The Capital Region of Denmark

AGREEMENT ON CO-FINANCED RESEARCH

(hereinafter the "Agreement")

Between

Righospitalet - Blegdamsvej
Department of Anaesthesia 6011 & Trauma Centre,
Centre of Head and Orthopaedics,
Copenhagen, Denmark

Inge Lehmanns Vej 6, opgang 6, 1. sal
2100 København Ø
Danmark

(Also referred to as Sponsor)
Represented by Jacob Steinmetz, MD, Ph.D.

and

[Department]

[Address]

(Also referred to as Site)
Represented by Primary Site Investigator [name, title]

(Separately, Sponsor and Site are also referred to as "the Party" and jointly "the Parties").

The Capital Region of Denmark

1. Background and purpose of the collaboration

1.1. The Parties have each developed special expertise in trauma treatment. The Parties have an interest in expanding their knowledge in supplemental oxygen treatment in the trauma population.

1.2. Under this Agreement the Parties shall be a part of the clinical study (TRAUMOX2) with the title "Comparing Restrictive vs. Liberal Oxygen Strategies for Trauma Patients: The TRAUMOX2 Trial" which will be specified in more detail in the study protocol including amendments (appendix 1) and any applicable law.

1.3. Whereas Rigshospitalet on behalf of the Parties will be the Sponsor for the purpose of the European Directive 2001/20/EC in connection with the conduct of the Study.

1.4. TRAUMOX2 is initiated by a research group of medical doctors in Department of Anaesthesia 6011 & Trauma Centre, Centre of Head and Orthopaedics, Rigshospitalet, Copenhagen, Denmark.

1.5. The randomized, controlled trial will be conducted in compliance with the published trial protocol, the Helsinki Declaration in its latest version, the Good Clinical Practice (ICH-GCP) guidelines and national laws in the participating country. The protocol will be sent to the Danish Committee on Health Research Ethics for the Capital Region of Denmark and the Danish Medicines Agency. Rigshospitalet have written the protocol in accordance with the SPIRIT 2013 statement and will register the trial in the www.clinicaltrials.gov and European Drug Regulating Authorities Clinical Trials (EudraCT) registries before the enrolment of the first participant. In case of a protocol amendment, an agreement between Sponsor and Site must be reached. No substantial deviation from the protocol will be implemented without prior review and approval of the regulatory authorities except where it may be necessary to eliminate an immediate hazard to the trial participants. In such case, the deviation will be reported to the authorities as soon as possible.

2. Obligations of the collaborators

2.1. Obligations for both Parties:
- 2.1.1. The Parties are both responsible for following the protocol
- 2.1.2. The Parties are each responsible for enrolment at their own site

2.2. Obligations for Sponsor:
- 2.2.1. Sponsor will be responsible for analysing and managing the complete dataset for the publication of the multisite study.
- 2.2.2. Sponsor will register the study and its results in one or more public clinical study registry(ies), according to national/international use, including both positive, negative and inconclusive results

2.3. Obligations for Site:

2.3.1. The Primary Site Investigator will be responsible for recording different types of adverse events and serious adverse events as outlined in the trial protocol. Sponsor will be responsible for notifying the authorities on this matter.

3. Economics

3.1. The study is partially funded by the Novo Nordisk Foundation over a 4-year grant period. The Novo Nordisk Foundation is not involved in the management of the study itself, or the decision to submit the manuscript for publication, but will be mentioned as *"The work presented in this article is supported by Novo Nordisk Foundation grant NNF20OC0063985".*

3.2. The Parties acknowledge that Sponsor will only provide partial funding as specified in the budget. (Appendix 2)

4. Intellectual Property Rights

4.1. For the purpose of the Agreement, the right of ownership to any software, inventions, patent applications, patents, know-how, data, results, intellectual property controlled or owned by either Party prior to the date of the Agreement or intellectual property generated by either Parties independent of the Study and controlled or owned by that Party (hereinafter "Background Knowledge"), shall belong to the Party owning such Background Knowledge prior the conclusion of the Agreement

4.2. During the Study, the Parties have a mutual royalty-free, non-exclusive license to each other's Background Knowledge and Results in connection with the research activities within the Study – to the extent the Party who owns such Background Knowledge is at liberty to grant such access right. The license neither involves the right to commercial exploitation nor rights to a third party. The access right expires without further notice and in every respect no later than upon expiry or termination of the Agreement and/or after publication has taken place, whichever occurs first.

