**ADDENDUM No.... TO THE CONTRACT BETWEEN THE FOUNDATION FOR BIOMEDICAL RESEARCH OF LA PAZ UNIVERSITY HOSPITAL, LA PAZ UNIVERSITY HOSPITAL, .................................... (LEAD INVESTIGATOR) AND ………………………….… (SPONSOR) FOR PERFORMANCE OF THE CLINICAL TRIAL…………………………………………………………………………………………….......................................................................................................“**

|  |  |  |  |
| --- | --- | --- | --- |
| **PROTOCOL CODE** |  | **HULP CODE** |  |

In Madrid, on …………………..

**BY AND BETWEEN**

**(\*) Change depending on the specific circumstances of the parties**

Of the one part, Mr/Ms.…………………..…………holder of Tax ID/ID No. ……………………….acting in the name and on behalf of ……………………………………….., (hereinafter, the **SPONSOR**), with registered office at ……………………………………….., and holder of CIF/VAT NUMBER/ID No. .................... being empowered for this act by deed of power of attorney No ………………., duly registered at the ………………. Companies Registry, executed before the Notary of the ……………………… Notarial Association, Mr/Ms. ................................... dated …………..

Of the one part, Mr/Ms. …………………………………. (name of the CRO's legal representative), holder of Tax ID/ID No. ……………………….as legal representative of …………………..……………… (CRO name), with registered office at ………………………….….……(CRO’s full address) and holder of CIF/VAT NUMBER/ID ………………..,(hereinafter, the **CRO**) acting in the name and on behalf of the **SPONSOR**(Full name, address and Tax ID Code of the SPONSOR - pharmaceutical laboratory, scientific company, or legal person), (hereinafter, the **SPONSOR**) authorised for this purpose under powers of attorney issued in ……………….. on ……………..(date), before the Notary, Mr/Ms……………………..

There is no exemption from the **SPONSOR**’s liability under **Royal Decree 1090/2015, of 4 December**, regulating clinical trials with medications, Research with medications’ Ethics Committees and the Spanish Clinical Trials Registry (hereinafter, **RD 1090/2015, of 4 December**).

**(\*) The Delegation of the Sponsor in the CRO must be notarised or bear the Hague Apostille.**

Of the other, Ms. Ana Coloma Zapatero, holder of Tax ID No. 29.151.547J, acting in the name and on behalf of the **FOUNDATION FOR BIOMEDICAL RESEARCH OF LA PAZ UNIVERSITY HOSPITAL**, (hereinafter, **FIBHULP**), with registered office at Paseo de la Castellana, 261, Madrid (28046) and holder of VAT NUMBER G83727057, under the powers of attorney issued in Madrid, on 26 December 2018, in the presence of the notary public, Miguel García Gil, under his record number 48.

Of the other, Mr. Rafael Pérez-Santamarina Feijóo, holder of Tax ID 35.243.627-Z, acting in the name and on behalf of the **MADRID HEALTH SERVICE** (hereinafter, **SERMAS**), for **LA PAZ UNIVERSITY HOSPITAL** (hereinafter, **HOSPITAL**), with registered office at Paseo dela Castellana, 261, Madrid (28046), in accordance with **RESOLUTION 385/2020, of 11 June**, of theDeputy Ministerfor Health Care, under powers of attorney in matters of procurement and economic-budgetary management.

And of the other part, Mr/Ms ………………………, holder of Tax ID No. ………………..acting in their own name and on their own behalf (hereinafter, the **LEAD INVESTIGATOR**), with address for the purposes of notifications at the **……………………. SERVICE** in the **HOSPITAL** located at Paseo de la Castellana, nº 261 de Madrid (28046)

The **PARTIES** mutually acknowledge that they have the necessary capacity to be bound by this Contract (hereinafter, the **PARTIES**)

**THEY STATE**

**1.** Whereas, due to: **(causes for the change)**

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Therefore, the parties have agreed to modify the text of clauses .........................:

**2.** The remaining clauses of the agreement remain in force and are unchanged by the present addendum.

**3.** Should a copy of this Agreement become available in any other language; the Spanish version shall prevail.

**4.** The **SPONSOR** shall pay the Foundation **€1.000** for Administrative and Contract Management Expenses on signing the addendum.

In witness where of and as proof of consent, the Parties sign the present document in three (3) copies to a single effect.

For the **SPONSOR**, For the **CRO** for and on behalf of the **SPONSOR**

(only if acting for and on behalf of the sponsor)

Mr/Ms ………………….. Mr/Ms …………………

For the **BIOMEDICAL RESEARCH FOUNDATION**

## OF LA PAZ UNIVERSITY HOSPITAL (FIBHULP)

Ms. Ana Coloma Zapatero

## For LA PAZ UNIVERSITY HOSPITAL

Dr. Rafael Pérez-Santamarina Feijóo

For **THE LEAD INVESTIGATOR**

Dr. ...........................................