Standard Clinical Trial Agreement

This Clinical Trial Agreement ("Agreement"), effective on the date of publication in the Register of contracts ("Effective Date") is made by and between;

Institution:

Fakultní nemocnice u sv. Anny v Brně

Pekařská 664/53, 656 91 Brno, Czech Republic

Identification number: 00159816

Represented by Ing. Vlastimil Vajdák, Director

(hereinafter called "Institution")

Represented by

[redacted]

DOB: [redacted]

Adress: [redacted]

(hereinafter called "Investigator")

[redacted], *an employee of Fakultní nemocnice u sv. Anny v Brně* will be responsible for the performance of the Study on behalf of the Institution

and

Sponsor:

Rigshospitalet

Blegdamsvej 9

2100 Copenhagen

Business Registration No.: 29190623

(hereinafter called "Sponsor")

The Institution and Sponsor are hereinafter each individually referred to as a "Party" and collectively referred to as the "Parties".

Preamble

WHEREAS Sponsor is the regulatory Sponsor of the clinical multi-centre study regarding **[Restriction of IV fluids]**, (hereinafter defined as "the Study Drug") as defined in the protocol entitled **[The conservative vs. Liberal Approach to fluid therapy of Septic Shock in Intensive Care (CLASSIC) Trial]**, with the version no. [2.1] dated [03 05 2018] a copy of which is incorporated herein by reference as Appendix A, (hereinafter defined as "the Study") and wishes to enter into an agreement with Institution; and has requested Principal Investigator

to conduct the Study according to this Agreement and it's Appendices, the Protocol including subsequent Protocol amendments.

WHEREAS, Institution is equipped and authorized to undertake the Study and Principal Investigator have agreed to perform the Study on the terms and conditions hereinafter set forth.

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

1. Obligations of the Parties

1.1 Authorizations

1.1.1 The Sponsor shall be responsible for obtaining and maintaining approvals from the Danish Medicines Agency and Data Protection Agency for the conduct of the Clinical Trial. Institution/Principal Investigator shall assist Sponsor in obtaining all necessary approvals from the Ethics Committee, hereunder but not limited to the Protocol and its amendments and informed consent form, and relevant regulatory authorities.

1.1.2 In the event that EC requires amendments in the Protocol or informed consent form, such amendments shall be agreed upon by both the Institution/Principal Investigator and Sponsor and be documented in writing.

1.2 Conduct of Study

1.2.1 The Parties shall conduct the Study in accordance with the Protocol and its amendments, the terms of this Agreement, and the terms and conditions of the approval of relevant authorities. Institution/Principal Investigator shall adhere to separate manuals and specific procedures provided by Sponsor applicable for conducting the Study.

1.2.2 Institution/Principal Investigator shall be fully informed of the Protocol and the Study Product. Sponsor shall provide all relevant clinical pharmacology and toxicology information and advice to Institution/Principal Investigator, which are required for the proper planning and conduct of the Study. Such information will include the Investigator's Brochure (IB) and information on Suspected Unexpected Serious Adverse Events (SUSARs) for unlicensed products or the Summary of Product Characteristics (SPC) for licensed products. Principal Investigator shall attend, or ensure a delegate attends, all Investigators' meetings for the Study from time to time as reasonably required by Sponsor, at Sponsors expense.

1.2.3 Institution/Principal Investigator shall ensure that all the Institution's employees and collaborators, who are involved in the Study fully, understand and adhere to the Protocol and the obligations of both the Institution and the Principal Investigator.

1.2.4 Sponsor hereby undertakes not to conclude any other contract with any employee of the Institution in connection with this Study.

1.3 Data and Safety Reporting

1.3.1 Institution/Principal Investigator shall on request submit written reports, in accordance with applicable laws, regulations and guidelines including the Ethics Committee standards, to Sponsor and the EC regarding the Study being conducted at the Institution.

1.3.2 Required Systems: Institution/Principal Investigator agrees to implement and use any electronic system that Sponsor may specify for use in the reporting and monitoring of the Study and Study findings at Sponsor's expense.

