Overview of required documents for Local Feasibility

Local Feasibility procedure without Site Suitability Declaration

Verklaring Geschiktheid Onderzoeksinstelling (VGO)

This procedure will expire when the VGO is mandatory (01 November 2021 for research involving medicinal products; for other research date is unknown, but in the course of 2022)

Radboudumc is the sponsor ('verrichter')	Radboudumc is participating center
Application via PaNaMa 'VGO ja/nee' on Tab General/Algemeen must be set to 'no'. Complete the task 'Aanvraag lokale uitvoerbaarheid'. Below is a list of documents/information to be uploaded.	**Application via PaNaMa** 'VGO ja/nee' on Tab General/Algemeen must be set to 'no'. Complete the task 'Aanvraag lokale uitvoerbaarheid'. Below is a list of documents/information to be uploaded.
Positive decision MREC	**Positive decision MREC**
Positive decision Competent Authority If applicable (only in case of research with medicinal products). This only applies to research involving medicinal products submitted to MREC/CCMO before November 1, 2021. Research submitted after 1 November 2021 must follow the VGO procedure	**Positive decision Competent Authority** If applicable (only in case of research with medicinal products). This only applies to research involving medicinal products submitted to MREC/CCMO before November 1, 2021. Research submitted after 1 November 2021 must follow the VGO procedure
A-number of the Clinical Trial Agreement Assigned by the Valorization Department Radboudumc	**A-number of the Clinical Trial Agreement** Assigned by the Valorization Department Radboudumc
Protocol Final, MREC-approved version	**Protocol** Final, MREC-approved version
ABR form Final, MREC-approved version	**ABR form** Final, MREC-approved version
Radboudumc subject information and Informed Consent Form: final, MREC-approved 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, MREC-approved version. Will be provided by the sponsor, with addition of the Radboudumc-specific information: see SOP Obtaining Informed Consent, §1.1, last bullet
Data management plan*	Not applicable
Monitoring plan*	Not applicable
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

* 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.