Green = instructions/ explanations Blue = fields to complete

**Site Suitability Declaration (VGO)**

*To be completed by sponsor based on the research protocol that will be submitted to the Reviewing Committee (RC).* *The signed VGO is submitted to the RC as part of the research file. The use of the VGO is mandatory on grounds of the CCMO-directive on the assessment of the suitability of the research centers (TGO) for clinical trials which are subject to the Medical Research Involving Humans Subjects Act (WMO) and the EU Clinical Trials Regulation 536/2014.*

**Study Information**

Research number submission portal: <ABR number or CTIS study number>

Full Study title: <Full Study title>

Name research institute, city: < Name research institute> in <city>

Department(s)/ location(s): < Department(s)/location(s)>

Name local principal investigator: <Name local principal investigator>

Planned number of trial participants in institution: <Planned number of trial participants in institution>

Role research institute: Choose an item.

**Proof coverage liability**[[1]](#footnote-2)

The submitter of the research file provides the reviewing committee with proof of liability coverage for damage caused by death or injury to the test subject of the:

[ ]  the above-mentioned institution as executor and/or provider of the investigation, name of insurer and policy number: <Name insurer>, <policy number>[[2]](#footnote-3)

[ ]  sponsor of the research, name of sponsor: <name of sponsor>[[3]](#footnote-4)

*The board of directors/ management of the above-mentioned research institute declares that the investigator(s) and institute have sufficient expertise and facilities to carry out this research.
This decision is based on the preliminary arrangements as described in the appendices or equivalent in which an overview is given of the arrangements between the principal investigator and the supporting departments of the research institute about the local feasibility of the research.*

**Conduct of the research**

The implementation of the research in this center can only be carried out after the Reviewing Committee has assessed the research file and the suitability of this institution and has issued a positive decision and after the research contract with the sponsor4 has been signed or, in the absence of a research contract, written permission for the execution of the research has been granted by the Executive Board/management.

Name mandated person BoD/ Management: <Name>

Position mandated person BoD/ Management: <Position>

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  <place>, <DD/MMM/YYYY>

Green = instructions/ explanations Blue = fields to complete
 **Appendix (general)**

**Overview of preliminary arrangements
local principal investigator and supporting departments**

*The appendix provides the scope of the local VGO process.*

*After the VGO process, the checklist local feasibility is used as a guide. Sponsor is obliged to provide a completed VGO and appendices in order for departments to know which study procedures are expected. Sites can use this information in a local process.*

*VGO appendices (overview local arrangements) are to be completed based on the research protocol.

Other study documents are to be provided by sponsor to the participating centers after submission to the Reviewing Committee and after the query round.*

By signing the appendix, the local principal investigator declares that consultations with the supporting departments have shown that given the assessments, the planning, and the preliminary budget, they *could* participate in the clinical trial.

*To be completed by sponsor based on the research protocol that will be submitted to the Reviewing Committee, unless otherwise indicated.*

**Study Information**

Study title: <study title>

Study name/short title/acronym: <Study name/short title/acronym>

EudraCT-number: <EudraCT-number> *(applicable to research with medicines)*

Protocol number Sponsor: <Protocol number sponsor>

Protocol version and date (on which the arrangements are based): <version>, <DD/MMM/YYYY>

Research with medicines: [ ]  Yes [ ]  No

Research phase: Choose an item.

Research with medical devices: [ ]  Yes [ ]  No

Classification per May 26th, 2021: Choose an item.

Or other type of research: [ ]  Observational research without invasive measurements

[ ]  Observational research with invasive measurements

[ ]  Other interventional research

[x]  Healthcare evaluation

[ ]  Other: <Other>

Research in assignment/ initiative of: [ ]  Sponsor [ ]  Investigator

Number of centers in NL: <number of sites> [ ]  Unknown

Planned number of trial participants at institute: <planned number of trial participants at institute>

Planned period of recruitment (in months): <planned period of recruitment>

Planned date first trial participant in: <month> <year>

Planned date last visit, last trial participant: <month> <year>

|  |  |
| --- | --- |
| **Deadline return of completed and signed VGO**  | <DD/MMM/YYYY> |
| **Expected submission date to EC or in EU portal CTIS** | <DD/MMM/YYYY> |

