Mark				
Technical documentation				
Manufacturer's Instructions for use if not included in the technical documentation				
PMCF Plan				
Proof of Insurance	AAHRPP-FORM-003	✓		
Information sheet and informed consent form	CEHF-DOE-092_FR, NL	✓		
Procedure and materials used for recruitment of patients				
Description of the compensation for investigation participants				
CV and GCP of Principal Investigator(s)		✓		PI
Declaration of potential conflicts of interest	AAHRPP-FORM-035	✓		PI

Initial submission				
Title	**Template**	**CUSL Document**	**FAMHP Document**	**Signed by**
Compliance with rules on Data Protection	AAHRPP-FORM-090	✓		Sponsor/PI
Suitability of sites	Written statement		✓	
Clinical Investigation Agreement	Academic contract template validated by academic hospitals	✓		
If comparator: CE certificate and manufacturer's instructions for use				

Substantial modifications				
Title	**Template**	**CUSL Document**	**FAMHP Document**	**Signed by**
Cover letter	AAHRPP-FORM-002	✓		Sponsor
List of submitted documents – **WORD** format	List of submitted document for substantial moditication		✓	
Description of the substantial modifications				
Application Form	Not available yet		✓	
Modified documents (track change and clean version)				
Supporting information				

1.2 Regulatory pathway: Consolidated opinion FAMHP and CE

- ➔ **Clinical investigations involving CE-marked devices used outside their intended purpose**
- ➔ **Clinical investigations involving devices without a CE mark which are not 'in-house' devices.**
- ➔ **Clinical investigations involving custom made devices for which data will be used for conformity assessment**

Initial submission				
Title	**Template**	**CUSL Document**	**FAMHP Document**	**Signed by**
Cover letter	AAHRPP-FORM-001	✓		Sponsor
List of submitted documents – **WORD** format	List of submitted document for initial application		✓	
Application Form	Initial application form		✓	
Clinical Investigation Plan (Protocol)	AAHRPP-DSQ-007	✓		Sponsor
Synopsis (English and French)				
Investigator's Brochure (IB)	Clinical investigations – Guidance on Dossier Content			Sponsor
Example of label	Clinical investigations – Guidance on Dossier Content			
CE Certificate and CE Mark if applicable				
Manufacturer's Instructions for use				
List of general safety and performance requirements	Not available yet		✓	
Proof of Insurance	AAHRPP-FORM-003	✓		
CV and GCP of Principal Investigator(s)				PI
Declaration of potential conflicts of interest	AAHRPP-FORM-035	✓		PI
Compliance with rules on Data Protection	AAHRPP-FORM-090			Sponsor and PI
Suitability of sites	Written statement		✓	

Initial submission				
Title	**Template**	**CUSL Document**	**FAMHP Document**	**Signed by**
Information sheet and informed consent form	CEHF-DOE-092_FR, NL	✓		
Procedure and materials used for recruitment of patients				
Description of the compensation for investigation participants				
Clinical Investigation Agreement	Academic contract template validated by academic hospitals			
If multinational: submission status in other countries and letter of agreement or refusal for each country				
If comparator : CE Certificate and Manufacturer's Instructions for use				

Substantial modifications				
Title	**Template**	**CUSL Document**	**FAMHP Document**	**Signed by**
Cover letter	AAHRPP-FORM-002	✓		Sponsor
List of submitted documents – **WORD** format	List of submitted document for substantial moditication		✓	
Description of the substantial modifications				
Application Form	Not available yet		✓	
Modified documents (track change and clean version)				
Supporting information				

1.3 Regulatory pathway: Separate opinion FAMHP and EC

➔ **Clinical investigations involving custom made or 'in-house' devices which will not be used for conformity assessment**

