Overview of required documents for Local Feasibility for research into medicinal products

with 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

1. Application for signing VGO page 1, prior to the MREC submission**

Radboudumc is sponsor	Radboudumc is participating centre
Application via PaNaMa If 'drug research' on tab General is put on 'yes', the task 'Application VGO signature' automatically appears	**Application via PaNaMa** If 'drug research' on tab General is put on 'yes', the task 'Application VGO signature' automatically appears
Perform the actions under the task: - Fill in VGO page 1 and upload it **in Word** in PaNaMa - Complete VGO appendices and have page 4 signed by the Principal Investigator (enclosures per supporting department are not required). Upload VGO appendices (with signed page 4) **as pdf** in PaNaMa - Upload protocol in PaNaMa	**Perform the actions under the task:** - Fill in VGO page 1 and upload it **in Word** in PaNaMa - Complete VGO appendices and have page 4 signed by the Principal Investigator (enclosures per supporting department are not required). Upload VGO appendices (with signed page 4) **as pdf** in PaNaMa

2. Application for local feasibility asap after MREC submission, for final approval of the Executive Board

Radboudumc is 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 .
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 Use the clinical trial agreement for use with VGO	**A-number Clinical Trial Agreement** Contract between Radboudumc and sponsor: A-number is assigned by the Radboudumc department of Valorization
Protocol: MREC approved version	**Protocol**: Final version, i.e., MREC submitted version, excluding possible modifications for approval MREC
ABR form: MREC submitted version Only applicable for research into medicinal products that is submitted under the EU Clinical Trial Directive (CTD) (so n.ap. under the Clinical Trial Regulation - CTR)	**ABR form**: Final version, i.e., MREC submitted version, excluding possible modifications for approval MREC. Only applicable for research into medicinal products that is submitted under the EU Clinical Trial Directive (CTD) (so n.ap. under the Clinical Trial Regulation - CTR)
Radboudumc Subject information sheet: MREC submitted version. Use the last version of the CCMO model For Radboudumc specific information: see SOP Obtaining Informed Consent, §3.1*	**Radboudumc Subject information sheet:** Final version, i.e. MREC submitted version excluding possible modifications for approval MREC, is provided by the sponsor with the addition of Radboudumc specific information (see SOP Obtaining Consent, §3.1*)
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.

Radboudumc is sponsor	Radboudumc is participating centre
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.
Datamanagement plan*	Not applicable
Monitoring plan*	Not applicable
Positive decision MREC **Positive decision Competent Authority** (only applicable for submittance under the EU Clinical Trial Directive (CTD) These approvals, as well as the MREC-approved documents, can be uploaded in PaNaMa at the final stage of the Local Feasibility procedure, as soon as available	**Positive decision MREC** **Positive decision Competent Authority** (only applicable for submittance under the EU Clinical Trial Directive (CTD) These approvals, as well as the MREC-approved documents, can be uploaded in PaNaMa at the final stage of the Local Feasibility procedure, as soon as available

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

** Work instruction Site Suitability Declaration (VGO)
CCMO web page: Site Suitability Declaration or Research Declaration

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