1.3.3 Institution/Principal Investigator agrees to report to Sponsor immediately but not later than twenty-four (24) hours after learning of any serious adverse events and other important medical events, as identified in the Protocol, affecting any Study subject in the Study. Institution/Principal Investigator further agrees to follow up such report with detailed, written reports in compliance with all applicable legal and regulatory requirements. Institution/Principal Investigator shall record and evaluate all Adverse Events experienced by the Study subjects in accordance with the Protocol.

1.4 Record Management

1.4.1 Institution/Principal Investigator will retain in a safe and secure location, one (1) copy of all printed and electronic data and reports resulting from the Study for a period of time according to applicable law.

1.4.2 Institution may store Study documents at a mutually agreed third party site. If the Institution/Principal Investigator wants to move the Study documents to another location, the Sponsor must be notified in writing.

1.4.3 Institution/Principal Investigator shall maintain accurate data collection and up-to-date records of all Study subjects.

1.5 Study Product and Equipment

1.5.1 Sponsor shall provide free of charge, or as appropriate, reimburse Institution for materials that Sponsor is required to provide per the Protocol including Study Product necessary for the conduct of the Study. Institution/Principal Investigator shall not use the Study Product for any purpose other than the conduct of the Study.

1.5.2 Study Product shall be supplied to the pharmacy of the Institution. Institution/Principal Investigator shall ensure that the Study Product are handled correctly and stored securely for the duration of the Study and any period thereafter as required by applicable law or this Agreement, whichever is later, in accordance with the Protocol. Only those persons who are under the Principal Investigator's direct control and who will be using the Study Product shall have access to the Study Product.

1.5.3 Upon termination or completion of the Study, all unused Study Product shall be returned to Sponsor at Sponsors expense or, at Sponsor's sole option and at Sponsor’s expense, destroyed.

1.5.4 Sponsor-Provided Equipment: The Parties acknowledge that certain equipment may be needed to properly conduct the Study. If Sponsor and Institution/Principal Investigator agree that Institution/Principal Investigator does not have sufficient access to some or all of that certain equipment, then such equipment shall be identified. The Sponsor will supply Institution/Principal Investigator with the Required Equipment free of charge or reimburse Institution/Principal Investigator for the costs of such, subject to the terms of this Agreement. Sponsor is responsible for maintaining service/maintenance agreements for the Sponsor-Provided Equipment and is liable for all taxes and insurance relating to the Equipment. Title and ownership of the Sponsor-Provided Equipment shall remain with Sponsor. If Institution/Principal Investigator upon termination or expiration of Study shall return Required Equipment to Sponsor, it shall be returned, less normal wear and tear, at Sponsors expense. If any equipment will be supplied to the Institution, a separate agreement will be concluded about it.

1.6 Informed Consent

1.6.1 Institution/Principal Investigator undertakes to use the patient information sheet as approved by the Ethics Committee and to obtain written informed consent from each Study subject prior to inclusion or initiation of any Study specific procedures for screening according to the Protocol.

1.7 Study subject Enrolment

1.7.1 Institution/Principal Investigator shall make reasonable efforts to ensure that the recruitment target of eligible subjects in accordance with the Protocol is met timely and that data from all eligible Study subjects are available on or before the expiration of the Study. If, after using its best endeavours, the Institution is unable to recruit the requisite number of trial subjects for the Study as specified in this Agreement and/or the Protocol, such inability shall not be deemed by Sponsor as a breach of the Agreement.

1.7.2 If the Study is part of a multi-centre trial, Institution/Principal Investigator may enrol Study subjects in mutual competition with other participating sites. Sponsor reserves the right to end Study subject enrolment under this Agreement when the desired number of Study subjects for all sites has been reached. Further, Institution and Principal Investigator agree that continued screening or randomisation of subjects must not take place after Study Subject enrolment has been ended by Sponsor and written notice hereof has been given to Institution and Principal Investigator by Sponsor.

1.8 Monitoring and Audit

1.8.1 Sponsor shall provide reasonable supervision, training and monitoring during the conduct of the Study.

1.8.2 Institution/Principal Investigator shall during the Study, on reasonable prior written notice and at an agreed upon time, permit authorized personnel of Sponsor to access the site during normal business hours in order to conduct monitoring and audits. Any review by Sponsor of source documents shall be performed with due regard for Study subject confidentiality.

