Contract on the Joint Implementation of the Research Project

concluded between

Universität zu Lübeck, represented by the University President [redacted] Ratzeburger Allee 160, 23562 Lübeck
and
University Clinics Schleswig-Holstein, represented by its CEO [redacted] and its CFO [redacted] Ratzeburger Allee 160, 23538 Lübeck
With its Medical Clinic II, Lübeck Campus, represented by the Clinic Director and Project Manager: [redacted]
As the implementing body of the Universität zu Lübeck

- hereinafter referred to as "**Sponsor**" –

and

Institute for Clinical and Experimental Medicine
Vídeňská 1958/9, 14021 Prague 4
Czech Republic
Represented by director Ing. Helena Rögnerová [redacted] conchita [redacted]

- hereinafter referred to as "**Study Centre**"-

[redacted]

Recitals

The Sponsor shall implement the clinical research project described in further detail in this contract on its own responsibility. The project is designed as a multi-centre clinical study in which the Study Centre shall participate as an additional study location. For this purpose, the parties hereby enter into the following agreement:

Section 1
Object of contract

The Sponsor shall implement the research project:

Left Atrial Appendage closure in patients with non-valvular atrial fibrillation and end-stage chronic KIDNEY disease (LAA-KIDNEY).

The Study Centre shall participate in this study as an additional study location in accordance with the provisions set out in the following. [redacted] will act as principal investigator for the Study Centre.

Section 2
Implementation and responsibility

(1) The Sponsor commissions the Study Centre to carry out the contractually agreed project in accordance with the study protocol and any necessary amendments. This study protocol in its current version is considered an integral part of the contract and is attached as Annex A. The principal investigator and the Study Centre must be informed immediately in writing of any subsequent amendments to the study protocol.

(2) The principal investigator of the study is [redacted] University Hospital Schleswig-Holstein Campus Lübeck, Medical Clinic II, Ratzeburger Allee 160, 23538 Lübeck, Tel: [redacted] fax: [redacted] Email: [redacted]

The principal investigator of the Study Centre has read and signed the study protocol.

(3) The study is subject to the applicable regulations under professional law. The regulations of the Medicinal Products Act or the Medical Devices Act shall not apply. The study shall be implemented in accordance with the requirements of the Federal Data Protection Act (BDSG) and/or the applicable data protection laws of the German states, the General Data Protection Regulation (GDPR), the requirements of Good Clinical Practice (GCP) and the Declaration of Helsinki in the respective applicable versions as well as in accordance with the relevant laws and regulations. Directly binding legal regulations must be strictly complied with; in all other respects, the aforementioned standards must be adequately taken into account. Both parties agree that the safety of the study participants shall always be top priority.

I. Obligations of the Sponsor

(1) The Sponsor shall conduct the necessary approval procedures before the competent ethics committee. Should the competent ethics committee have objections regarding the content or conduct of the study or raise such objections during the implementation of the study and (temporarily) suspend a an already granted vote, the contracting parties shall jointly draw up amendment proposals taking account of the concerns expressed under consideration of the study objective. Should it nevertheless be possible to achieve a positive vote from the ethics committee, either of the contracting parties may withdraw from the contract or terminate it without notice. This shall not result in any claims for compensation on the part of the sponsor.

(2) Furthermore, the Sponsor will inform all participating Study Centres about the results of the clinical study and the risks likely to be associated with the clinical study.

(3) The Sponsor shall ensure that the documents required for the implementation of the clinical study are provided properly and on time.

(4) The Sponsor shall ensure that all legal requirements for the implementation of the clinical study are met.

(5) The Sponsor shall inform the principal investigator or the staff entrusted with activities within the scope of the clinical study in writing of the study protocol and the applicable legal conditions.

II. Obligations of the Study Centre

(1) The Study Centre undertakes to provide the Sponsor, without delay and upon request, with all necessary information and documents required for the conduct of the approval procedures (e.g. curriculum vitae, information on the suitability of the investigation centre, etc.).

(2) The Study Centre commissions the principal investigator to conduct the investigation on a local basis.

