ADDENDUM No. ....... to the Clinical Trial Contract entitled: ".............................................................................................................................................................................................................................................................................................................................................................................". Protocol Code ...............................

Madrid, a de ....... de 20....

The reason for this Addendum is: ....................................................................................

JOINED

On the one hand, Mr. ........................................., on behalf of ............................................... with N.I.F. .................. with registered office at C/ ............................................ (Spain) and with C.I.F. no. ................. (hereinafter CRO or PPD), acting in its own name and in the name and on behalf of ...................................., (hereinafter PROMOTER), with N.I.F. ........................... and registered office at ......................................................... authorised for this purpose, in accordance with the powers of attorney issued at ..............., dated .. of .................. of 20.., before the notary .............................. Not exempting the responsibility incumbent on the PROMOTOR according to RD 1090/2015, whereby clinical trials with medicines are regulated.

On the other hand, Ms. Emma Méndez Calleja, with NIF 71.512.802-Y, acts on behalf and representation of the FUNDACIÓN DE INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESÚS (hereinafter FUNDACIÓN), with registered office at Avda. Menéndez Pelayo, 65 (28009 Madrid), with Tax Identification Number G-85289924, authorised for this purpose in accordance with the powers of attorney issued in Madrid on 18 March 2021 before the Notary Public of Madrid, Ms Carmen Boulet Alonso, with number 604 of her protocol, C/Alfonso XII, nº 20 (28014 - Madrid).

Of the other, D. Cesar Adolfo Gómez Derch, with NIF 50.825.913F, in his capacity as Managing Director of the HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESÚS (hereinafter, the "HOSPITAL"), with CIF no. Q-2877003-J, with address at Avda. Menéndez Pelayo nº 65 (28009 Madrid), in the name and on behalf of the aforementioned Hospital.

And on the other hand, Dr. ...................................... with NIF nº .................... acting in his own name and right, as Principal Investigator (hereinafter, the "PRINCIPAL INVESTIGATOR"), with address for notification purposes, at the .................................. Service of the HOSPITAL INFANTIL UNIVERSITARIO NIÑO JESÚS, located at Avda. Menéndez Pelayo, nº 65 (28009 Madrid).

Mutually acknowledging, as they intervene, the necessary legal capacity to contract and bind themselves,

MANIFEST

I. That on .. of ......... .. of 20.., the PROMOTER, the FOUNDATION, the HOSPITAL and the PRINCIPAL INVESTIGATOR, signed a contract for the performance of the Clinical Trial whose title appears in the heading and protocol code ........................ (hereinafter, the "Contract").

II. That due to the Amendment ..................... to the Protocol dated ... of ............ of 20.. which has the favourable report issued by the CEIm of the Hospital ...................................... dated ... of .................. of 202.. and the corresponding authorisation of the AEMPS dated ... of .................. of 20.. to said Amendment .. the TRIAL BUDGET is impacted and the parties wish to amend it in accordance with the changes to the protocol.

III. that it is the wish of the parties to amend the said clinical trial contract ................................................................, which was approved by the IRB of ........................ dated .................. of ............ of .....................\_\_\_\_.

By virtue of the foregoing, the parties hereto enter into this document in accordance with and subject to the following

STIPULATIONS

FIRST. The parties agree to amend and replace the Economic Report (Annex 1) accompanying the initial Contract, with the Economic Report (Annex 1) attached to this Addendum 1.

SECOND. The Parties agree to amend the clause of the Contract at item ..... as follows:

Where it read:

.......

..................................................................................................................................................................................................................................................................................................................................................................................

Now reads:

..... .............................................................................................................. ...........................................................................................................................................................................................................................................................................................................................................................................................................................................................

THIRD: The PROMOTER shall pay the amount of One Thousand and sixty-one Euros //1,061.00 ¤// to the FOUNDATION as Administrative and Management Expenses of this Addendum to the Contract upon signature of the Contract.

FOURTH. - The parties ratify the full validity of all the clauses contained in the contract dated ... of ............ of 20.., for the conduct of the Clinical Trial whose conditions have not been replaced or repealed by what has been agreed in this Addendum.

And for the record, the parties hereto sign this Addendum 1 by electronic signature at the place and date indicated in the heading.

For the CRO and the PROMOTER, For the FOUNDATION,

D. ................................ Ms. Emma Méndez Calleja

Legal Representative Director

For the HOSPITAL, For the PRINCIPAL INVESTIGATOR,

D. César Adolfo Gómez Derch Dr. ..............................................

Managing Director