1.8.3 Sponsor shall notify Institution via Clinical Trials Department regarding any dates of scheduled initiation, close-out and/or monitoring visits, and also the dates of initiation or end of patient enrollment, via e-mail at trials.icrc@fnusa.cz. Sponsor shall also perform the aforementioned visits during standard business hours of the Institution and at mutually agreeable times with the Insvestigator, or another authorized employee of the Institution, as the case may be. Sponsor agree that if appropriate, such visits may (jointly with the Investigator) be also attended by other appointed Institution´s representative.

2. Compensation

2.1 The budget and compensation to be paid for the Study is included in Appendix B. Payment shall be due and payable in accordance with the schedule and details set forth in Appendix B.

2.2 The Parties acknowledge and agree that the compensation and support provided by Sponsor to Institution pursuant to this Agreement represents the fair market value for the Study conducted by Institution, has been negotiated in an arms-length transaction, and has not been determined in a manner that takes into account the volume or value of any referrals or other business otherwise generated between Sponsor and Institution. Nothing contained in this Agreement shall be construed in any manner as an obligation or inducement for the Institution to recommend that any person or entity purchase the Sponsor’s products or those of any entity affiliated with Sponsor.

2.3 Institution shall not bill any third party for any Study Product or other items or services furnished by Sponsor in connection with the Study, or any services provided to Study subjects in connection with the Study for which payment is made as part of the Study.

2.4 Changes to the Protocol: In the event of a change to the Study Protocol that results in an increased cost, or if any increase in the compensation due for the conduct of the Study is necessary or appropriate, the Parties shall negotiate further remuneration and written amendment to this Agreement should be concluded.

2.5 The estimated value of financial payment under this Agreement shall be approximately 6000 Euro equalling 162.083 CZK. This number is based on an estimatet inclusion of 15 patients, as the financial compensation equals 400 EUR pr. included patient.

3. Confidentiality

3.1 All information furnished by Sponsor ("Confidential Information") pursuant to this Agreement, to Institution/Principal Investigator, shall be treated by Institution/Principal Investigator as confidential for a period of five (5) years after termination of this Agreement. Institution/Principal Investigator shall i) hold the Confidential Information in confidence and not disclose or permit it to be made available to any third party, without Sponsor's prior written consent, ii) only use the Confidential Information for the Study, iii) take any reasonable steps to the effect that each person employed at the Institution to whom disclosure of the Confidential Information is made will be under the same confidentiality obligations as applies for Institution under this Agreement, and iv) upon written demand from Sponsor either at Sponsor's expense to return the Confidential Information and any copies of it or to confirm in writing that it has been destroyed. However, Institution/Principal Investigator may keep one copy for documentation purposes.

3.2 The foregoing Section 3.1 does not apply to any of the Confidential Information which Institution/Principal Investigator can show i) is already lawfully known to Institution/Principal Investigator at the date it was disclosed to it by Sponsor and is or becomes free of restriction on the disclosure or use in question, or ii) is or becomes generally known or freely available to the public (except by reason of any breach by Institution/Principal Investigator of its obligations hereunder), or iii) is disclosed to Institution/Principal Investigator, free of restriction on the disclosure or use in question, by a third party who was entitled to make such unrestricted disclosure, or iv) is independently developed by Institution/Principal Investigator, or v) is disclosed, retained or maintained by law or any regulatory or government authority.

4. Publication

4.1 The Parties recognize that Danish law places an obligation on hospitals carrying out health and social care research to publish their work.

The Parties agree that this Section 4 should be interpreted in light of such obligation.

4.2 Following completion of the entire Study at all sites, Sponsor shall use all reasonable endeavors to ensure the appropriate publication or other dissemination of the conclusions of the Study, and Institution/Principal Investigator for such Study shall not publish data/results derived from the individual institution site until the combined results from the entire Study has been published in a joint, multi-centre publication. If such a multi-centre publication is not submitted within twelve (12) months after conclusion, abandonment or termination of the Study at all sites, or after the Sponsor confirms there will be no multi-centre clinical trial publication, Institution/Principal Investigator may publish the data/results from the Institution individually in accordance with this Section 4.