(3) The Study Centre undertakes to notify the Sponsor in writing in advance of any change to the principal investigator and to include documentation on the experience and qualifications of the new principal investigator. A new principal investigator may not be appointed until the Sponsor has been advised by the relevant ethics committee and has received a positive feedback in this matter and has submitted this advice to the Study Centre.

(4) For the duration of the recruitment phase of the contractual commitment entered into here, the Study Centre undertakes to conduct further studies with the patient population suitable for the study only after consultation with the study management.

(5) The Study Centre undertakes to create the equipment-related and personnel conditions required for the conduct of the study and to maintain them during the study.

(6) Furthermore, the Study Centre undertakes to conduct the study in accordance with the study protocol. The eCRFs shall be completed in full without delay and within 7 days at the latest. Any queries from the Sponsor or the Sponsor's representative shall be answered immediately or at the latest within 7 days.

(7) The Study Centre is obligated to inform the Sponsor within 24 hours of all serious incidents that occur to any patient participating in the study. Excluded from this are any incidents that do not require immediate reporting according to the study protocol. The initial reporting of incidents will be supplemented after a short period of time by detailed written reports, including a descriptive summary. The Study Centre will inform the Sponsor immediately of any deviation from the study protocol.

(8) If the Study Centre fails to comply with the obligation to provide information or fails to do so in due time, it shall indemnify the Sponsor against any and all claims resulting therefrom.

(9) Only patients who fulfil all inclusion criteria but no exclusion criteria and who have duly consented to the study may be included in the study under this contract. For this purpose, the patient information and consent forms attached to the study protocol must be used.

(10) The Study Centre is solely responsible for the proper treatment of its patients.

(11) The Study Centre will retain all essential documents of the clinical study, including the case report forms, after the termination or discontinuation of the study for the period of time specified in the study protocol, unless the law requires longer retention periods.

(12) The Study Centre is aware that it must provide the Sponsor with information on the progress of the study if requested to do so and must regularly provide information on developments. The Study Centre will support the Sponsor in fulfilling these obligations in a timely manner.

Section 3
Quality assurance

(1) During the implementation of the study and the contract, compliance with Good Clinical Practice must be ensured by all participating parties. The Study Centre will therefore submit to the GCP requirements that have been specified in the study protocol.

(2) In particular, the Study Centre undertakes to participate in quality assurance measures and to support the Sponsor in the implementation of corresponding measures as appropriate and to the customary extent. In particular, the Study Centre will allow the Sponsor or the authorised representative to enter the

investigation centre during normal business hours and to inspect the required documents. In doing so, the Sponsor take the operations of the Study Centre into consideration.

(3) In particular, the Study Centre also agrees that the monitors of the Sponsor may inspect the original patient records and make copies thereof, in accordance with the declaration of consent of the patients.

Section 4 Remuneration

The Sponsor pays the investigation centre €1000 incl. VAT per patient.
Payments are made in two steps.

The first payment is made after screening + baseline + randomisation + discharge → € 500 incl. VAT per patient.

The second payment is made after the last follow-up (end of study) → € 500 incl. VAT per patient.

V1 – 3 Month → 150€ incl. VAT. per patient
V2 – Phone visit → 50€ incl. VAT. per patient
V3 – 12 Month → 150€ incl. VAT. per patient
V4 – Phone visit → 50€ incl. VAT. per patient
V5 – 24 Month → 100€ incl. VAT. per patient

(1) Payment will be made exclusively by bank transfer to the following third-party funding account of the investigation centre:

Account holder:	Institute for Clinical and Experimental Medicine
Credit institution:	Czech National Bank
IBAN:	CZ4007100345340042334041
SWIFT:	CNBACZPP
Payment purpose:	Clinical study Agreement

(2) The remuneration is due 30 days after receipt of an invoice in accordance with Sections 14, 14a of the German VAT Act (UstG).

Section 5
Term and termination of the contract

(1) The term of this contract shall commence upon signing by all parties, but at the earliest with the availability of a positive evaluation by the ethics committee, and shall end either by notice of termination or automatically at the end of the study.

