Overview of required documents for Local Feasibility

Revised Local Feasibility procedure per 1 November 2021, with Site Suitability Declaration

Verklaring Geschiktheid Onderzoeksinstelling (VGO)

Research with medicinal products	Other research
VGO is mandatory per 1 November 2021	VGO is not mandatory but is allowed. Mandatory in the course of 2022 (date unknown)
References to information on the VGO	
IKS: Werkinstructie voor onderzoekers t.b.v. VGO-procedure bij het opstarten van WMO-plichtig onderzoek (only available in Dutch and can only be viewed by Radboudumc employees)	
CCMO: I2. Site Suitability Declaration (VGO) or Research Declaration	

1. Application for signing VGO part A, prior to the METC submission

Radboudumc is sponsor ('verrichter')	Radboudumc is participating center
Application via PaNaMa 'VGO ja/nee' on Tab General/Algemeen must be set to 'yes'	**Application via PaNaMa** 'VGO ja/nee' on Tab General/Algemeen must be set to 'yes'
Perform the actions in PaNaMa under the task ' 'Aanvraag RvB ondertekening VGO (deel A)': - Fill in VGO part A and upload this form **in Word** in PaNaMa. - Complete VGO part B (appendices not required) and have it signed by the **PI** and **head of department** (mandate of the Executive Board). Upload VGO part B **as PDF** in PaNaMa	**Perform the actions in PaNaMa under the task ' 'Aanvraag RvB ondertekening VGO (deel A)':** - VGO part A is supplied by the sponsor (filled in). Upload this form **in Word** in PaNaMa - Complete VGO part B (appendices not required) and have it signed by the **PI** and **head of department** (mandate of the Executive Board). Upload VGO part B **as PDF** in PaNaMa

2. Application for local feasibility asap after METC submission, for final approval by the Executive Board

Radboudumc is sponsor ('verrichter')	Radboudumc is participating center
Application via PaNaMa Complete the task 'Aanvraag lokale uitvoerbaarheid'. Below is a list of documents/information to be uploaded	**Application via PaNaMa** Complete the task 'Aanvraag lokale uitvoerbaarheid'. Below is a list of documents/information to be uploaded
A-number of the Clinical Trial Agreement (assigned by the Radboudumc dept. of Valorization) Use the Clinical Trial Agreement for use with VGO	**A-number of the Clinical Trial Agreement (assigned by the Radboudumc dept. of Valorization)** Contract is supplied by the sponsor.
Protocol: MREC-submitted version	**Protocol**: final version, i.e. MREC-submitted version, including any changes in order to obtain MREC-approval
ABR form: MREC-submitted version	**ABR form**: final version, i.e. MREC-submitted version, including any changes in order to obtain MREC-approval
Radboudumc subject information and Informed Consent Form: MREC-submitted version. Always use the last template version of the CCMO Radboudumc-specific information: see SOP Obtaining Informed Consent, §1.1, last bullet	**Radboudumc subject information and Informed Consent Form:** final version, i.e. MREC-submitted version, including any changes in order to obtain MREC-approval, provided with Radboudumc-specific information (see SOP Obtaining Informed Consent, §1.1, last bullet)
Declaration of expertise* (concerning BROK registration a.o.)	**Declaration of expertise*** (concerning BROK registration a.o.)
Radiation Ethics form* Approved by the clinical physicist of the Radboudumc. In case there is a higher dose of radiation for the volunteer subject in the context of the study	**Radiation Ethics form*** Approved by the clinical physicist of the Radboudumc. In case there is a higher dose of radiation for the volunteer subject in the context of the study
Not applicable	**Billing Information formulier*** For the local feasibility costs of € 1.500,-- (excl. VAT) in case of *geldstroom-4* projects - if a (pharmaceutical) company is the sponsor of the study)
Data management Plan (DMP)*	Not applicable
Monitoring Plan (MP)*	Not applicable
Positive decision MREC **Positive decision Competent Authority (if applicable)** These approvals, as well as the final approved documents, can be uploaded in PaNaMa at the final stage of the local feasibility procedure, as soon as available	Not applicable

* For Radboudumc employees templates of these documents are in the Integral Quality System (IQS).

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