4.3 If Institution/Principal Investigator wish to publish data/results from the Study, a copy of the manuscript must be provided to the Sponsor for review at least thirty (30) days prior to submission for publication, presentation or release. The Sponsor and Principal Investigator will arrange expedited reviews for abstracts, poster presentations or other materials. Within this 30-day period, the Sponsor shall review such proposed publication or presentation or release to determine whether it contains any Confidential Information of Sponsor (as defined in Section 3), or whether Sponsor desires to file patent applications on subject matter contained therein. Upon receiving any notification from Sponsor requesting deletion of Confidential Information of Sponsor or requesting a delay in publication to allow the filing of patent applications before publication or release, Principal

Investigator shall take the requested action; provided however, that any delay in publication shall not exceed ninety (90) days from the date on which Sponsor received the draft manuscript for review.

5. Publicity

5.1 None of the Parties shall use the name of any other Party for marketing or promotional purposes without the prior written consent of the Party whose name is proposed to be used, nor shall either Party disclose the existence or substance of this Agreement except as required by law or otherwise provided for in this Agreement. Furthermore, Institution being a Danish public body is encompassed by the Act of Publicity within the Public Administration.

5.2 Notwithstanding the foregoing, Institution and Sponsor hereby acknowledge that this Agreement shall be published pursuant to Act no. 340/2015 Sb., on Register of Contracts. The version of the Agreement to be published shall be mutually agreed by the Parties by e-mail.

6. Ownership of Data

6.1 All data/results generated by Institution/Principal Investigator in the direct course of conducting the Study ("Data") shall be transferred to Sponsor, which may utilize the Data in any way it deems appropriate, subject to and in accordance with applicable privacy and security laws and regulations and the terms of this Agreement and informed consent of the Study Subject.

6.2 Institution/Principal Investigator retain right to use Data for further research, education and treatment purposes.

6.3 Sponsor acknowledges and agrees that the medical documentation of the Study Subjects is and remains the property of the Institution after the end of the Study.

7. Ownership of Inventions

7.1 Any inventions/improvements within the field of research, as resulting directly from the Study shall be owned by Sponsor ("Inventions"). Sponsor shall be entitled to file in its own name relevant patent applications or in other ways protect the Inventions, and the said Inventions will become and remain the property of Sponsor solely.

7.2 Institution/Principal Investigator shall promptly disclose and assign to Sponsor all Inventions generated by Institution/Principal Investigator pursuant to this Agreement.

8. Indemnification

8.1 Sponsor shall defend, indemnify and hold harmless Institution, its trustees, officers, agents and employees (including the Principal Investigator and co-investigators) from any and all losses, costs, expenses, liabilities, claims, actions and damages, based on a personal injury or death to a Study subject caused by the use of the Study Product during the course of the Study.

9. Liability and Insurance

9.1 Sponsor is as a public Danish body self-insured according to Danish law. Sponsor's assets are sufficient to cover any contemplated liability assumed by Sponsor under this Agreement. Sponsor hereby represents and warrants that the self-insurance is in accordance with sec. 52 par. 3 letter f) of Act No. 378/2007 Coll., on Pharmaceuticals. This Insurance shall be maintained for the entire duration of the Study

9.2 Institution represents to have taken out liability insurance pursuant to sec. 45 par. 2 letter n) of Act No. 372/2011 Coll., on Medical Services, covering all injury and damage caused

while providing medical care. This insurance complies with the extent required by law and does not cover liability for injury or damage resulting from clinical trials.

9.3 While dealing with third party claims, the Sponsor may not admit any misconduct of the Institution or the Principal Investigator without Institution's prior written consent.

10. Term and Termination

10.1 This Agreement shall be considered fully executed on the date of publication in the Register of contracts and will remain in effect until completion of the Study, close-out of Institution or completion of the obligations of the Parties under this Agreement or earlier termination in accordance with this Section 10 whichever occurs first.

10.2 This Agreement may be terminated by either Party at any time in the exercise of its sole discretion upon thirty (30) calendar days prior written notice to the other Party, if i) a material breach of this Agreement occurs, including failure to comply with the Protocol and applicable laws and regulations, ii) receipt of safety information makes it advisable to do so.