**Appendix** **Continued (general)**

 **Contact details (representative) sponsor**

*To be completed by sponsor based on the research protocol that will be submitted to the Reviewing Committee, unless otherwise indicated.*

Organization: <organization>

Name contact person 1: <name contact person 1>

E-mail: <e-mail>

Phone number: <phone number>

Mobile number: <mobile number>

Name contact person 2: <name contact person 2>

E-mail: <e-mail>

Phone number: <phone number>

Mobile number: <mobile number>

**Standard clinical trial agreement (CTA CCMO/ DCRF)** [ ]  Yes [ ]  No

If yes, note used template version: <version>

*(current version available on CCMO website)*

Global budget (per subject): <amount> Euro

**In case of medical equipment delivery:** [ ]  Not applicable

Medical technology department involved? [ ]  Yes [ ]  No

**Research Network involved?**  [ ]  Yes [ ]  No

*This is important as the network can support in the coordination of the VGO process and also can provide centralized services.*

If yes, complete the details of the network below:

Network: Choose an item. In case of other, please specify: <Name other network>

Address: <address>

Name contact person: <name contact person>

E-mail: <e-mail>

Phone number: <phone number>

Mobile number: <mobile number>

*To be completed by the local participating investigator.*

**Details Local Principal Investigator Details research coordinator**

Name: <name> Name: <name>

E-mail: <e-mail> E-mail: <e-mail>

Phone number: <phone number> Phone number: <phone number>

Mobile number: <mobile number> Mobile number: <mobile number>

**Continued**

Appendix (general)

**Table 1: supporting/ involved departments**

*Grey columns to be completed by sponsor.*

*Remaining columns to be completed by local principal investigator after consultation with departments listed below.*

*If a department or service falls under the responsibility of an investigator not employed by the institute, the services are outside of the scope of the institute.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Services/ departments | Department involved in research | Contact person department | Responsibility institute\*? | Responsibility Investigator? | Preliminary approval department |
| 1. Pharmacy
 | Choose an item. | <name contact person> | Choose an item. | Choose an item. | Choose an item. |
| 1. Laboratory
 | Choose an item. | <name contact person> | Choose an item. | Choose an item. | Choose an item. |
| 1. Medical Micro-biology Laboratory
 | Choose an item. | <name contact person> | Choose an item. | Choose an item. | Choose an item. |
| 1. Pathology
 | Choose an item. | <name contact person> | Choose an item. | Choose an item. | Choose an item. |
| 1. Cardiology
 | Choose an item. | <name contact person> | Choose an item. | Choose an item. | Choose an item. |
| 1. Radiology/ Nuclear medicine
 | Choose an item. | <name contact person> | Choose an item. | Choose an item. | Choose an item. |
| 1. Staff workload
 | Choose an item. | <name contact person> | Choose an item. | Choose an item. | Choose an item. |
| 1. Other\*\*: <Department>
 | Choose an item. | <name contact person> | Choose an item. | Choose an item. | Choose an item. |

*\* The (Mandated) board of directors signs only for the services provided by their hospital, not for external services or business which is owned by the investigator.*

*\*\*When other departments are involved sponsor has to add a clean appendix.*

Herewith the local principal investigator declares (on behalf of the above-mentioned supporting departments) and the research institute that they have informed each other about the execution of the above-mentioned research and the activities required for this purpose and that they are able to carry out the research according to the research protocol. The procedures on which this declaration is based are listed in the appendices. Before the start of the research the necessary arrangements will be further elaborated and laid down in the (standard) clinical trial agreement (CTA) indicated above. In case of monocenter studies, the arrangements will be established locally. In this case a CTA is not used.

*Disclaimer: If changes occur before the start of, or during the research, adjustments to the arrangements made, including financial agreements, will follow in accordance with the changed services.*

**Local information** *(tick what applies)*

[ ]  Local principal investigator employed by the institute and staff at the expense and responsibility of the institute:
→ Attach arrangements for availability of suitable personnel.

[ ]  In case of independent medical specialist as local principal investigator who bears costs for research personnel:
→ Hereby I declare that there are sufficient competent and skilled personnel available to carry out the research for the planned number of trial participants within the envisioned timelines.
→ Indicate on Annex(es) whether they are applicable or not.

