**AGREEMENT BETWEEN LA FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL UNIVERSITARIO LA PAZ, HOSPITAL UNIVERSITARIO LA PAZ, ................................. (PRINCIPAL INVESTIGATOR) AND ………..…………………… (SPONSOR) FOR THE CONDUCT OF THE CLINICAL TRIAL ENTITLED: "………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………...…...."**

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

In Madrid, on …of ………………., 2023

**BY AND BETWEEN**

**(\*) To be adapted according to the specific situation of the parties to the agreement.**

On the one part, Mr/Ms ................................... with tax number / ID no. ..................... acting on behalf of ..............................................., (the “**SPONSOR**”), with registered office at .............................. of .......................... and with Tax Code no./VAT NUMBER/ID. no. ...................., being empowered for this act by virtue of power of attorney no. , duly registered in the Mercantile Register of ................................ , granted before the Notary Public of the Notaries Association of Mr..................................... on ........................

On the other part, Mr/Ms/.................................... with tax number / ID no. ..................... as legal representative of ........................... (name of the **CRO**) with registered office at .............................. of .......................... and Tax Code no./VAT NUMBER/ID. no. .................... (hereinafter **CRO)** acting for and on behalf of the **SPONSOR**, authorised for this purpose, in accordance with the powers of attorney issued at ....................., dated ...................., before the notary Mr/Ms.................................. This does not relieve the **SPONSOR** of its responsibilities under **RD 1090/2015 of 4 December**, which regulates clinical trials on medicinal products, the Ethics Committees for Research with medicinal products 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 carry the Apostille of The Hague.**

On the other part, Ms Ana Coloma Zapatero, with tax number 29.151.547-J, acting on behalf of the **FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL UNIVERSITARIO LA PAZ**, (“**FIBHULP**”), with registered address at Paseo de la Castellana, nº 261, Madrid (28046) and with tax code no. G83727057, in accordance with the powers of attorney issued in Madrid, dated 26 December 2018, before the notary Mr Miguel García Gil, with record no. 2324.

On the other part, Mr Rafael Pérez-Santamarina Feijóo, with tax number 35.243.627-Z, acting for and on behalf of the **SERVICIO MADRILEÑO DE SALUD** (“**SERMAS**”), for the **HOSPITAL UNIVERSITARIO LA PAZ** (the “**HOSPITAL**”), with registered address at Paseo de la Castellana, nº 261 in Madrid (28046), in accordance with **RESOLUTION 342/2021, of 13 September**, of the Vice-Ministry of Health Care and Public Health and Directorate General of the Madrid Health Service.

And on the other part Mr/Ms ......................, with tax number ..................... acting in his/her own name and right (the “**PRINCIPAL INVESTIGATOR**”), with address, for notification purposes, at the **..................... SERVICE** of the **HOSPITAL** located at Paseo de la Castellana, nº 261, Madrid (28046)

The Parties (“**THE PARTIES**”) acknowledge that they have the mutual capacity to be bound by this Agreement.

**THEY STATE**

**1.** That due to: **(causes of change)**

* .....................................................................
* …………………………………………………
* …………………………………………………

The parties have therefore agreed to amend the text of the following 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 **FIBHULP** **ONE THOUSAND EUROS** (**€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 and equally binding.

For the **SPONSOR**, For the **CRO** in the name and on behalf of the **SPONSOR**

  **(only if acting for and on behalf of the Sponsor)**

Mr/Ms ........................... Mr/Ms ....................................

## For FUNDACIÓN DE INVESTIGACIÓN BIOMÉDICA

## DEL HOSPITAL UNIVERSITARIO LA PAZ (FIBHULP)

Ms. Ana Coloma Zapatero

## For HOSPITAL UNIVERSITARIO LA PAZ

Dr. Rafael Pérez-Santamarina Feijoó

For the **PRINCIPAL INVESTIGATOR**

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