10.3 Notwithstanding the above, Sponsor may immediately terminate the Study if, within its sole judgment, such immediate termination is necessary based upon considerations of subject safety or upon receipt of data suggesting lack of sufficient efficacy. Upon receipt of notice of termination, Institution/Principal Investigator agrees to promptly terminate the conduct of the Study to the extent medically permissible for any individual who participates in the Study.

10.4 Notwithstanding the above, Institution may terminate this Agreement upon 30 calendar days written notice to Sponsor, if the Principal Investigator becomes unavailable due to death, disability or other reasons beyond the control of Institution and not attributable to Institution's own acts or omissions. However, Institution agrees to first use its best efforts to identify a replacement Principal Investigator acceptable to Sponsor.

10.5 The Institution may also terminate this Agreement by a thirty (30) day written notice to Sponsor if, for reasons beyond the Institution's control, the Institution will be unable to complete the Study without the completion having a negative impact on its main activity, i.e. provision of medical services. Institution will not be entitled to terminate the Agreement for this reason should the safety of study subjects be compromised.

10.6 In the event of termination hereunder, other than as a result of a material breach by Institution/Principal Investigator, the total sums payable by Sponsor pursuant to this 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 by Sponsor to Institution being refunded to Sponsor.

10.7 Institution/Principal Investigator shall immediately deliver to Sponsor all Data generated as a direct result of the Study and shall, at Sponsor's expense return to Sponsor or destroy upon instructions of the Sponsor, all unused Study Product, all documents, materials and equipment provided by Sponsor and all Sponsor Confidential Information, as defined in Section 3, at the earlier of the conclusion of the Study or termination of this Agreement. This provision does not apply to those documents that should be maintained and retained by Institution/Principal Investigator at Institution, as defined in the Protocol and as requested by applicable laws and regulations.

10.8 The rights and obligations of the Parties which by intent or meaning have validity beyond termination as set forth above, including, but not limited to, rights with respect to patent rights, ownership of Inventions, confidentiality, liability limitations, indemnification and insurance, and publication shall survive five (5) years after the termination or expiration of this Agreement.

11. Applicable Law and Regulations

11.1 The Parties shall comply with all applicable national and international laws, regulations and guidelines, especially those governing the conduct of clinical trials, dealings in medicinal products, responsibilities of clinical investigators, informed consents, protection and privacy of personal data and storage of data and records, including, without limitation, the ICH Guidelines and the European Guidelines on Good Clinical Practice (hereinafter referred to as "ICH-GCP"), Good Laboratory Practice, the revised versions of the Declaration of Helsinki Directive 95/46/EC and Directive 2001/20/EC of the European Parliament and of the Council, and professional industry association regulations.

11.2 The Institution confirms that neither it, and to the best of its knowledge nor any of its investigators, employees, agents or other personnel providing services for the Study pursuant to this Agreement, has ever been debarred, disqualified, or banned from conducting Investigations or is under investigation by the competent authority or any equivalent regulatory authority within the US for debarment, disqualification or any similar regulatory action.

12. Personal Data

12.1 The Parties agree that the collection, processing and disclosure of personal data and medical information related to the Study subject, and personal data related to Principal Investigator and any investigational staff (e.g., name, hospital or clinic address and phone number, curriculum vitae) is subject to compliance with applicable personal data protection and security laws and regulations. Institution/Principal Investigator shall not disclose to the Sponsor the identity of the subjects or information from which the identity of the subject can be deduced without prior written consent of the subject. These data fall within the scope of the law and regulations relating to the protection of personal data, in particular Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

12.2 Institution/Principal Investigator agrees to inform the investigational staff that their personal data may be collected. In such case the Sponsor may transmit such personal data to other affiliates or group companies and their respective agents worldwide. Accordingly, personal data may be transmitted to countries outside the European Economic Area, such as the United States, which the EU has determined currently lack appropriate privacy laws providing an adequate level of privacy protection. Nonetheless, Sponsor will apply adequate privacy safeguards to protect such personal data. Personal data may also be disclosed as required by individual regulatory agencies or applicable law, such as to report serious adverse events.