(2) The contracting parties are entitled to terminate the study covered by this contract for good cause and to terminate the contract without notice. Good cause shall be in particular deemed to exist if

- no favourable evaluation by the responsible ethics committee is achieved,

- no patients are enrolled 6 months after initiation of the Study Centre despite ongoing recruitment at the Study Centre and at other centres,
- the investigator is permanently unavailable and no substitute investigator is proposed by the Study Centre who is professionally qualified to implement the study,
- this appears reasonable for reasons related to the safety of the study participants,
- deviations from the study protocol in breach of duty and GCP violations are not remedied despite requests to do so,
- documents are falsified at the Study Centre,
- the quality of the documentation at the Study Centre remains insufficient despite a written request to remedy the situation, or
- there is a not insignificant delay in payment despite a reminder with an appropriate deadline (at least 2 weeks).

(3) Notwithstanding the above provisions, the Sponsor is entitled to terminate the contract without notice at any time without stating a reason.

(4) Such notice of termination must be made in writing.

(5) In the event of termination, the Study Centre shall immediately provide the Sponsor with all data, results, study documents and other documents as well as property belonging to the Sponsor that have been collected up to that point within 2 weeks of termination of the contract or, at the written request of the Sponsor, destroy them at the Sponsor's expense.

(6) This contract ends automatically with the fully completed close-out visit after the end of the study as specified in the study protocol, without the need for an express termination. Furthermore, an end of contract may arise due to the reasons set out in (2).

Section 6
Confidentiality

(1) The Study Centre and the principal investigator undertake to keep any information provided to them by the Sponsor as well as any data resulting from the study confidential. This also applies to materials provided by the Sponsor to the investigator for the implementation of the study. Disclosure of data, results and materials is only permitted with the consent of the Sponsor or as contractually stipulated, unless the data and results

- are generally known, or
- were already known before being provided by the Sponsor, or
- have become known after being provided through a publication or in any other way;
- or for which the Study Centre can provide evidence that the data, results and materials were in its possession before being provided by the Sponsor;
- must be disclosed by law or by order of a court, authority or other governmental body.

(2) This obligation shall remain effective for 5 years beyond the end of the contract.
(3) The confidentiality obligation as well as the above exceptions shall apply accordingly to the Sponsor with regard to Confidential Information of the Study Centre. Confidential information of the Study Centre includes in particular patient data, personal data of employees, business and trade secrets, other information marked as confidential as well as otherwise recognisably confidential information which is to be regarded as confidential according to the type of information or the circumstances of the provision. This confidential information is only to be disclosed as stipulated in the contract and is otherwise to be kept secret and - without prejudice to statutory retention obligations - to be deleted if it is not (or no longer) required for the conduct of the study.

Section 7
Warranty and liability

(1) The contracting parties are aware of the risk of success associated with research activities. The Study Centre undertakes to carry out all research activities prudently and in accordance with the study protocol, the latest scientific standards and the legal requirements. Due to the research character of the activities, the Study Centre shall not assume any warranty for the achievement of a certain result or for the fact that the result can be used or commercially exploited for a certain purpose or that the results of the study are commercially exploitable and free of property rights of third parties. Insofar as conflicting property rights become known, the Study Centre shall inform the Sponsor of these without delay.

(2) Claims for damages and other claims for reimbursement by the Sponsor against the Study Centre are excluded - with the exception of claims for compensation due to bodily injury (life, body, health) - irrespective of the type of breach of duty, insofar as no intentional or grossly negligent breach of duty is involved. In the event of a breach of essential contractual obligations (main performance obligations/cardinal obligations), the Study Centre shall also be liable for only simple negligent breaches of obligations. Material contractual obligations means such obligations whose fulfilment characterises the contract and on which the contractual partner may rely. The liability of the Study Centre for negligent breach of such cardinal obligations shall be limited to the amount of the damage typical for the contract and foreseeable at the time of conclusion of the contract. Furthermore, the Study Centre's liability for breaches of duty - subject to injury to life, limb or health - in the internal relationship vis-à-vis the Sponsor shall be limited to the amount of the contractually agreed remuneration for the study. The Study Centre shall not be liable for loss of profit, indirect damage and consequential damage - subject to injury to life, body, health, intent or gross negligence. Insofar as the liability of the Study Centre is limited, this limitation shall also apply to the principal investigator as well as their representatives, employees and other vicarious agents.