**Name local principal investigator:** <name>

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: <DD/MMM/YYYY>

[ ]  Not Applicable: Local process determines if this has to be signed.

**Appendix supporting department: Pharmacy**

[ ]  Not Applicable

*To be completed by sponsor based on the research protocol that will be submitted to the Reviewing Committee. Local Investigator and concerned department will discuss the feasibility: Can you do this?*

*After the VGO process is completed there will be further discussions on arrangements and budget followed by a final Contract (CTA).*

Who will provide the service?

External party [ ]  Yes [ ]  No
*If Yes: costs are with sponsor, Annex not applicable (NA)*

Hospital Pharmacy [ ]  Yes [ ]  No
*If yes: please complete the information below*

Radioactive materials? [ ]  Yes*\** [ ]  No

*\*Consult radiation safety department*

**Available information** *(documents provided by sponsor)*

[ ]  Research protocol

[ ]  Pharmacy Manual (draft)*\**

[ ]  Investigator Brochure

[ ]  SmPC / EPAR

*\*optional document*

**Research procedures**

Is it an Investigational Medicinal Product (IMP) research:

[ ]  Which meets the requirements of GMP (no manufacturing or labelling required and IMP has EU QP release certificate)

[ ]  For which import must be arranged

[ ]  Requiring manufacture or labelling by the pharmacy, namely: <namely>

 **Research medication**

*Grey columns to be completed by sponsor.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Name, form, strength*For example Paracetamol infusion liquid 1000mg=100 ml / placebo* | Route of administration | Storage Conditions | Other |
| 1. | <name research medication/ placebo> <form> <strength> | [ ]  Oral[ ]  IV[ ]  SC[ ]  other: <other> | [ ]  fridge 15-25˚C [ ]  fridge 15-30˚C [ ]  fridge 2-8˚C [ ]  other: <other> | [ ]  Opium Act[ ]  High Risk[ ]  ATMP\*[ ]  GMO\*\* |
| 2. | <name research medication/ placebo> <form> <strength> | [ ]  Oral[ ]  IV[ ]  SC[ ]  other: <other> | [ ]  fridge 15-25˚C [ ]  fridge 15-30˚C [ ]  fridge 2-8˚C [ ]  other: <other> | [ ]  Opium Act[ ]  High Risk[ ]  ATMP\*[ ]  GMO\*\* |

*\*ATMP: Advanced Therapy Medicinal Products; \*\*GMO: Genetic Modified Organism*

 **What do the research activities consist of?**

[ ]  Register in IVRS/ IXRS

[ ]  Randomization by the pharmacy

[ ]  Emergency procedure for unblinding

[ ]  PFA Actions (Preparing for Administration)

**Where are PFA procedures described:**

[ ]  Supplied Pharmacy Manual

[ ]  If no Pharmacy Manual is provided, describe here whether there is dissolution and required time, form (infusion, injection, etc.), volume of final product, product specific issues: <description>

**Shelf Life after PFA:** <Shelf life after PFA>

Storage conditions after PFA: [ ]  Fridge 15-25˚C [ ]  Fridge 15-30˚C [ ]  Fridge 2-8˚C [ ]  other: <other>

Should temperature of IMP after PFA be recorded [ ]  Yes [ ]  No

Does the pharmacy itself have to supply the placebo product [ ]  Yes [ ]  No

**Delivery**

[ ]  To the trial participant in hospital

[ ]  In the hospital for administration

[ ]  Other: <namely>

Are there scheduled deliveries/ administrations *(> 24 hours prior)* [ ]  Yes [ ]  No

Are there scheduled deliveries for administration needed outside office hours [ ]  Yes [ ]  No

[ ]  Other: <namely>

**Local price agreements/ quote**

Based on the above information, make a quote for the requested services, and possibly other services (including specification), based on standard research rates of the research institution. This quote is for internal use and is still to be amended after the VGO is signed and is ratified with the signing of the Clinical Trial Agreement.