4.3. The right of ownership to inventions generated in direct connection to the Study, hereunder any, theories, methods, knowhow, data, regardless of form (hereinafter "Results"), shall belong to the Party whose employees have generated such Results. Results created jointly by the Parties shall be jointly owned in shares corresponding to the Parties intellectual contribution in generating the Results ("Joint Result"). If the respective contributions of the Parties cannot be documented, the Joint Results shall be owned jointly in equal shares.

4.4. Any Results, generated in direct connection to the Study, capable of protection via patent law, trademark law, design law, or any other legally binding protection (hereinafter "Intellectual Property") shall belong to the Party whose employees have generated such Intellectual Property. Intellectual Property created jointly by the Parties shall be jointly owned in shares corresponding to the Parties intellectual contribution in generating the Intellectual Property ("Joint Intellectual Property"). If the respective contributions of the Parties cannot be documented, the Joint Results shall be owned jointly in equal shares. Expenses for the patent protection process and continues maintenance must correspond to the respective shares of the Parties.

4.5. All forms of commercial use of Joint Results and Joint Intellectual Property shall require agreement between the Parties.

4.6. The Parties are both granted a royalty-free, non-exclusive, perpetual license to use all Results and Intellectual Property for further non-commercial educational, research and patient treatment purposes.

5. Monitoring

5.1. The Study will be monitored by the Parties' respective local GCP-unit.

5.2. Sponsor is obliged to have the opportunity to do initiate monitoring and audit at Site if necessary. In addition, the applicable authorities are obliged to being able to do inspections at both Site and Sponsor.

6. Confidentiality

6.1. All information received by one Party from the other Party in connection with the Study marked confidential or which by its nature would be considered confidential (hereinafter "Confidential Information") shall only be used for the completion of the Study and shall not without the written consent of the other Party be passed on to individuals not taking part in the Study.

6.2. A Party's obligation to treat Confidential Information as confidential apply to all individuals who through employment or other association with the Party gain access to the other Party's Confidential Information.

6.3. A Party's duty of confidentiality as set out in Clauses 5.1 and 5.2 shall not apply to Confidential Information that:

- at the time of receipt was or later became publicly available through no fault of the receiving Party;
- was already known by the receiving Party as documented by written evidence;
- was received without any restrictions regarding confidentiality from a third party who was entitled to pass on the information in question;

- a Party has developed independently of their participation in the Study.
- is required to be disclosed by law, regulatory or government authority.

6.4. The duty of confidentiality shall terminate 3 years after expiration or termination of the Agreement. However, obligations of confidentiality in respect of any personal data of study subjects shall survive the termination of this Agreement indefinitely.

7. Publication

7.1. Multisite publication:

7.1.1. The Study is intended to lead to a multisite publication. For the purpose of a multisite publication Sponsor will take initiative to form a steering committee. The members and rules of the steering committee will be defined by the protocol.

7.1.2. Both the members of the steering committee and the Primary Site Investigator (active) will be listed as co-authors in the multisite publication, as long as Site has enrolled at least 1 patient. In cases involving a Prehospital Site Investigator (active) they will also be listed as co-authors.

7.1.3. In addition, top-enrolling sites will be able to designate one additional co-author for every completely documented 100 patients. Each contributing centre can designate a reasonable number of active collaborators that participates in the study administration. These collaborators will be mentioned in the TRAUMOX2-study group and will be trackable via PubMed.

7.2. Independent publication:

7.2.1. Both Parties shall be entitled to independently publish their own Results and Data after the multisite publication or 12 months after the last follow-up visit by the last patient, whichever comes first.

7.2.2. All independent publications must reference the multisite publication and acknowledge the work done by TRAUMOX2.

7.3. For review purposes, the Party who wishes to publish Results, shall notify the other Party at least 30 days prior to the intended time of publication and forward the text and any additional material the Party wishes to publish. Until 30 days after receipt of the notice, the receiving Party can request the deletion of any Confidential Information contained in the publication, and that the publication is postponed by up to a total of 90 days from the date of receipt, provided that the Party proves that the postponement is important for the Party's prospects of acquiring protection of intellectual property rights contained in the publication.

