Biomedical research file submission

1. Introduction

The establishment of a Single Entry Point meets the need to centralize the process of submitting new clinical research to the Clinical Trial Centre (CTC) and the Ethics Committee of Hôpital Erasme and the medical school of Université Libre de Bruxelles (EC). This new process allows us to have a global and comprehensive view of the various research projects that take place at Hôpital Erasme and to ensure the safety of the participants by respecting our HRPP accreditation.

2. Purpose

The purpose of this procedure is to define the stages of submission of a clinical research project at Hôpital Erasme.

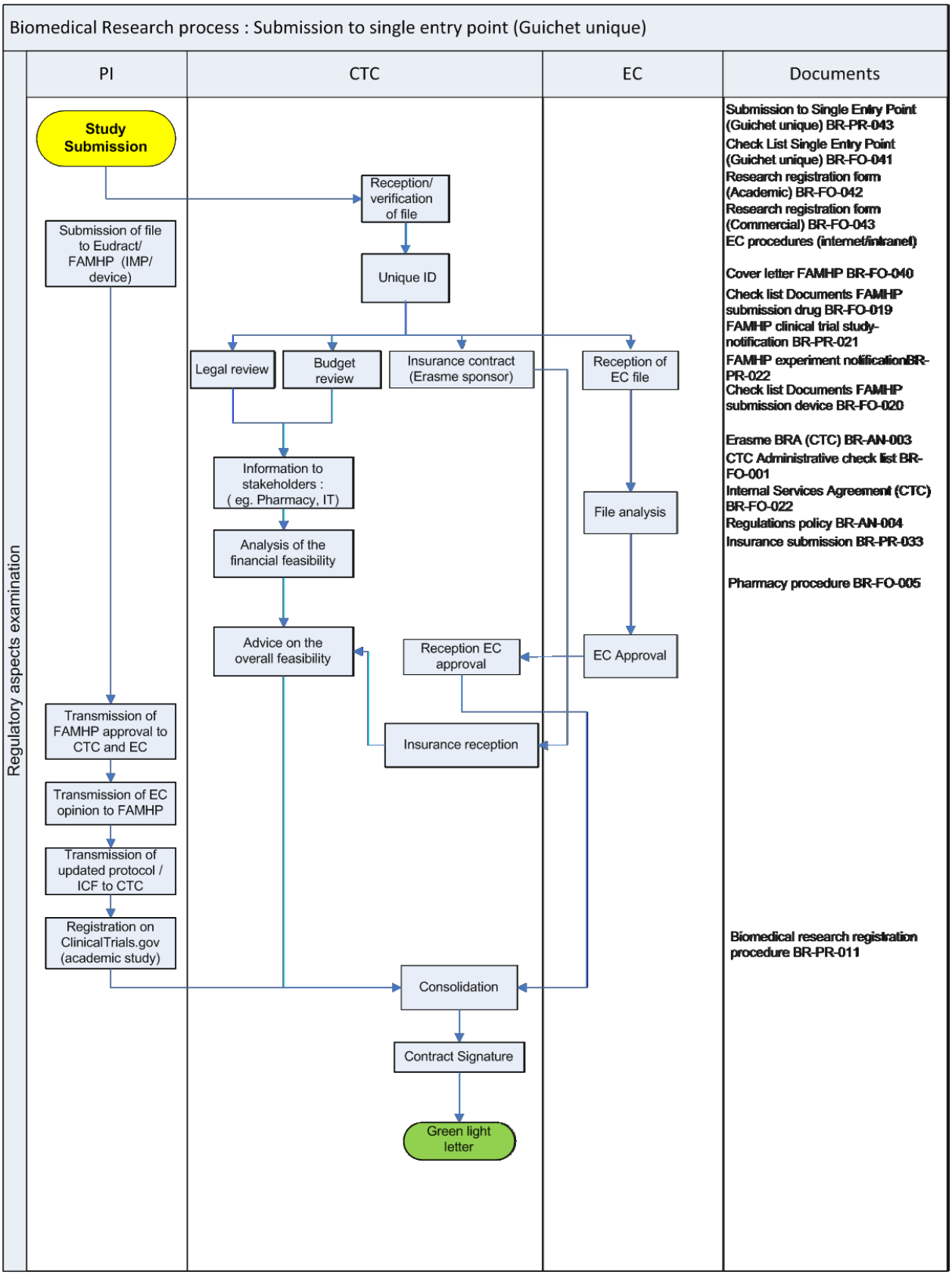
3. Operation of Single Entry Point

All clinical research projects involving patients from Hôpital Erasme or performed on healthy volunteers at Hôpital Erasme must be submitted to the "Single Entry Point" of the Biomedical Research Centre. The latter is responsible for verifying the presence of all documents necessary for the analysis and processing of the file, in accordance with the procedure outlined below. The CTC then submits the complete file to the Hospital-Faculty Ethics Committee of Hôpital Erasme. If necessary, additional information on the file will be requested from the principle investigator (PI). The contractual and budgetary review will be carried out by the CTC, in parallel with submission to the EC. A consolidation phase is then carried out by the CTC, thus ensuring that all required elements (insurance, contract, EC agreement, FAMHP agreement, registration on Clinicaltrials.gov, ...) are in order. Once the consolidation phase is completed, the contracts are signed by the various parties involved. The investigator will be able to start his study upon receipt of the "green light" letter.

Biomedical research file submission

Hôpital Erasme — ULB

Service de la Recherche Biomédicale



Preparation of submission file by PI

All clinical research projects must be submitted to the CTC through its Single Entry Point. All the documents required for the analysis and processing of the application (see Tables 1A and 1B below) must be provided:

- Electronically at the following e-mail address: Service.Rech-biomed@erasme.ulb.ac.be.

  For practical reasons, it is advised by the EC that these files are provided exclusively in **.pdf** format or in **.doc** format (without protection through password).

- And as a paper file containing all documents classified and grouped according to the following 3 items and in the following order:
  - Administrative documents
  - Documents related to the protocol
  - Additional documents for members of the ethics committee

