Overview of required documents for Local Feasibility for other research subject to the WMO

without Site Suitability Declaration – *Verklaring Geschiktheid Onderzoeksinstelling (VGO)*

As of 1 November 2021 the VGO is mandatory for research into medicinal products;

so far not mandatory for other research subject to the WMO

Radboudumc is sponsor ('verrichter')	Radboudumc is participating centre
Application via PaNaMa Below a list of necessary documents/information	**Application via PaNaMa** Below a list of necessary documents/information
Positive decision MREC	**Positive decision MREC**
A-number Clinical Trial Agreement Contract between Radboudumc and participating centres (if applicable) - per centre one A-number: A-number is assigned by the Radboudumc department of Valorization	**A-number Clinical Trial Agreement** Contract between Radboudumc and sponsor: A-number is assigned by the Radboudumc department of Valorization
Protocol Final, MREC-approved version	**Protocol** Final, MREC-approved version
Radboudumc Subject information sheet Use the last version of the CCMO model For Radboudumc specific information: see SOP Obtaining Informed Consent, §3.1*	**Radboudumc Subject information sheet** Will be provided by the sponsor with addition of the Radboudumc specific information (see SOP Obtaining Consent, §3.1*)
ABR form Final, MREC-approved version	**ABR form** Final, MREC-approved version
Datamanagement plan*	Not applicable
Monitoring plan*	Not applicable
Declaration of expertise* The Head of Department declares that research staff comply with the Radboudumc Policy guideline on training*. At the Local Feasibility procedure, it is checked whether the Principal Investigator is BROK-certified. If not, a positive decision of the Executive Board cannot be granted.	**Declaration of expertise*** The Head of Department declares that research staff comply with the Radboudumc Policy guideline on training*. At the Local Feasibility procedure, it is checked whether the Principal Investigator is BROK-certified. If not, a positive decision of the Executive Board cannot be granted.
Radiation Ethics form* In case there is a higher dose of radiation for the research participant in the context of the study. Approved by the clinical physicist of the Radboudumc.	**Radiation Ethics form*** In case there is a higher dose of radiation for the research participant in the context of the study. Approved by the clinical physicist of the Radboudumc.
Not applicable	**Billing Information form*** For the local feasibility costs of € 1.500, -- (excl. VAT) in case of *geldstroom-4* projects - if a (pharmaceutical) company is sponsor of the study.

* The above mentioned hyperlinks to the specific documents in the Integral Quality System (IQS) can only be used by Radboudumc employees.

Service point Local Feasibility checks the documents for completeness and accuracy. The applicant will be contacted in case of questions.