

Documents to prepare - Academic, thesis and commercial research project
(without an investigational medicinal product/medical device/*in vitro* diagnostic
device) not going through CTR/MDR/IVDR

NA = not applicable

Folder	Documents	Prospective	Retrospective
02	Curriculum Vitae	Mandatory	Mandatory
02	GCP certificate	Mandatory	Mandatory
02	Declarations of conflict of interest	If applicable	If applicable
04	Informed consent forms in French	Mandatory	If applicable
04	Informed consent forms in Dutch	Mandatory	If applicable
05	Ethics committee's application form (ECAFD/DACE) (new version!)	Mandatory	Mandatory
05	Project Summary/Synopsis	Mandatory	Mandatory
05	Protocol	Mandatory	Mandatory
05	Manuals (lab, radio, anatomopathology, etc.)	If applicable	NA
05	Electronic case report form [empty database]	Mandatory	Mandatory
05	Questionnaires	If applicable	NA
06	Safety data sheet	If applicable	NA
07	Patient diary	If applicable	NA
07	Information on patient payment or compensation	If applicable	NA
08	Detailed info on local and central EC	If applicable	NA
08	Proof of payment to the EC	If applicable	If applicable
08	Authorization from the biobank manager	If applicable	If applicable
09	Insurance request	Mandatory	NA
09	Insurance certificate (once received)	Mandatory	NA
11	Clinical trial agreement or Material (or Data) transfer agreement [draft]	If applicable	If applicable
11	Budget grid [draft]	If applicable	If applicable
11	GDPR Statement	Mandatory	Mandatory
12	Cover letter	Mandatory	Mandatory
13	Recruitment advertising (poster, letter, flyer, etc.)	If applicable	If applicable