: The UZ/KU Leuven logo’s may be removed from header section, as appropriate, along with these instructions.

# AMENDMENT NR. INSERT NUMBER

# STUDY PROTOCOL NR. INSERT NUMBER

|  |  |
| --- | --- |
| BETWEEN | INSERT NAMEINSERT ADDRESSduly represented by INSERT NAME,hereinafter referred to as the “**SPONSOR**”, |
| AND | INSERT NAMEINSERT ADDRESSduly represented by INSERT NAME,hereinafter referred to as “**UZ LEUVEN**”, |
| OPTIONALAND  | INSERT NAMEINSERT ADDRESShereinafter referred to as “**INSERT NAME**”, |

The Parties are hereinafter individually referred to as “**Party**” and collectively referred to as the “**Parties**”.

# RECITALS

**WHEREAS**, the Parties have entered into agreement ‘*INSERT TITLE AGREEMENT’* on INSERT EFFECTIVE DATE OF AGREEMENT (hereinafter referred to as the “**Agreement**”) to participate in a clinical study according to the document entitled: ‘*INSERT TITLE PROTOCOL*’ (hereinafter referred to as "**Protocol**"), hereinafter referred to as "**Study**";

**WHEREAS,** SPONSOR wishes to delegate its monitoring duties regarding the Study Kies een item. to UZ LEUVEN, who accepts, and Parties therefore mutually desire to amend, modify and restate certain terms and conditions of the Agreement, in particular with respect to the performance of monitoring services by UZ LEUVEN on behalf of SPONSOR.

**WHEREAS,** all other provisions of the Agreement, including its appendixes, remain unchanged.

**NOW, THEREFORE, in consideration of the premises and of the following mutual promises, covenants and conditions, the Parties hereto agree as follows:**

**OPERATIVE PROVISIONS**

1. **SUBJECT MATTER**

The purpose of this amendment to the Agreement (hereinafter referred to as "**Amendment**"), is to mutually agree upon the description and financial arrangements of the monitoring services.

1. **AMENDMENT TO THE AGREEMENT**

DESCRIBE THE MODIFICATIONS IN THE AGREEMENT

1. **RESPONSIBILITIES OF THE PARTIES AND INVESTIGATOR**

The Parties hereby agree that measures shall be taken to formally inform and obtain approval from the relevant ethical committee(s) and regulatory authorities (if applicable) of this change, as required by applicable legislation.

1. **MISCELLANEOUS**
	1. **Entire Agreement**

Upon entry into force of this Amendment at the Effective Date, this Amendment shall be incorporated into and deemed part of the Agreement and any future reference to the Agreement shall include the terms and conditions of this Amendment.

The Parties agree that, except for the sections of the Agreement specifically amended hereunder, all terms and conditions of the Agreement shall remain unchanged and remain in full force and effect.

* 1. **Applicable Law**

This Amendment shall be governed by and construed in accordance with the laws which govern the Agreement.

* 1. **Settlement of Disputes**

In the event of any disputes, controversies or claims arising from or in connection with this Amendment or the breach thereof, the Parties shall submit to the jurisdiction or dispute resolution provisions as set forth in the Agreement.

* 1. **Counterparts**

The Amendment is executed in three (3) original copies and each Party acknowledges having received an original. TO ADD DURING COVID [In the event that any signature is delivered by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such signature page were an original thereof.]

This Amendment is effective as of the date of last signature below OR Klik of tik om een datum in te voeren. (hereinafter referred to as "**Effective Date**").

OPTIONAL: APPENDICES

As of the Effective Date of the Amendment the Exhibits contained in the Appendices of the present Amendment shall form an integral part of the Agreement.

APPENDICES:

**Appendix 1:** Exhibit INSERT NUMBER OF THE EXHIBIT to the Agreement to ADD DESCRIPTION OF THE APPENDIX, e.g. include the description of the Services

**Appendix 2:** Exhibit INSERT NUMBER OF THE EXHIBIT to the Agreement to ADD DESCRIPTION OF THE APPENDIX, e.g. include the financial arrangements regarding such Services

**IN WITNESS WHEREOF, the undersigned by their duly authorised representatives**

|  |  |
| --- | --- |
| On behalf of **INSERT NAME PARTY**Name: Title: Date: | On behalf of **INSERT NAME PARTY**Name: Title: Date: |
| Read and acknowledged by:On behalf of **INSERT NAME PARTY**Name: Title: Date: | Read and acknowledged by:On behalf of **INSERT NAME PARTY**Name: Title: Date: |
| OPTIONALOn behalf of **INSERT NAME PARTY**Name: Title: Date: | OPTIONALOn behalf of **INSERT NAME PARTY**Name: Title: Date: |

# APPENDIX 1

**EXHIBIT INSERT NUMBER OF THE EXHIBIT - ADD DESCRIPTION OF THE APPENDIX**

DESCRIBE THE MONITORING SERVICES

*It is up to the monitors to describe the tasks to be performed, e.g.*

* *Who will draft the monitoring plan [CTC or is the monitoring plan to be provided by Sponsor?]*
* *Number of visits to be performed*
* *Which sites are going to be monitored*
* *Source Data Verification on site and/or remote monitoring*

# APPENDIX 2

**EXHIBIT INSERT NUMBER OF THE EXHIBIT - ADD DESCRIPTION OF THE APPENDIX**

**Monitoring fee**

In consideration for Institution’s monitoring activities pursuant to this Agreement and the monitoring plan, Sponsor shall pay UZ Leuven the sum of [amount in words] (AMOUNT €) Euros as follows:

After signature of the monitoring plan, a first invoice of €1600 will be made. As soon as monitoring activities start, Sponsor will be invoiced twice a year:

* First yearly invoice will be made at the end of Q1.
* Second yearly invoice will be made at the end of Q3.

In case of early termination of the Study/Agreement, the Sponsor agrees to pay on a pro rata basis for the actual visits that were monitored until the effective date of termination including the close out visit, even if this visit took place after the effective date of termination.

All amounts mentioned in the Agreement are exclusive of VAT and Kies een item.of institutional overhead and shall be paid for in addition.

VAT will be regulated in accordance with the provisions foreseen in the European Directives of 2008/8/EC and 2006/112/EC. The regulations valid at the time of invoicing will be applicable.

In case services provided under this Agreement should be subject to VAT, the UZ Leuven shall be entitled to charge VAT at the legal rate in addition to the fees stated in this Agreement, provided the VAT is stated separately on the invoice made out to Sponsor.

In case the invoices are addressed to a place outside of Belgium [Under the current provisions stated in the Directives mentioned above, Belgian VAT will currently not be charged because Sponsor is not a Belgian based corporation; reverse charges will be applicable.]

Payments shall be made to UZ Leuven within thirty (30) days upon receipt of the invoice to:

Name: Universitaire Ziekenhuizen Leuven

VAT identification number: BE 0419 052 173

Address: Herestraat 49, 3000 Leuven, Belgium

Payment currency: EUR

Payment Method: Bank transfer

Bank account holder: Universitaire Ziekenhuizen Leuven

Bank account number: 432-0017221-01

IBAN: BE43 4320 0172 2101

Bank name: KBC BANK, Brusselsesteenweg 100, 3000 Leuven, Belgium

Bank identifier code (SWIFT): KREDBEBB

# OPTIONAL: Possibility to add more appendices