Section 8
Property rights, publications, inventions

(1) After completion of the study covered by the contract, the Sponsor intends to prepare a detailed final report on the research project that meets the scientific requirements. The Study Centre will therefore support the Sponsor to the best of its ability and hand over the documents at the latest at the close-out visit.

(2) All materials provided by or on behalf of Sponsor, including documents, data, programmes and proposals of any kind, are and will remain the property of Sponsor unless otherwise agreed in writing.

(3) Data collected as part of the study are the property of Sponsor. The Sponsor acquires the exploitation rights to all findings and all results of this clinical study to the exclusion of the rights of third parties and subject to the right of publication regulated below. This also applies if the study is discontinued - for whatever reason.

(4) The rights of the Study Centre to the patient data contained in the medical records remain unaffected by this.

(5) The Study Centre reserves a free right of use to the results for its own purposes in research and teaching.

(6) The Sponsor acknowledges the right of the investigator and the Study Centre to publish the nature, subject and result of the work performed. The Study Centre and the investigator are therefore permitted to publish the scientific findings obtained for non-commercial purposes after completion of the study, irrespective of the results. The overall study results may only be published by the Sponsor and after completion and evaluation of the multicentre study. The publication of study data from the individual centres is only permitted prior to the publication of the overall study results with the written consent of the Sponsor. If a multicentre publication is no longer planned or if no multicentre publication has occured after 12 months following the end/termination of the study, the Study Centre and the investigator are entitled to publish their own study results. The Sponsor's consent must be obtained and may not be refused by the Sponsor unless the Sponsor provides written evidence that the planned publication violates its rights. If no written statement is received from the Sponsor within three weeks of notification of a publication request by the investigator or Study Centre, the respective publication is deemed to have been released. Requests for changes can only be taken into account by the Study Centre or investigator if they do not impair the scientific nature and independence of the publication.

(7) The device is approved and is used within the scope of its intended purpose. The contracting parties therefore assume that during the term of this contract no inventions capable of being protected by property rights will arise in the field of the research work covered by this contract. Otherwise, the parties shall agree on the use, registration, exploitation and remuneration of these inventions in a separate contract and under the conditions customary on the market. Each of the parties undertakes to conclude a corresponding contract with the other party before claiming, applying for or exploiting these inventions.

Section 9
Data protection

The Sponsor and the Study Centre undertake to comply with the requirements of Regulation (EU) 2016/679 (General Data Protection Regulation - GDPR), the applicable national data protection laws, the legal confidentiality requirements and the professional secrecy and confidentiality obligations and to commit their employees, subcontractors or other third parties involved in the implementation of the clinical study to comply with them and to instruct them in the relevant data protection provisions before they commence their activities. They shall also ensure that their employees, subcontractors or other third parties involved maintain the confidentiality of the data for the duration of their activities and after their activities have ended.
The Sponsor shall be solely responsible for the processing of the personal data of the investigator and the members of the study team.
With regard to the personal data of the study participants processed in the conduct of the clinical study, the Sponsor and the Study Centre shall jointly determine the purposes and means of the data processing. They are therefore jointly responsible parties within the meaning of Article 26 GDPR. The responsibility for the fulfilment of each obligation under the GDPR is governed by this Section 9 and the Joint Responsibility Agreement under Article 26 GDPR attached as Annex A to this agreement. The essential points of the agreement are made available to the data subject as Annex B.

Section 10
Final provisions

(1) The parties shall impose the obligation entered into in this contract on all employees insofar as they are involved in the execution of the contract.

(2) To come into force, any and all amendments and supplements to this contract must be made in writing through numbered amendments. This also applies to the annulment of this written form clause. No ancillary agreements have been entered into. This agreement is made in two copies which of one is for each party.

(3) This agreement shall be governed by law where the Study Centre has its statuary seat. The place of jurisdiction is a competent court where the Study Centre has its statuary seat.

(4) In the event of any deviations between the provisions of this agreement and the study protocol, the provisions of this agreement shall take precedence in legal terms. In all matters of medical practice, patient safety and the reliability and validity of clinical investigation data, the provisions of the study protocol shall prevail.