12.3 The Parties undertake to comply with any applicable laws and regulations as applicable in the Czech Republic regarding the protection of Study Subjects' personal data. Each Party shall bear responsibility for their own data processing and ensure that personal data of Study Subject shall be collected, stored, disclosed and transferred in compliance with all applicable supranational and national regulations on data protection and this Agreement. The Parties undertake to adopt measures in order to prevent any accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to personal data, their other unauthorized processing, as well as other abuse of personal data.

12.4 With respect to the activities governed by this Agreement, the Institution and the Sponsor agree that they will act as independent controllers in the processing of the personal data of Study Subjects in accordance with applicable data protection regulations.

12. 5 Investigator shall obtain each Study Subject's written consent for the collection and use of such Study Subject's personal data for Study purposes, including the disclosure, transfer and processing of data collected in accordance with the Protocol, in compliance with applicable Data Protection Laws. The Site shall use the informed consent form as provided by the Sponsor that is in compliance with applicable laws and regulations.

12.6 All data provided to the Sponsor shall be provided in a coded format that protects Study Subject identity. Except to the extent provided by law, Sponsor will not have access to Study Subject names or other materials which allow any identification of Study Subject. Sponsor's review of medical records to verify the accuracy of data reports shall be subject to all necessary safeguards required for the protection of patient confidentiality.

12.7 The personal data shall be processed for the term of the Agreement. The Institution and Principal Investigator shall cease to process the personal data upon the discharge or other termination of this Agreement. This does not prejudice any obligations of the Institution and the Investigator as data controllers, as the case may be, to store the processed personal data according to applicable legal regulations.

12.8 The Parties undetake to inform each other of any personal data breach without undue delay after learning of such breach, however, at the latest within 24 hours, so that the other party wil have the possibility to assess the incident and fulfil its obligations towards the regulatory authority or the subjects themselves. If a personal data breach occurs that would require notification of the regulatory authority, Institution will inform the regulatory authority within 72 hours from learning about the incident. If the breach posed a high risk for the rights of the subjects concerned, Institution will also inform these subjects.

12.9 The Parties undertake to cooperate and assist in the resolution of any substantial problems that may arise in connection with the performance of the Agreement in connection with the protection of personal data. The obligation to cooperate also includes effective cooperation in case of supervisory review, handling of patients' requests and complaints, and reporting of security incidents. The same applies in the case of a lawsuit concerning the protection of personal data or privacy.

12.10 As soon as the Parties lose legal grounds for the processing of personal data under applicable law and this Agreement, personal data will be destroyed by irreversibly destroying the key to interconnect pseudonymized data by Institution, so that the data subject becomes unidentifiable.

12. Law and Venue

12.1 In the event of any dispute arising between the Parties in relation to the terms of this Agreement, the Parties shall use their best endeavours to resolve the matter on an amicable basis. This Agreement shall be governed by and shall be constructed in accordance with the laws of the Czech Republic without regard to any conflicts of law's provisions. The Parties consent to the competent courts of the Czech Republic for the resolution of all disputes or controversies between the Parties hereto that the Parties are unable to settle amicably.

13. Miscellaneous

13.1 Sponsor shall have the right to assign this Agreement to an affiliate of Sponsor upon prior written notice to Institution. In all other instances, neither Party shall assign its rights or duties under this Agreement to another without prior written consent of the other Party. Subject to the foregoing, this Agreement shall bind and inure to the benefit of the respective Parties and their successors and assigns.

13.2 Institution is an independent contractor to Sponsor, and not a partner, agent, employee, representative, or joint-venture of Sponsor. Except as set forth in this Agreement, no Party, or its employees, agents, or subcontractors, has any right or authority to bind or act on behalf of another Party.

13.3 Principal Investigator confirms that there is no conflict of interest that will inhibit or affect the Principal Investigator's performance under this Agreement and confirm that their performance under this Agreement does not violate any other agreement with third parties. For the avoidance of doubt, Institution and Principal Investigator are free to enter into any other agreement with any third parties as long as this does not prevent Institution and/or Principal Investigator from fulfilling their obligations according to this Agreement.

