

Standard Sub-site Agreement for Clinical Trial

(referred to as "Sub-site Agreement")

Preamble

WHEREAS this Standard Sub-site Agreement for Clinical Trial ("sub-site Agreement") was approved by the Danish Regions on May 1, 2012 as version 1;

WHEREAS this Sub-site Agreement shall be used between two parties, both being public institutions in Denmark.

WHEREAS the purpose of using this Sub-site Agreement is to enable the Parties, as defined in Appendix A to enter into an agreement under standardised legal terms;

WHEREAS the main body of this Agreement may not be changed;

WHEREAS the Parties on a project by project basis agree on the specific work and payments to be executed under this Sub-Site Agreement, and define these in details using Appendix A-E and signing the complete Sub-Site Agreement using Appendix F.

WHEREAS Sponsor, Institution and Site have agreed that Site shall perform part of the work contracted for under this Sub-site Agreement and outlined in Appendix A-E.

WHEREAS it has been agreed between the Institution and Sponsor, defined as outlined in Appendix B, that Institution will be the co-ordinator in Denmark for the Study, defined as outlined in Appendix B and will subcontract a number of institutions in Denmark.

WHEREAS the Institution wishes to engage Site, defined as outlined in Appendix A in participation of the execution of the Study, defined as outlined in Appendix A, this Sub-site Agreement is made and entered into by and between Institution and Site.

NOW THEREFORE in consideration of the premises and the mutual promises and covenants expressed herein, the Parties agree as follows:

1. Objective of this Sub-site Agreement

1.1 The objective of this Sub-site Agreement is for Site to contribute to the achievement of the requirements of the Sponsor Contract, defined as outlined in Appendix B together with the Institution in accordance with the terms and conditions as stated in this Sub-site Agreement.

2. Terms and Conditions

2.1 The terms and conditions, obligations and rights of the Sponsor Contract shall apply to the Parties subject to the modifications according to this Sub-site Agreement. Unless otherwise agreed, the Institution and the Site shall be bound mutatis mutandis by the same terms and conditions, obligations and rights of

the Sponsor Contract (Appendix B), the work outlined in the Protocol (Appendix C) and the work outlined in Appendix D.

3. Payments

3.1 Site shall submit invoices for services provided under the Sponsor Contract (enclosed as Appendix B) to Institution. Such invoices shall be received by Institution no later than one week before Institution's invoicing of Sponsor as outlined in Appendix D. Payments to Site from Institution will be made without undue delay after receipt of payment under the Sponsor Contract.

3.2 In recognition for tasks carried out by Site in fulfilment of the Sponsor Contract, the Sponsor will provide the Site with payments, if relevant, as outlined in Appendix D and E.

3.3 The amounts in Appendix D include applicable taxes and other indirect costs.

3.4 Institution will pay the invoices by bank transfer according to Appendix E.

3.5 In case the Study, defined as outlined in Appendix A, is discontinued prematurely or in case the Sponsor Contract (Appendix 2) is terminated, the total sums payable pursuant to this Sub-site Agreement shall be equitably prorated for actual work performed to the date of termination including any reasonably non-cancellable costs and start-up costs, with any unexpended funds previously paid being refunded.

3.6 The stipulated compensation in Appendix D constitutes Site's only right to payment for the services rendered.

3.7 Site accepts that the payments made by Institution pursuant to this Sub-Site Agreement, are pass-through payments, and Institution shall only be obligated to make payments to Site, provided that Institution has actually received payments from Sponsor.

4. Liability/Indemnification obligations

4.1 Site shall have the same liability and indemnification obligations as Institution, towards Sponsor as described in the Sponsor Contract (Appendix 2) between Sponsor and Institution.

5. Work to be completed under this Sub-site Agreement

5.1 The work to be performed under this Sub-site Agreement shall be executed as described in, and be deemed to be completed in accordance with the description in Appendices B, C and D.

5.2 Site agrees to provide the Institution with data and reports in accordance with the Sponsor Contract (Appendix B) and as outlined in the Protocol (Appendix C). However, the Site shall timely provide such data and reports as agreed in Appendix D, allowing the Institution to prepare joint data and reports to Sponsor.

5.3 In case the Study is terminated or when this Sub-site Agreement is completed, all Data, as defined in Appendix B that have been generated up to this point in time are to be handed over to the Institution by the Site.

6. Termination

6.1 This Sub-site Agreement shall be deemed to be terminated immediately if the Sponsor Contract (Appendix B) is terminated.

6.2 Institution shall without undue delay inform Site if the Sponsor Contract (Appendix B) is terminated.

7. Applicable law and Venue

7.1 This Sub-site Agreement shall be governed by the laws of Denmark.

7.2 The Parties consent to the competent courts of Denmark for the resolution of all disputes or controversies between the Parties hereto that the Parties are unable to settle amicably.

8. Effective date of the Sub-site Agreement

8.1 This Sub-site Agreement shall become effective upon signature of the Sponsor Contract (Appendix B) between Sponsor and Institution.

8.2 In case this Sub-site Agreement has not been signed at the time outlined in 8.1, it shall become effective retroactively upon signature.

11. Amendments

11.1 Amendments or changes to this Sub-site Agreement shall be made in writing and signed by the duly authorised representatives of the Parties.

12. Signatures

12.1 Both the Institution appointed signee(s) and Principal Investigator shall sign this Agreement in order for it to be legally binding.

12.2 This Agreement is executed in three counterparts, each of which shall constitute the original.

Appendix A – The Parties

[Insert name and address]

(in this Sub-site Agreement jointly referred to as “Institution”), with

[Insert name]

acting as national coordinator in Denmark (hereinafter “National Coordinator”).

and

[Insert name and address]

(hereinafter “Site”).

With

[Insert name]

acting as investigator on behalf of Site (hereinafter “Investigator”).

- also individually referred to as a “Party” and collectively as the “Parties”.

The Institution has entered into a contract with

[Insert name of the Sponsor]

(in this Sub-site Contract referred to as the “Sponsor”) on

[Insert date]

for the Study named

“ _____ ”

and in this Sub-site Agreement referred to as “the Sponsor Contract”. The Sponsor Contract is formally incorporated into this Sub-site Agreement as Appendix B.

Appendix B – Sponsor Contract copy

Appendix C – Protocol copy

(“Protocol”)

Appendix D – Work and Budget as agreed between Site and Institution

(Can be left blank if not relevant)

[If the work to be carried out by the Site deviates from the work to be performed according to the Protocol, the changes must be described in this Appendix].

Site must invoice Institution by the following dates according to section 5.1 of the Sub-site Agreement:

_____ [insert dates] _____.

Appendix E – Payment details

(Can be left blank if not relevant)

The payment details for transfer of payments:

To: ____ [Site; not investigator] _____

Sort code and account number: _____

Account or payment reference: _____

Appendix F – Signatures

We hereby sign the Sub-site Agreement and verify that the Standard Sub-site Agreement section 1 to 12 in its entirety has not been modified.

On behalf of:

Site:

Institution:

Date

Date

[Insert name]

[Insert name]

[Insert title]

[Insert title]

I hereby acknowledge that I have read and agree with the terms of this Sub-site Agreement, and that I will act and perform my duties in the Study in accordance therewith.

Investigator

Date:

[Insert name]

[Insert title]