(5) Unless otherwise permitted by this agreement or provided for by law, neither party may use the name, trademark, logo or trade names of the other party without the other party's prior written consent (i.e., by fax or letter), including for press releases, other public announcements or promotional purposes.

(6) This agreement becomes valid on the date of its execution by the last party and effective upon publication in the Registry of Agreements in accordance with Act No. 340/2015 Coll., on the Registry of Agreements, as amended.

Section 11 Separation principle

(1) The contracting parties confirm that the conclusion of the contract will not influence the investigation centre's turnover operations, i.e. in particular procurement transactions/pricing, and that there are no expectations in this respect.
(2) The parties undertake not to provide any party directly or indirectly involved in the performance of the contract with a gift, payment or other kind of advantage, which could be seen as an inducement or reward for the conclusion or performance of any part of the contract.

Section 12
Severability clause

Should one or more provisions of this contract be or become invalid, this shall not affect the validity of the contract unless the invalid provision is so essential that adherence to the contract cannot be reasonably expected. In all other cases, the contracting parties shall replace the invalid provisions with provisions that come as close as possible to what was intended by the invalid provision. The parties shall endeavour to amicably settle any disagreements arising in connection with this contract or on the occasion of its execution.

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For and on behalf of the UKSH and on behalf of the Universität zu Lübeck

Lübeck, 27.07.2023
Place/Date

[redacted]
Office of the Legal Counsel

Lübeck, 28.07.23
Place/Date

[redacted]
i.A.
Head of [redacted]ty Funding Management

Lübeck, 17.07.23
Place/Date

[redacted]
[redacted]ctor of the Medical Clinic II and Project Manager

For and on behalf of the Study Centre

Place/Date

Clinics Management

Prague - 7. 09. 2023
Place/Date

[redacted]
Director

PRAGUE 5. 09. 2023
Place/Date

[redacted]
Principal Investigator

Place/Date

5. 09. 2023

Director Clinic [redacted]

For the attention of the principal investigator and the executing centre:

Investigator's declaration:

By signing this document, I confirm that I have taken note of and agree to the contractual regulations, in particular with regard to the tasks assigned to me by the Study Centre and the data protection regulations. I agree to the processing of my personal data in accordance with the contract. I declare my agreement with the obligations contained in the contract, which are to be fulfilled by me, and I assure the Study Centre of their compliance, also independently of the existing employment relationship. I waive my positive and negative publication rights vis-à-vis the Sponsor to the extent necessary to comply with the contractual regulations and assure that I am aware of the legal regulations on the implementation of clinical studies directed at the responsible investigators and that I will comply with them. Insofar as an assignment of rights to research results is contractually agreed, I declare this assignment or my consent to it with my signature.

[redacted] [redacted]

Principal Investigator

Annex A

Shared responsibility agreement pursuant to Article 26 GDPR

All terms used in this agreement shall have the meanings ascribed to them in the Investigation Centre Agreement unless otherwise defined herein.

1. Subject matter of the agreement

1.1. The Sponsor and the Study Centre (hereinafter also referred to as the "Parties" or "Responsible Parties") have entered into a contract for the conduct of the research project entitled "**Left Atrial Appendage closure in patients with non-valvular atrial fibrillation and end-stage chronic KIDNEY disease (LAA-KIDNEY)**" ("Clinical Investigation") ("Study Centre Agreement"). In the context of the conduct of the Clinical Investigation, the Parties process personal data of the study participants and the study team members as joint controllers. For the purpose of compliance with the requirements of the GDPR as well as the further applicable national data protection laws), the Parties hereby define their respective data protection responsibilities pursuant to Article 26 of the GDPR in addition to Section 9 of the Investigation Centre Agreement. A tabular overview of the various tasks is provided at the end of this annex in Table 1.

1.2. The agreement applies to all activities in the context of the implementation of the clinical investigation in which employees of the parties or third parties commissioned by them process personal data of the study participants on behalf of the controllers.

1.3. The parties undertake to make the essential content of the agreement on joint data protection responsibility available to the data subjects (Article 26(2) GDPR; provided as Annex B). This information will be communicated by the Sponsor in an information sheet addressed to the study participants and made available to the Study Centre. The Study Centre will hand over this information sheet to the respective study participant and document the provision.