7.4. Authorship of both multisite and independently published Results and Data must concur with, and be based on, the criteria of the ICMJE.

7.5. If one of the Parties allocates a PHD student to participate in the Study, the Parties shall respect the defence of the PHD in connection with publication of Results and Data.

8. Breach

8.1. If a Party commits a serious breach or repeatedly breaches its obligations under this Agreement and the breach has not been remedied within 15 days from request by the other Party to remedy such breach, the other Party shall be entitled to terminate the Agreement.

8.2. Neither Party shall be liable to the other Party or shall be in default of its obligations hereunder if such default is the result of Force Majeure.

8.3. If a Party terminates the Agreement due to a breach as described in 7.1, said Party can claim compensation for the loss caused by the breach.

9. Force Majeure

9.1. Either Party shall be excused from performing its obligation with respect to the performance under this Agreement if their performance is delayed or prevented by any cause beyond such Party's control, including, but not limited to, terrorist acts, fire, explosion, war, civil strife, riots, strike, lockout or major/regional power or utility supply failure.

9.2. Performance shall be excused only to the extent of and during the reasonable continuance of such disability. Any deadline or time for performance specified in this Agreement which falls due during or subsequent to the occurrence of any of the disabilities referred to herein shall be automatically extended for a period of time equal to the period of such disability.

9.3. Each party shall promptly notify the other party in writing upon becoming aware of an event of force majeure as well as the expiration thereof. However, if the force majeure persists for a period of one (1) month after receipt of notice, such other party shall be entitled to terminate this Agreement in writing without further notice.

10. Liability

10.1. The Parties shall be mutually responsible for the design of the Protocol.

10.2. The Parties shall not provide any guarantee and cannot be held liable if their performance in connection with the completion of the Study does not lead to a specific result.

10.3. A Party shall be liable for negligence or intentional neglect of its obligations under the Agreement.

10.4. The liability of one Party to compensate the other Party shall not apply to consequential losses such as production interruptions, and other loss of turnover/profit or other indirect losses.

11. Insurance

11.1. The Parties are obligated to take out adequate clinical trial insurance or make alternative arrangements (including programmes of self-insurance) as necessary and required by applicable regulatory requirements to cover their participation in the Study.

12. Data Protection

12.1. The Parties acknowledge and agree that the Parties are separately responsible for complying with applicable data protection law. If any personal data is to be processed on behalf of the other party during the performance of the Study, the regulations regarding the processing must be agreed on in a separate written agreement between the Parties.

13. Amendments to the Agreement

13.1. Any amendments to the Agreement shall be in writing and be signed by both Parties.

13.2. The Agreement shall constitute the full basis for agreement concerning the legal aspects of the Study. Any attachments to which a reference is made shall constitute an integral part of the Agreement. In case of discrepancies regarding any legal aspects between the terms and conditions of the Agreement and any such attachments the Protocol, the terms and conditions of the Agreement shall prevail. In case of discrepancies regarding any clinical aspects between the terms and conditions of the Agreement and any such attachments the Protocol, the terms and conditions of the Protocol shall prevail.

14. Notices

14.1. Notices regarding the Agreement shall be forwarded to:
Sponsor:
- INSERT NAME: INSERT NAME, ADDRESS AND E-MAIL, IF APPLICABLE

Site:
- INSERT NAME: INSERT NAME, ADDRESS AND E-MAIL, IF APPLICABLE

15. Term and Termination

15.1. Except for the provisions of the Agreement that according to their content are intended to be in effect for longer, the Agreement shall expire when the Study has been completed, cf. the Protocol.

15.2. Both Parties can terminate the Agreement with one month written notice to the other Party, or in accordance with clause 7.1.

16. Disputes

16.1. This Agreement shall be governed by and construed and enforced in accordance with the laws of the defendant. All disputes arising out of this Agreement will be subject to the exclusive jurisdiction and venue of the competent court in the country of the defendant and each Party hereby consents to the personal jurisdiction thereof.

Signatures

Sponsor: Per Jørgensen Deputy Director	Site: [Name] [Title]
On behalf of Rigshospitalet – Blegdamsvej	On behalf of [Department, hospital]
Date:	Date:
_____	_____

I hereby acknowledge that I have read and agree with the terms of this Agreement

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