Submit to local principal investigator no later than: Date: <DD/MMM/YYYY>
Attachment local price list *(for internal use only)* [ ]  Yes [ ]  No

**Local agreement between investigator and supporting department to be recorded locally.**

**Appendix supporting department: Clinical Laboratory (CL)**

[ ]  Not Applicable

*To be completed by sponsor based on the research protocol that will be submitted to the Reviewing Committee. Local Investigator and concerned department will discuss the feasibility: Can you do this? After the VGO process is completed there will be further discussions on arrangements and budget followed by in a final Contract (CTA).*

Who will provide the service?

[ ]  Clinical chemistry laboratory of the institute *(complete research procedures below)*

[ ]  Central laboratory (*costs are not for the institute)*

**Available information** *(documents provided by sponsor)*

Documents provided by the sponsor:

[ ]  Research protocol

[ ]  Lab Manual (draft)\*

*\* optional document*

[ ]  ISO15189-accreditated CL? [ ]  Yes [ ]  No

**Research procedures**

|  |
| --- |
| *In principle, all activities mentioned in the research protocol’s schedule of assessments falls under the term research procedure, unless it is specifically stated as standard care in the research protocol.**Grey columns to be completed by sponsor.* *Other columns to be completed by local principal investigator, after consultation with the department.* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *Local CL:* diagnostic tests hospital | Standard care | Research procedure | Staff member department | Research Staff investigator | Evaluation of the clinical chemist*\** |
| <diagnostic 1> |[ ] [ ] [ ] [ ] [ ]
| <diagnostic 2> |[ ] [ ] [ ] [ ] [ ]
| <diagnostic 3> | [ ]  |[ ] [ ] [ ] [ ]
| <diagnostic 4> | [ ]  |[ ] [ ] [ ] [ ]
| <diagnostic 5> | [ ]  |[ ] [ ] [ ] [ ]

*\*Evaluation of procedure after execution occurs locally or centrally (item not applicable when done centrally).*

|  |  |  |
| --- | --- | --- |
| *Central laboratory:* activities institute | Staff member department | Research staff investigator |
| Storing and sending samples |[ ] [ ]
| Processing and sending samples |[ ] [ ]
| Processing, storing and sending samples |[ ] [ ]
| <......> |[ ] [ ]
| <......> |[ ] [ ]
| <......> |[ ] [ ]
| <......> |[ ] [ ]

**Storage location of samples**

[ ]  In the laboratory

[ ]  With the investigator

[ ]  Other: <other>

[ ]  Not applicable

**Details biobank**

[ ]  Not applicable

[ ]  A central biobank is involved

[ ]  A local biobank is involved

**Local price agreements/ quote**

Based on the above information, make a quote for the requested services, and possibly other services (including specification), based on standard research rates of the research institution. This quote is for internal use and is still to be amended after the VGO is signed and is ratified with the signing of the Clinical Trial Agreement.

Submit to local principal investigator no later than: Date: <DD/MMM/YYYY>
Attachment local price list *(for internal use only)* [ ]  Yes [ ]  No

**Local agreement between investigator and supporting department to be recorded locally.**

**Appendix supporting department: Medical Microbiology Laboratory (MML)**

[ ]  Not Applicable

*To be completed by sponsor based on the research protocol that will be submitted to the Reviewing Committee. Local Investigator and concerned department will discuss the feasibility: Can you do this? After the VGO process is completed there will be further discussions on arrangements and budget followed by in a final Contract (CTA).*

Who will provide the service?

[ ]  Medical Microbiology Laboratory (MML) of the hospital *(complete below research procedures)*