2. Compliance with data protection provisions and attribution

2.1. Unless otherwise provided for below, each Party shall ensure compliance with the applicable data protection provisions, in particular the lawfulness of the data processing carried out by it. Without affecting the remuneration and the further contractual obligations, the Parties shall be entitled to refuse to provide or transfer personal data to the other party if and to the extent that there are serious doubts as to the legal basis for the data processing.

2.2. Data processing carried out by a subcontractor of a party shall be attributed to that party.

3. Data flow and corresponding responsibilities under data protection law

3.1. Personal data are processed in the clinical investigation. Depending on the process stage, the processing of this data takes place in the joint area of responsibility or under independent responsibility of the Parties. The Sponsor and the Study Centre determine the process stages in which personal data are processed under joint responsibility (Art. 26 GDPR).

3.2. For the remaining process stages, where there is no joint definition of the purposes and means of individual phases of data processing, each contracting party is an independent controller within the meaning of Art. 4 No. 7 of the GDPR. Insofar as the contracting parties are joint data controllers within the meaning of Art. 26 GDPR, the following agreements shall apply.

3.3. Within the scope of joint responsibility, the Study Centre is responsible for the processing of personal data to the extent that it both collects and stores personal data via the investigator and their study team in the eCRF for the purposes of the implementation and for the duration of the clinical study (as specified in the protocol as amended from time to time) and may subsequently make rectifications or erasures in the database operated by the Sponsor exclusively in Germany (sphere of activity A). The subject of the processing, for which the consent of the respective study participants forms the legal basis, are the data types/categories as resulting from the study protocol.

3.4. The Sponsor is responsible for the processing of personal data within the scope of joint responsibility to the extent that it has access to the data exported to the database by the Study Centre (sphere of activity B). The subject of the processing, the legal basis of which is the consent of the respective study participants, is the data types/categories as resulting from the protocol and as actually stored in the database.

3.5. The Study Centre is solely responsible for processing the personal data of the study participants in the patient file.

3.6. The Sponsor is solely responsible for the processing of the personal data of the study participants in the context of the evaluation of such data stored in the database. The Study Centre has no access to this evaluation. In addition, the Sponsor is solely responsible for the processing of personal data of the study team members, the legal basis of which is the provided consent.

3.7. Furthermore, the Sponsor is solely responsible for the processing of personal data of the study team members according to Art. 44 ff. GDPR if these are transferred to third countries or international organisations. This requires the prior declaration of consent of the respective study team member. Personal data of the study participants may not be transferred to third countries.

3.8. Under no circumstances is the Sponsor able, nor does it intend, to identify study participants on the basis of the personal data contained in the eCRF. The Study Centre ensures that the personal data of the study participants are only transmitted to the Sponsor in encrypted/pseudonymised form. Both parties shall take appropriate technical and organisational measures in accordance with Article 32 of the GDPR to ensure a level of protection appropriate to the risk of the processing of personal data in connection with the implementation of the clinical study and to be able to comply at any time with the rights of the study participants, in particular in accordance with Articles 12 to 22 of the GDPR, within the legal time limits.

3.9. The responsibility for the database lies with the Sponsor. It shall ensure that the implementation, default setting and operation of the database is carried out in compliance with the applicable laws, in particular the requirements of the GDPR.

The personal data processed in connection with the implementation of the clinical study are stored on specially protected servers. The Sponsor is solely responsible for the technical and organisational measures relating to the CRF/eCRF, while the Study Centre is solely responsible for the technical and organisational measures relating to the patient file. The responsibility of the Sponsor also includes the responsibility for a transmission channel that complies with the requirements of Article 32 GDPR.