13.4 This Agreement may not be altered, amended or modified except by written document signed by the Parties.

13.5 If any of the provisions of this Agreement conflicts with any provision of the Protocol or any other relevant document, this Agreement shall take precedence.

13.6 This Agreement constitutes the entire agreement of the Parties with respect to the subject matter hereof. It expressly supersedes any prior or contemporaneous oral or written representations or agreements. The Appendices form an integral part of the Agreement. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect.

13.7 In compliance with Sec. 558 par. 2 of Act No. 89/2012 Coll., Civil Code, as amended, the Parties hereby exclude the use of business practices between the parties.

13.8 This Agreement shall be executed in three (3) original counterparts of which one is for Institution, one for Sponsor and one for Principal Investigator.

For **Institution**:

Fakultní nemocnice u sv. Anny v Brně

Date: 16.6.2020

_____

Ing. Vlastimil Vajdák

[Director]

For and on behalf of **Sponsor**:

Rigshospitalet

Date: 6.7.2020

_____

[redacted]

Deputy Director

Read and acknowledged by:

Date: 6.7.2020

_____

[redacted]

Principal Investigator:

I hereby acknowledge that I have read and agree with the terms of this Agreement, and that I will act and perform my duties in the study in accordance with the content of this Agreement and the details outlined in the Appendices.

Date: 12.6.2020

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[……]

[Principal Investigator]

Appendix A – Protocol

Version [2.1] [03-05-2018]

Protocol can be downloaded from http://www.cric.nu/hot-icu-protocol-approved/

Appendix B – Budget

Payment terms:

Service	**Time required**	**Hourly rate**	**Amount**
Inclusion and follow-up of one patient. This includes the following:		**133,3 EUR**	**400 EUR**
Patient information and collection of informed consent	60 min		Included in total amount
Documentation of patient data from file into eCRF incl. query solution	60 min		Included in total amount
Transfer of entries from patient questionnaries into eCRF	30 min		Included in total amount
90-days and 1-year follow-up	30 min		Included in total amount
TOTAL PER PATIENT			**Max 400 EUR**

The amount referred to above shall be internal devided: 60 % Investigator and 40 % Institution.

A maximum of **[50]**patients can be included by the site.

Additional services:

The following expenses that the investigator/institution incurs in connection with site initiation and monitoring visits will be reimbursed on an hourly basis:

Service	**Time required**	**Hourly rate:**	**Amount**
Start-up fee**			**400 EUR**
Participation in initiation visit	max. 2 hours	**0 EUR**	**0 EUR**
Provision of documentation and availability for discussion during (optional*) monitoring visit	max. 3 hours	**0 EUR**	**0 EUR**
Role as National Coordinator		**0 EUR**	**0 EUR**
TOTAL PER SITE			**max 400 EUR**

*Monitoring will be performed for approx. 10% of patients, selected by a risk-based approach.

** Fee only for Institution.

General:

Payments for completed patients and additional services will be made in quarterly intervals upon receipt of a formally correct invoice, with the exception of the start-up fee which is an one-time payment invoiced after the signing the agreement. The invoice will be issued on the basis of the documents approved by the Institution. Invoice documentation will be sent to email address: fakturace.trials@fnusa.cz. Invoices must be paid within 30 days.

All amounts are exclusive of VAT.

The bank fees of the payer's bank (inculded correspondent bank) are paid by the payer and the bank fees of the payee's bank are paid by the payee.

Invoice address:

CRIC

At: Department of Intensive Care 4131

Rigshospitalet

Blegdamsvej 9

2100 Copenhagen

VAT no. 29 76 57 90

Payments will be made per completed and valid patient, i.e. patients for whom all required data have been documented in the electronic Case Report Form (eCRF), all queries have been solved and the patient has been finalized in the eCRF.

All procedures and complementary examinations will be performed as per routine practice. There are no study specific investigations.

The payment details for transfer of payments, as advised by the Institution:

Bank address: Česká národní banka, pobočka Brno, Rooseveltova 18, 601 10 Brno
Account number: 20001-71138621/0710
IBAN: CZ83 0710 0200 0100 7113 8621
SWIFT: CNBACZPP
IČ: 00159816
DIČ: CZ00159816