[ ]  External (central) laboratory *(costs are not for the institute)*

**Available information** *(documents provided by sponsor)*

[ ]  Research protocol

[ ]  Lab Manual (draft)*\**

*\*optional document*

[ ]  ISO15189-accreditated MML? [ ]  Yes [ ]  No

**Research procedures**

|  |
| --- |
| *In principle, all activities mentioned in the research protocol’s schedule of assessments falls under the term research procedure, unless it is specifically stated as standard care in the research protocol.**Grey columns to be completed by sponsor.* *Other columns to be completed by local principal investigator, after consultation with the department.* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *Local MML:* diagnostic tests hospital | Standard Care | Research Procedure | Staff member department | Research staff investigator | Evaluation microbiologist*\** |
| Processing, diagnostic tests (and no storage or shipping) | [ ]  |[ ]  [ ]  | [ ]  | [ ]  |
| Processing, diagnostic tests and storage | [ ]  |[ ]  [ ]  | [ ]  | [ ]  |
| Processing, diagnostic tests, storage and shipping | [ ]  |[ ]  [ ]  | [ ]  | [ ]  |
| Processing and shipping | [ ]  |[ ]  [ ]  | [ ]  | [ ]  |
| Processing, storage and shipping | [ ]  |[ ]  [ ]  | [ ]  | [ ]  |
| Other: <other> | [ ]  |[ ]  [ ]  | [ ]  | [ ]  |
| Other: <other> | [ ]  |[ ]  [ ]  | [ ]  | [ ]  |
| Other: <other> | [ ]  |[ ]  [ ]  | [ ]  | [ ]  |

*\*Evaluation of procedure after execution occurs locally or centrally (item not applicable when done centrally).*

**Storage location of samples**

[ ]  In the laboratory

[ ]  With the investigator

[ ]  Other: <other>

[ ]  Not applicable

**Local price agreements/ quote**

Based on the above information, make a quote for the requested services, and possibly other services (including specification), based on standard research rates of the research institution. This quote is for internal use and is still to be amended after the VGO is signed and is ratified with the signing of the Clinical Trial Agreement.

Submit to local principal investigator no later than: Date: <DD/MMM/YYYY>
Attachment local price list *(for internal use only)* [ ]  Yes [ ]  No

**Local agreement between investigator and supporting department to be recorded locally.**

**Appendix supporting department: Pathology**

[ ]  Not Applicable

*To be completed by sponsor based on the research protocol that will be submitted to the Reviewing Committee. Local Investigator and concerned department will discuss the feasibility: Can you do this? After the VGO process is completed there will be further discussions on arrangements and budget followed by in a final Contract (CTA).*

Who will provide the service?

Pathologist, not employed by institute [ ]  Yes [ ]  No

*If yes: local principal investigator make arrangements with the pathologist*

Clinical Molecular Biologist in Pathology (CMBP)

CMBP, not employed by institute [ ]  Yes [ ]  No

*If yes: local principal investigator make arrangements with CMBP*

Institute department/independent pathology organization [ ]  Yes [ ]  No

*If yes: please complete the below tariff agreements*

**Available information** *(documents provided by sponsor)*

[ ]  Research protocol

[ ]  Pathology Manual (draft)\*

[ ]  Material and Data Transfer Agreement (MDTA)\*

*\*optional document*

**Research procedures**

*In principle, all activities mentioned in the research protocol’s schedule of assessments falls under the term research procedure, unless it is specifically stated as standard care in the research protocol.*

 *Grey columns to be completed by sponsor.*

|  |  |  |
| --- | --- | --- |
| Research procedure | Standard Care | Research procedure |
| Implement and embedding tissue (paraffin) | Choose an item. | Choose an item. |
| Cut blank sections | Choose an item. | Choose an item. |
| HE and other histological colorings | Choose an item. | Choose an item. |
| Immunohistology | Choose an item. | Choose an item. |
| Molecular determinations  | Choose an item. | Choose an item. |
| Make Tissue Multi Array (TMA)  | Choose an item. | Choose an item. |
| Request external pathology department | Choose an item. | Choose an item. |
| Collection and storage of freezing and/or biopsy material | Choose an item. | Choose an item. |
| Laser Microdissection Microscopy | Choose an item. | Choose an item. |
| Whole Slide Image (WSI) Scanning | Choose an item. | Choose an item. |
| Storage/ release Central Biobank | Choose an item. | Choose an item. |
| Shipping of frozen material on dry ice by courier | Choose an item. | Choose an item. |
| Printing of anonymous reports | Choose an item. | Choose an item. |
| Shipping (not on dry ice) | Choose an item. | Choose an item. |
| Selection/ Evaluation by Pathologist | Choose an item. | Choose an item. |
| Evaluation by CMBP | Choose an item. | Choose an item. |
| Processing radioactivity\* | Choose an item. | Choose an item. |
| Other: <please specify> | Choose an item. | Choose an item. |
| Other: <please specify> | Choose an item. | Choose an item. |
| Other: <please specify> | Choose an item. | Choose an item. |

*\*When applicable, consult radiation safety department as needed.*

**Storage location**

[ ]  At the pathology department

[ ]  With the investigator

[ ]  Other: <other>

**Local price agreements/ quote**

Based on the above information, make a quote for the requested services, and possibly other services (including specification), based on standard research rates of the research institution. This quote is for internal use and is still to be amended after the VGO is signed and is ratified with the signing of the Clinical Trial Agreement.

