**ADDENDUM X TO THE CLINICAL TRIAL/OBSERVATIONAL STUDY/CLINICAL INVESTIGATION WITH A MEDICAL DEVICE BETWEEN THE HOSPITAL (CENTRE), THE FOUNDATION (MANAGEMENT BODY) AND (*SPONSOR*)**

**In (Place), on (Date)**

**BY AND BETWEEN**

The party of the first part, Mr/Ms **XXXXXXXXXXXXXXXXX**, holder of Tax Identification Number **XXXXXXXXX**, Managing Director of the **XXXXXXXXXXXXXXXXX** Hospital, (hereinafter, Centre), with address for the purposes of this contract at **XXXXXXXXXXXXXXXXXXXXXXXXXXXXX**, in his/her capacity as the representative of the Centre.

The party of the second part, Mr/Ms **XXXXXXXXXXXXXXXXX**, holder of Tax Identification Number **XXXXXXXXX**, Managing Director of the **XXXXXXXXXXXXXXXXX** Foundation, (hereinafter, Management Body), holder of Tax Identification Code **XXXXXXXXX** and with address at **XXXXXXXXXXXXXXXXXXXXXXXXXXXXX**.

The party of the third part, Mr/Ms **XXXXXXXXXXXXXXXXX**, holder of Tax Identification Number **XXXXXXXXX**, on behalf of, and representing **XXXXXXXXXXXXXXXXX** (hereinafter, Sponsor), in his/her capacity as **XXXXXXXXXX** and the legal representative of said body.

The appearing parties acknowledge the necessary legal capacity to formalise this addendum and, for to this effect,

**THEY STATE**

**I -** That on the **XX of XXXXXX20XX,** the parties signed an agreement to carry out the **CLINICAL TRIAL/OBSERVATIONAL STUDY/CLINICAL INVESTIGATION WITH A MEDICAL DEVICE**, called “Title of the study” with protocol code **“**Code**”**, the principal investigator of said study is Dr XXXXXXXXXXXXXXXXX, holder of Tax Identification Number **XXXXXXXXX** of the **XXXXXXXXXXXXXXXXX** Service/Clinical Management Unit of the Centre.

**II -** That in accordance with the *manifest XXXXXXXXX/the clause XXXXXXXXX* of said contract, XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX.

**III -** That, due to a change, it has become necessary to modify the provisions of said section.

**IV -** In the event of said circumstances, the parties agree to sign this present document, which constitutes an addendum to the **CLINICAL TRIAL/OBSERVATIONAL STUDY/CLINICAL INVESTIGATION WITH A MEDICAL DEVICE** agreement, which shall be governed by the following

**CLAUSES**

**FIRST - PURPOSE**

The purpose of this present addendum is to modify XXXXXXXXXXXXXXXXXXXXXXXXXXXXX of the signed agreement.

Specifically, XXXXXXXXXXXXXXXXXXXXXXXXXXXXX.

**SECOND - MANAGEMENT COSTS**

The management costs incurred by this present addendum, formed of the administrative management costs are fixed at \_\_\_\_\_ Euros (XXX), plus the corresponding VAT. Said amount shall be paid by the Sponsor or the CRO where appropriate, to the Management Body upon signing this present contract, with the bank details being those included in the agreement which was initially signed.

**THIRD - MAINTENANCE OF THE REMAINING PROVISIONS**

The remaining provisions that have not been expressly modified in this addendum retain their validity.

**FOURTH - ENTRY INTO FORCE**

This addendum will enter into force on the date it is signed, although it will be applicable to all subjects participating in the clinical trial/study/investigation. Notwithstanding this, as a consequence of this present addendum none of the invoices previously issued during the clinical trial/study/investigation shall be rectified, annulled or modified, and, under no circumstances shall amounts corresponding to concepts included, approved, and executed prior to the processing of this present addendum, be refunded or discounted.

In witness whereof, and for all pertinent purposes, the parties sign **XXXXXXX** copies of this present document, for a single purpose, in the place indicated in the heading, with this forming an integral part and indivisible part of the agreement signed by the aforementioned entities, on the date stated.

**The Centre** (*Complete with as many centres as are included in this present addendum)*

Signed: Mr/Ms \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**The Management Body The Sponsor**

Signed: Mr/Ms \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signed: Mr/Ms\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Read and understood by the Principal Investigator:**

*(Complete with as many centres as are included in this addendum)*

Signed: Mr/Ms \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Explanatory notes:*

1. *This addendum is signed by the clinical trial/study/investigation sponsor, the representative of the centre where it will be conducted and the management body. The principal investigators are not part of the addendum. Notwithstanding this, as a display of their commitment to the development of the clinical trial/study/investigation, they can sign the addendum, as a sign of their understanding and acceptance of its contents. Due to not forming part of the addendum, said signature will not be necessary for the initiation of the activities arising from it, nor should it be considered for the addendum’s entry into force.*
2. *In the event that it concerns a modification, which implies an increase in the budget of the clinical trial/study/investigation, annexes 1 and 2 of the sole model contract must be completed, only for the amount by which the financial report increases, with regards to the report that was initially signed, in said situation, said financial report will not substitute the one that was initially signed, but will complement it.*
3. *In the event of a budget decrease, a new financial report will be signed, completing annex 1 and 2. In said event, the new financial report will substitute the one that was initially signed.*