4. Data subjects' rights

4.1. The Sponsor is responsible for providing and ensuring the accuracy of the content of a statement on data privacy and a declaration of consent that complies with the requirements of Article 12 ff. of the GDPR and for the accuracy of the content of the statement on data privacy and a declaration of consent. This must contain the information in a precise, transparent, understandable and easily accessible form in clear and simple language, in particular:

a. the information that the Sponsor and the Study Centre are joint controllers pursuant to Article 26 of the GDPR as well as information on the essential points of this agreement pursuant to Article 26 (2) sentence 2 of the GDPR;
b. the contact details of both data controllers;
c. the contact details of the data protection officer of the Sponsor and the Study Centre;
d. the purposes for which the personal data are to be processed and the legal basis for the processing;
e. where applicable, the recipients or categories of recipients of the personal data;
f. the duration for which the personal data will be stored;
g. the existence of a right of access on the part of the study participant to the personal data concerned, as well as to rectification or erasure or to restriction of processing or a right to object to processing, as well as the right to data portability;
h. the existence of a right to revoke the granted consent at any time without affecting the lawfulness of the processing carried out on the basis of consent until revocation;
i. the existence of a right of appeal to a supervisory authority.

4.2. The Study Centre is responsible for properly informing the study participants (or their legal representatives) about the processing of their personal data in connection with the implementation of the clinical study, using the data protection information and consent form provided by the Sponsor. The Study Centre is not obligated to separately check the statement on data privacy and declaration of consent for their lawfulness.

4.3. The Study Centre is also responsible for ensuring that the study participant gives their written consent to the data processing before the commencement of the processing of their personal data. For this purpose, the consent form attached to the data protection information must be signed by both the study participant (or their legal representative) and the investigator. The original of the signed data

protection consent form is kept at the Study Centre together with the other study materials.

4.4. The study participant may assert the rights to which they are entitled under Articles 15 to 22 of the GDPR against the Sponsor and the Study Centre. In the event that a data subject asserts their rights under Articles 15 to 20 of the GDPR, the Party against whom the assertion of the rights is made shall be responsible for compliance. The Parties shall notify each other without undue delay if a data subject asserts any of their rights under Articles 15 to 20 GDPR. Insofar as a study participant contacts one of the Parties in exercise of their data subject rights, in particular for information or rectification and erasure of their personal data, the Parties undertake to forward this request to the other Party without delay, irrespective of the obligation to guarantee the data subject right. The latter is obligated to immediately provide the requesting contracting party with the information from its sphere of activity necessary for the provision of information. If personal data is to be erased, the parties shall inform each other beforehand. The other Party may object to the erasure for a justified reason, for example if it has a legal obligation to retain data.

4.5. The responsible contact persons for the parties are:

On behalf of the Sponsor:
Name:
Telephone number:
Email address: [redacted]

On behalf of the Study Centre:

Email address: [redacted]

The other party must be informed immediately of any change of the respective contact person. Any notifications under this Subsection 4.4 shall be made in pseudonymised form by using the study-specific identification number of the study participant. Where necessary and appropriate, the Parties shall assist each other by providing the necessary information to ensure full and effective implementation of the rights of the data subject. If personal data is to be erased, the parties shall inform each other beforehand. The other Party may object to the erasure for a justified reason, for example if it has a legal obligation to retain data.

5. Records of processing activities

The parties shall keep records of the processing activities within the meaning of Article 30(1) of the GDPR for the data processing operations carried out by each of them in the context of the conduct of the clinical study, including and in particular a note on the nature of the processing operation under joint or sole responsibility. They shall support each other in preparing such records.

The Parties shall inform each other immediately and completely if they discover errors or irregularities with regard to data protection provisions during the examination of the processing activities.

6. Data protection impact assessment

The clinical study requires extensive processing of special categories of personal data pursuant to Article 9(1) of the GDPR, so that a data protection impact assessment pursuant to Article 35 of the GDPR is required. The Sponsor and the Study Centre will carry out a data protection impact assessment for their respective areas of activity and will provide each other with the best possible support in its preparation. A copy of the respective data protection impact assessment shall be made available to the other partner without delay.

7. Processor

7.1. The Parties undertake to conclude a contract pursuant to Article 28 of the GDPR when using Processors within the scope of this agreement. The Parties shall inform each other in good time of any intended change with regard to the use or replacement of Processors assigned as subcontractors. They will only assign subcontractors who agree to comply with the requirements of applicable data protection laws and this agreement.

7.2. Services obtained from third parties as an ancillary service to support the implementation of the clinical study (e.g. telecommunication and maintenance services) are not considered subcontracted services for the purposes of this agreement. However, in order to ensure the protection and security of personal data, the Parties undertake to enter into appropriate contractual agreements and to take any necessary control measures also in the case of such ancillary services.