Submit to local principal investigator no later than: Date: <DD/MMM/YYYY>
Attachment local price list *(for internal use only)* [ ]  Yes [ ]  No

**Local agreement between investigator and supporting department to be recorded locally.**

**Appendix supporting department: Cardiology**

[ ]  Not Applicable

*To be completed by sponsor based on the research protocol that will be submitted to the Reviewing Committee. Local Investigator and concerned department will discuss the feasibility: Can you do this? After the VGO process is completed there will be further discussions on arrangements and budget followed by in a final Contract (CTA).*

**Available information** *(documents provided by sponsor)*

[ ]  Research protocol

**Research procedures**

*In principle, all activities mentioned in the research protocol’s schedule of assessments falls under the term research procedure, unless it is specifically stated as standard care in the research protocol.*

*Grey columns to be completed by sponsor.*

*Other columns to be completed by local principal investigator, after consultation with the department.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Research procedures | Standard care | Research Procedure | Staff member department | Research staff investigator | Evaluation cardiologist\*\* |
| Electrocardiogram |[ ] [ ] [ ] [ ] [ ]
| Holter examination |[ ] [ ] [ ] [ ] [ ]
| Echocardiogram |[ ] [ ] [ ] [ ] [ ]
|  Trans-esophageal |[ ] [ ] [ ] [ ] [ ]
| Ergometrics |[ ] [ ] [ ] [ ] [ ]
| Coronary angiogram |[ ] [ ] [ ] [ ] [ ]
| Electrophysiological examination |[ ] [ ] [ ] [ ] [ ]
| Invasive circulation measurement |[ ] [ ] [ ] [ ] [ ]
| Cardiac CT-scan\* |[ ] [ ] [ ] [ ] [ ]
| Cardiac MRI-scan\* |[ ] [ ] [ ] [ ] [ ]
| Nuclear research\* |[ ] [ ] [ ] [ ] [ ]
| Reading CIED |[ ] [ ] [ ] [ ] [ ]
| Other:<namely> |[ ] [ ] [ ] [ ] [ ]
| Other:<namely> |[ ] [ ] [ ] [ ] [ ]
| Other:<namely> |[ ] [ ] [ ] [ ] [ ]

*\*When applicable, consult radiation safety department as needed.*

*\*\*Evaluation of procedure after execution occurs locally or centrally (item not applicable when done centrally).*

 **Local price agreements/ quote**

Based on the above information, make a quote for the requested services, and possibly other services (including specification), based on standard research rates of the research institution. This quote is for internal use and is still to be amended after the VGO is signed and is ratified with the signing of the Clinical Trial Agreement.

Submit to local principal investigator no later than: Date: <DD/MMM/YYYY>
Attachment local price list *(for internal use only)* [ ]  Yes [ ]  No

**Local agreement between investigator and supporting department to be recorded locally.**

**Appendix supporting department: Radiology/ Nuclear Medicine**

[ ]  Not Applicable

*To be completed by sponsor based on the research protocol that will be submitted to the Reviewing Committee. Local Investigator and concerned department will discuss the feasibility: Can you do this? After the VGO process is completed there will be further discussions on arrangements and budget followed by in a final Contract (CTA).*

Who will provide the service?

