: 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 NAME  INSERT ADDRESS  duly represented by INSERT NAME,  hereinafter referred to as the “**INSERT NAME (e.g. SPONSOR)**”, |
| AND | INSERT NAME  INSERT ADDRESS  duly represented by INSERT NAME,  hereinafter referred to as the “**INSERT NAME, (e.g. PARTICIPATING SITE or COMPANY)**”, |
| OPTIONAL  AND | INSERT NAME  INSERT ADDRESS  hereinafter 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**, the Parties mutually desire to amend, modify and restate certain terms and conditions of the Agreement regarding the Study;

**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 a change of VAT regime applicable to all invoices under the Agreement related to the Study.

1. **AMENDMENT TO THE AGREEMENT**

Since the PARTICIPATING SITE opted in the Agreement for the special regime on VAT as foreseen under the Decision 116.111 of February 21st 2011; by which it chose for the self-billing system; and now wishes to amend the VAT regime, the Parties agree that, as from the Effective Date of this Amendment, the normal regime on VAT shall be applicable on all invoices for reimbursement related to the Study.

As from the Effective Date, all invoices for reimbursement related to the Study shall be made out to: Universitaire Ziekenhuizen Leuven, Herestraat 49, 3000 Leuven, Belgium, VAT: BE0419.052.173.

All invoices will be sent to Universitaire Ziekenhuizen Leuven, INSERT DEPARTMENT OF PI, Herestraat 49, 3000 Leuven, Belgium.

After receipt of a complete and correct invoice, reimbursement for the invoice will be made within the ninety (90) days of receipt.

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: |
| OPTIONAL  On behalf of **INSERT NAME PARTY**  Name:  Title:  Date: | OPTIONAL  On behalf of **INSERT NAME PARTY**  Name:  Title:  Date: |

# OPTIONAL: APPENDIX 1

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

ADD APPENDIX

# OPTIONAL: APPENDIX 2

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

ADD APPENDIX

# OPTIONAL: Possibility to add more appendices