

Documents to prepare - TFE

A detailed User Guide for TFE is available in French in the EC submission platform (“support” tab).

NA = not applicable

Folder	Documents	Prospective	Retrospective
02	Curriculum Vitae	Mandatory	Mandatory
02	GCP certificate	Mandatory	Supervisor’s GCP mandatory
04	Informed consent forms in French	Mandatory	If applicable
04	Informed consent forms in Dutch	If applicable	If applicable
05	Ethics committee’s application form (ECAF/DACE) (new version!)	Mandatory	Mandatory
05	Protocol	Mandatory	Mandatory
05	Electronic case report form [empty database]	Mandatory	Mandatory
05	Questionnaires – Interview guides	If applicable	NA
08	Authorization from the biobank manager	If applicable	If applicable
09	Insurance certification (once available)	Mandatory	NA
09	Insurance request	Mandatory	NA
08	Detailed info on local and central EC	If applicable	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 adverting (poster, letter, etc.)	If applicable	If applicable