➢ This paper version is to be submitted to the CTC. From a practical point of view, and for reasons of security and confidentiality, the CTC favors hand-delivery. However, investigators who work in the hospital will be able to use postal sorting (internal mail) in order to submit their files. In this case, of course, account must be taken of the processing time and the possible loss of confidentiality of the files, for which the CTC cannot be held responsible.

➢ The Biomedical Research Department (local CAH-3W-1040) is located on the 3rd floor of the CAH (Centre Administratif Hospitalier) building.

➢ From the main building of the hospital, go to the day hospital, cross the parking lot of the day hospital and take the small road between the nursing school (on your right) and the Sport hospital (on your left). The CAH building is located behind this road.

Monday	Between 9h00 and 12h00 and between 14h00 and 16h00
Tuesday	Between 9h00 and 12h00 and between 14h00 and 16h00
Wednesday	Between 14h00 and 16h00
Thursday	Between 9h00 and 12h00 and between 14h00 and 16h00
Friday	Between 9h00 and 12h00 and between 14h00 and 16h00

Files may be submitted by both the Principal Investigator (PI) and the sponsor or other contact person (Clinical Research Associate) to whom the submission procedure has been delegated. In this case, the file will contain, on penalty of inadmissibility, a written power of attorney justifying such delegation.

Depending on the type of research, the folder must contain the following documents:

Documents associated with submission

Commercial studies

Commercial	Administrative documents														Documents related to the protocol									
	CV	Info on CHRAU or local EC list	Insurance certificate	draft contract	Excel tables of costs/activities/visits (flow chart)	Copy of the AFMPS (device) submission form or CE approval certificate	Copy of the European Clinical Trial Application or EudraCT application form	Proof of CE payment	Proof of AFMPS payment	Cover letter	GCP certificate	Attestation to honor Net ID	Letter of approval from department chair	Synopsis of the project (max. 1 page)	Internal Registration Form	DACE / ECAF	Protocol and amendments	Observation notebook / CRF	ICF FR and NL	Patient journal	Questionnaires	If healthy volunteers: recruitment procedure (poster, advertising) + information on the payment or compensation	Investigator Brochure	Manual (lab, radio, anapath,...)
Retrospective	x	x		x	x			x				x	x	x	x	x	x	x	x[3]					
MCH	x	x	x[2]	x	x			x				x	x	x	x	x	x		x[3]					x[4]
Prospective	x	x	x	x	x			x			x	x	x	x	x	x	x	x	x	x[4]	x[4]	x		x[4]
Device	x	x	x	x	x	x		x			x	x	x	x	x	x	x	x	x	x[4]	x[4]	x	x	x[4]
Observational test	x	x	x	x	x			x		x	x	x	x	x	x	x	x	x	x	x[4]	x[4]		x[4]	
Interventional test	x	x	x	x	x		x	x	x	x	x	x	x	x	x	x	x	x	x	x[4]	x[4]	x	x	x[4]

x1: non-applicable if study is monocentric
x2: if prospective
x3: unless exempted
x4: if available

Table 1A. Commercial Studies

Documents associated with submission

Non commercial studies (academic)

