Documents to prepare - Research project involving a medical device or an *in vitro* diagnostic device submitted to CESP, going through MDR or IVDR

By default, please add all the document submitted to national authorities (AFMPS) in the institutional submission platform. Procedures available on the AFMHP site.

Folder	Documents	
02	Declarations of conflict of interest	**Mandatory**
04	Informed consent forms in French	Mandatory
04	Informed consent forms in Dutch	Mandatory
05	Protocol	Mandatory
05	Manuals (lab, radio, anatomopathology, etc.)	Recommended
06	Investigator brochure	Mandatory
06	Summary of product characteristics (SmPC)	Mandatory
07	Patient diary	Recommended
07	Information on patient payment or compensation	Recommended
09	Insurance request	If applicable
09	Insurance certificate	Mandatory
11	Clinical trial agreement [draft]	Mandatory
11	Budget grid [draft]	Mandatory
11	GDPR Statement	**Mandatory**