Initial submission				
Title	**Template**	**CUSL Document**	**FAMHP Document**	**Signed by**
Cover letter	AAHRPP-FORM-001	✓		Sponsor
List of submitted documents – **WORD** format	List of submitted document for initial application		✓	
Application Form	Initial application form		✓	
Synopsis (English and French)				
Clinical Investigation Plan (Protocol)	AAHRPP-DSQ-007	✓		Sponsor
Investigator's Brochure (IB)	Clinical investigations – Guidance on Dossier Content			Sponsor
Manufacturer's Instructions for use				
List of general safety and performance requirements	Not available yet		✓	
Proof of Insurance	AAHRPP-FORM-003	✓		
Proof of parallel application to EC		✓		
Information sheet and informed consent form	CEHF-DOE-092_FR, NL	✓		
CV and GCP of Principal Investigator(s)				PI
Example of label	Clinical investigations – Guidance on Dossier Content			
Compliance with rules on Data Protection	AAHRPP-FORM-090	✓		Sponsor and PI
Clinical Investigation Agreement	Academic contract template validated by academic hospitals			

Initial submission				
Title	**Template**	**CUSL Document**	**FAMHP Document**	**Signed by**
If multinational: submission status in other countries and letter of agreement or refusal for each country				
If comparator: CE certificate and manufacturer's instructions for use				

Substantial modifications				
Title	**Template**	**CUSL Document**	**FAMHP Document**	**Signed by**
Cover letter	AAHRPP-FORM-002	✓		Sponsor
List of submitted documents – **WORD** format	List of submitted document for substantial moditication		✓	
Description of the substantial modifications				
Application Form	Not available yet		✓	
Modified documents (track change and clean version)				
Supporting information				

2 DOCUMENTS TO BE PROVIDED TO THE CEHF FOR THE SUBMISSION OF A CLINICAL INVESTIGATION WITH A MEDICAL DEVICE

The initial submission to the CEHF is made by the academic office following the procedure for submission of a prospective study (AAHRPP-SOP-104).

In the case of a multi-center study, the sponsor submits to all local ethics committees at the same time.

Regulatory pathway: EC only

- ➔ **PMCF investigations without additional burdensome or invasive procedures.**
- ➔ **Other clinical investigations involving CE-marked devices used within their intended purpose.**

Regulatory pathway : Separate opinion FAMHP and EC

- ➔ **Clinical investigations involving custom made or 'in-house' devices which will not be used for conformity assessment**

Initial submission		
Titre	**Modèle disponible**	**Signé par**
Protocol	AAHRPP-DSQ-007	
Synopsis in french (1 page)		
Document 1	CEHF-FORM-097	Sponsor
Questionnaire 1	AAHRPP-FORM-082	Sponsor et PI
Inform consent form	CEHF-DOE-092	
Proof of insurance (+ insurance certificate if external sponsor)	AAHRPP-FORM-003	
Contract draft and budget		
Conflict of Interest Declaration Form for Principal Investigator and Co-Investigators	AAHRPP-FORM-035	
Aknowledge of receipt	CEHF-FORM-104	
Dated and signed CV (<3 years) and GCP certificat (<3years) for Principal Investigator and Co-Investigators		PI
If CE label and in the indication: CE label and notice of the device		
If CE label but not indicated: CE label, investigator's brochure, device leaflet		
If no CE mark: Investigator brochure and FAMHP file		

Substantial modifications: See document CEHF-SOP-109_Procedure for submitting amendments

3 REFERENCE DOCUMENTS

AAHRPP-SOP-008

AAHRPP-SOP-104

AAHRPP-FORM-001

AAHRPP-FORM-002

AAHRPP-FORM-003

AAHRPP-FORM-035

AAHRPP-FORM-082

AAHRPP-FORM-090

AAHRPP-DSQ-007

CEHF-DOE-092_FR, NL, EN

CEHF-SOP-109

CEHF-FORM-097

CEHF-FORM-104

Academic contract template validated by academic hospitals

WEB site FAMHP/AFMPS

Clinical investigations – Guidance on Dossier Content

Initial application form for clinical investigation under MDR

GSPR form for "general safety and performance requirements and list of standards applied"

List of submitted document for initial application

List of submitted document for substantial modification

Written statement – suitability of sites.

Application form – substantial modifications (not available yet)

Annex A, Annex B, Annex C