[ ]  Radiology

[ ]  Nuclear medicine

[ ]  Radiology & Nuclear medicine

**Available information** *(documents provided by sponsor)*

Documents provided by the sponsor:

[ ]  Research protocol

[ ]  Imaging Manual (draft)\*

*\*optional document*

**Research procedures**

*In principle, all activities mentioned in the research protocol’s schedule of assessments falls under the term research procedure, unless it is specifically stated as standard care in the research protocol.*

*Grey columns to be completed by sponsor.*

*Other columns to be completed by local principal investigator, after consultation with the department.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Modality*(type of imaging technique)\** | Units per trial participant | Standard care | Research procedure | Availability guaranteed | Contrast and/ or tracer*\*\** | Procedure and storage defined |
| <procedure> | <#> |[ ] [ ] [ ] [ ] [ ]
| <procedure> | <#> |[ ] [ ] [ ] [ ] [ ]
| <procedure> | <#> |[ ] [ ] [ ] [ ] [ ]

*\*E.g. CT, MRI, echo, intervention, SPECT, PET, or radionuclide therapy. Consult radiation safety department as needed.*

*\*\*In case of SPECT/ PECT/ radionuclide therapy also complete preferred tracer.*

**Additional explanation research procedures as mentioned in research protocol**

*Like specification of the parameters.*

<Complete here>

**Local price agreements/ quote**

Based on the above information, make a quote for the requested services, and possibly other services (including specification), based on standard research rates of the research institution. This quote is for internal use and is still to be amended after the VGO is signed and is ratified with the signing of the Clinical Trial Agreement.

Submit to local principal investigator no later than: Date: <DD/MMM/YYYY>
Attachment local price list *(for internal use only)* [ ]  Yes [ ]  No

**Local agreement between investigator and supporting department to be recorded locally.**

**Appendix: Staff workload department local principal investigator**

[ ]  Not Applicable

*To be completed by sponsor based on the research protocol that will be submitted to the Reviewing Committee. Local Investigator and concerned department will discuss the feasibility: Can you do this? After the VGO process is completed there will be further discussions on arrangements and budget followed by in a final Contract (CTA).*

Which procedures will fall under the responsibility of the department of the local principal investigator?

*This includes all activities performed by the local principal investigator and/or his/her department.*

*Excluding all the above-mentioned departments.*

*Activities in the role of sponsor fall outside the scope of the VGO and are not included in this appendix.*

**Personnel costs are covered by:**

*Please indicate who bears the costs for research personnel. The Annex is not applicable in the case of an independent medical specialist with their own research entity – unless principal investigator has requested the annex to be completed.*

[ ]  Local principal investigator *(tick box at top of the page)*

[ ]  Research institute

**Research procedures**

|  |
| --- |
| *Grey columns to be completed by sponsor – indicate which visits are part of the research protocol (remove or duplicate rows as needed).* *Remaining columns to be completed by local principal investigator based on the research protocol’s visit scheme. Complete per visit the total amount of hours of workload. Number of hours for preparations are a one-off, screening is monthly and visits are per trial participant.*  |

|  |  |  |
| --- | --- | --- |
| **General workload** | Research staff*(total amount* *of hours)* | Other: <other> *(total amount* *of hours)* |
| **Preparations** *(reading research protocol, meeting(s)/ training(s)/ providing information, etc.)* | <#> | <#> |
| **Screening** <…> months recruitment period | <#> *(amount of hours per month)* | <#> *(amount of hours per month)* |
| **Close-out** *(closing research)* | <#> | <#> |
| <…>  | <#> | <#> |

*Beside the personnel workload there are other important costs, like monitoring visits, administration, maintaining Investigator Site File, etc. These costs need to be included in the final budget.*