Academic	Administrative Documents											Documents related to the protocol								
	CV	Info for CHRAU or local EC list	Application for insurance (Erasmus sponsor) or insurance certificate	Draft Contract	Copy of the letter for the Federal Commission on embryos	Copy of the AFMPS (device) submission form or CE approval certificate	Copy of the European Clinical Trial Application or EudraCT application form	GCP Certificate	Attestation to honor Net ID	Letter of approval from the department chair	Synopsis of the project (max. 1 page)	Internal registration form	DACE / ECAF	Protocol and amendments	Notebook / CFR	ICF FR and NL	Patient journals	Questionnaires	Investigator brochure / Instructions for use	If healthy volunteers: recruitment procedure (poster, advertising) + information on the payment or compensation
Retrospective	x	x[1]		x[1]					x	x	x	x	x	x	x	x[3]				
MCH	x	x[1]	x[2]	x[1]					x	x	x	x	x	x		x[3]				
Embryo in vitro	x				x				x	x	x	x	x	x		x				
Prospective	x	x[1]	x	x[1]				x	x	x	x	x	x	x	x	x	x[4]	x[4]		x
Device	x	x[1]	x	x[1]		x		x	x	x	x	x	x	x	x	x	x[4]	x[4]	x	x
Observational test	x	x[1]	x	x[1]				x	x	x	x	x	x	x	x	x	x[4]	x[4]	x[4]	
Interventional test	x	x[1]	x	x[1]			x	x	x	x	x	x	x	x	x	x	x[4]	x[4]	x	x
Register	x	x[1]		x[1]				x	x	x	x	x	x	x	x	x				

x[1]: non applicable if study is monocentric

x[2]: if prospective

x[3]: unless exempted

x[4]: if available

Table 1B. Non-commercial studies

Verification of the file and assignment of a unique number

Each file must be submitted to the CTC Single Entry Point for verification and preliminary analysis. The purpose of this analysis is to ensure the completeness of the submitted dossier, both from the point of view of the documents required by the CTC and those required by the EC. The file will be analyzed by the CTC within 5 working days, and the PI / sponsor / contact person will be informed of the status of the application (complete or incomplete). Incomplete files are returned to the contact person to be put in order.

Finally, each complete submission dossier receives a unique reference number of type: *ERASME_CTC_YYYYMM_ ###.* Note that this reference number is specific to the CTC and does not replace the CE reference related to your submission file.

Submission to CE / Contract Management / Insurance

The administrative management of submitted dossiers and their evaluation requires the EC to set the deadline for submission of applications 14 days before the evaluation meeting. In practice, for a dossier to be put on the agenda of an upcoming EC meeting, it must be submitted to the CTC no later than 5 working days before the closing date of the EC's agenda. The CTC is responsible for forwarding the complete files to the EC.

The agenda of the EC can be found at : https://www.erasme.ulb.ac.be/fr/enseignement-recherche/comite-d-ethique/etudes-cliniques/agenda-du-comite-d-ethique. Attention: The CTC is responsible for submitting the completed dossiers to the EC. However, for reasons of legally required independence, the CTC will not analyze the content of the documents submitted to the EC.

According to Article 11, §5 of the Law of 07 May, 2004 on experiments on the human person, "The ethics committee shall have a maximum of 15 days in the case of a single-center phase 1 study to communicate its reasoned opinion to the investigator and up to 28 days in the case of other experiments. Such time limits shall be reckoned from the date of receipt of the duly drawn up application, provided that the fees referred to in Article 30 have been paid. "This applies both to new clinical research projects and to amendments to existing studies.

For example :

14/08	15/08	16/08	17/08	18/08
	Deadline for submission of a file to CTC			
21/08	22/08	23/08	24/08	25/08
	Closure of the Agenda for the meeting of 05/09			
28/08	29/08	30/08	31/08	01/09
04/09	05/09	06/09	07/09	08/09
	EC evaluation meeting			

The contracts will be analyzed at the budgetary (feasibility) and legal level in parallel with the submission to the EC. For studies in which Hôpital Erasme is the sponsor, an insurance policy with Ethias will be requested, and will also be carried out in parallel with the legal, budgetary, and ethical revisions.

Consolidation and signature

During this stage, the various approvals of the 4 entities (legal, budget, ethics, and insurance) working in parallel are collected and consolidated. The contract is then signed by the sponsor, the head of the service, the principal investigator, and the general and medical directorates. This period of consolidation and signature of contracts can take up to 10 working days.

« Green light » letter

As soon as the contract is signed by all parties, the "green light" authorization to start the study is sent by the CTC to the lead investigator and the EC.

4. References

5. Appendices

6. Internal Links

7. External Links

Documents :
https://www.erasme.ulb.ac.be/fr/enseignement-recherche/recherche-biomedicale/documents-utiles