|  |  |  |
| --- | --- | --- |
| **Workload per trial participant** | Research staff*(total amount* *of hours)* | Other: <other> *(total amount* *of hours)* |
| **V1** <title/ visit description>  |
| Visit, including preparations and follow-up | <#> | <#> |
| Data processing, if not outsourced to third a party | <#> | <#> |
| <…>  | <#> | <#> |
| **V2** <title/ visit description> |
| Visit, including preparations and follow-up | <#> | <#> |
| Data processing, if not outsourced to third a party | <#> | <#> |
| <…> | <#> | <#> |
| **V3** <title/ visit description> |
| Visit, including preparations and follow-up | <#> | <#> |
| Data processing, if not outsourced to third a party | <#> | <#> |
| <…> | <#> | <#> |
| **V4** <title/ visit description> |
| Visit, including preparations and follow-up | <#> | <#> |
| Data processing, if not outsourced to third a party | <#> | <#> |
| <…>  | <#> | <#> |
| **V5** <title/ visit description> |
| Visit, including preparations and follow-up | <#> | <#> |
| Data processing, if not outsourced to third a party | <#> | <#> |
| <…> | <#> | <#> |
| **V6** <title/ visit description> |
| Visit, including preparations and follow-up | <#> | <#> |
| Data processing, if not outsourced to third a party | <#> | <#> |
| <…> | <#> | <#> |
| **V7** <title/ visit description> |
| Visit, including preparations and follow-up | <#> | <#> |
| Data processing, if not outsourced to third a party | <#> | <#> |
| <…>  | <#> | <#> |
| **V8** <title/ visit description> |
| Visit, including preparations and follow-up | <#> | <#> |
| Data processing, if not outsourced to third a party | <#> | <#> |
| <…> | <#> | <#> |
| **V9** <title/ visit description> |
| Visit, including preparations and follow-up | <#> | <#> |
| Data processing, if not outsourced to third a party | <#> | <#> |
| <…> | <#> | <#> |
| **V** #> **final visit** |
| Visit, including preparations and follow-up | <#> | <#> |
| Data processing, if not outsourced to third a party | <#> | <#> |
| <…>  | <#> | <#> |
| **V** <#> **follow-up** |
| Visit, including preparations and follow-up | <#> | <#> |
| Data processing, if not outsourced to third a party | <#> | <#> |
| <…> | <#> | <#> |

**Appendix supporting department: Other** <department>

[ ]  Not Applicable

*To be completed by sponsor based on the research protocol that will be submitted to the Reviewing Committee. Local Investigator and concerned department will discuss the feasibility: Can you do this? After the VGO process is completed there will be further discussions on arrangements and budget followed by in a final Contract (CTA).*

**Available information** *(documents provided by sponsor)*

[ ]  Research protocol

[ ]  Other: <namely>

**Research procedures**

|  |
| --- |
| *In principle, all activities mentioned in the research protocol’s schedule of assessments falls under the term research procedure, unless it is specifically stated as standard care in the research protocol.**Grey columns to be completed by sponsor.* *Other columns to be completed by local principal investigator, after consultation with the department.* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Research procedures | Standard care | Research Procedure | Staff member department | Research staff investigator |
| <procedure> |[ ] [ ] [ ] [ ]
| <procedure> |[ ] [ ] [ ] [ ]
| <procedure> |[ ] [ ] [ ] [ ]
| <procedure> |[ ] [ ] [ ] [ ]
| <procedure> |[ ] [ ] [ ] [ ]
| <procedure> |[ ] [ ] [ ] [ ]
| <procedure> |[ ] [ ] [ ] [ ]

 **Local price agreements/ quote**

Based on the above information, make a quote for the requested services, and possibly other services (including specification), based on standard research rates of the research institution. This quote is for internal use and is still to be amended after the VGO is signed and is ratified with the signing of the Clinical Trial Agreement.

Submit to local principal investigator no later than: Date: <DD/MMM/YYYY>
Attachment local price list *(for internal use only)* [ ]  Yes [ ]  No

**Local agreement between investigator and supporting department to be recorded locally.**

1. Proof of cover for liability can be liability insurance or another guarantee of financial security, such as a bank guarantee (article 7 paragraph 9 WMO). The proof does **not** concern the WMO subject insurance as referred to in Article 7(1) of the WMO. Proof from the executor or sponsor is sufficient, but it is up to the assessing review committee whether it deems proof from both the executor and the sponsor necessary under specific circumstances. [↑](#footnote-ref-2)
2. If the institution provides liability insurance, the research file does not have to contain proof of this. In this case, the name of the insurer and the policy number will suffice. This also applies to an institution that is executor of the research as well as sponsor. [↑](#footnote-ref-3)
3. Does the sponsor, not being the institution, provide proof of liability cover? In that case, this proof must always be part of the research file.

4 This refers to an external sponsor. In case of investigator initiated monocenter studies, the institution is both conductor as well as sponsor and a Board of Directors approval is sufficient instead of a CTA. [↑](#footnote-ref-4)