8. Information obligations in the event of data protection violations

8.1. The Parties shall notify each other without undue delay, at the latest within 24 (twenty-four) hours, both in the event of a personal data breach and in the event of suspicion of such a breach. The same shall apply if other errors or irregularities are discovered with regard to compliance with data protection provisions concerning joint responsibility.

8.2. In the event of a breach of the protection of personal data of the study participants or study team members, each party is responsible for fulfilling the reporting and notification obligations resulting from Articles 33, 34 of the GDPR vis-à-vis the respective supervisory authority with regard to its sphere of activity or the data processing operations carried out by it in each case under its own responsibility. On the other hand, the Study Centre is responsible for notifying the data subject in accordance with Article 34 of the GDPR. For this purpose, the Sponsor shall promptly provide the Study Centre with all the information necessary to notify the data subject. The information shall be provided to the contact persons set out in Subsection 4.5.

9. Confidentiality

Within their sphere of activity, the Parties shall ensure that all employees involved in data processing maintain the confidentiality of the data in accordance with Articles 28 (3), 29 and 32 of the GDPR for the duration of their employment as well as after termination of the employment relationship and that they are appropriately committed to maintain data secrecy and instructed in the data protection provisions relevant to them before taking up their employment.

10. Liability

Without prejudice to the provisions of this agreement, the Parties shall be jointly and severally liable vis-à-vis the data subjects for any damage caused by a processing of personal data that does not comply with the GDPR (cf. Article 82(4) GDPR).
Insofar as the Sponsor or the Study Centre incurs damage due to the breach of a data protection obligation of the respective other party, the party in breach of duty shall be obligated to compensate the damaged party for the damage incurred. The Study Centre's liability vis-à-vis the Sponsor is limited to gross negligence and intent.

11. Term and termination

This agreement shall enter into force on the day after it is signed and may only be terminated for good cause. Good cause shall be deemed to exist in particular in the event of a serious or continuing breach of data protection regulations or the provisions of this agreement. The agreement shall continue to apply beyond the end of the investigation centre contract for the implementation of the clinical study until the processing of personal data is no longer necessary on the basis of the investigation centre contract.

12. Archiving

Each party shall retain documentation serving as proof of due and proper data processing in accordance with the applicable statutory provisions beyond the term of this agreement. Unless otherwise stipulated by law, the retention period provided for in the investigation centre contract or the study protocol shall apply to the essential study documents. The Parties shall independently ensure that they comply with all statutory retention obligations existing in relation to the data and take appropriate data security precautions (Article 32 ff. GDPR). This applies in particular in the event of a termination of the cooperation.

Table 1
Delimitation of responsibilities

The crosses represent which responsible party assumes which obligations. The specified articles are taken from the GDPR.

Responsibility	Study Centre	Sponsor
Determination of the purposes of and means for data processing	x	x
Determination of the types of personal data		x
Technical and organisational set-up and technical maintenance of the investigation database and interface		x
Drafting and provision of the eCRFs		x
Drafting and provision of the statement on data privacy and declaration of consent for the study participants		x
Obligation to provide information when collecting personal data from the data subject (using the information sheet provided by the Sponsor) (Art. 13)	x	
Obtaining the study participant's declaration of consent under data protection law	x	
Retention of the original documents for the statement on data privacy and declaration of consent of the study participant	x	
Ensuring appropriate access restriction to the eCRFs and the study database	x	x
Ensuring the accuracy of the records entered into the investigation database	x	

Responsibility for the diligent management of the eCRFs	x	
Processing of requests for right of access to information (Art. 15)	x	x
Processing of rectification requests (Art. 16)	x	x
Processing of requests for erasure (Art. 17)	x	x
Processing of requests for restriction of processing (Art. 18)	x	x
Transfer of notifications regarding the rectification or erasure of personal data or the restriction of processing (Art. 19)	x	x
Processing of requests related to the right to data portability (Art. 20)	x	x
Processing of objections to data processing (Art. 21)	x	x
Determination of the appropriate technical and organisational measures after risk assessment (Art. 24 (1) and Art. 32)	x	x
Documentation of the appropriate technical and organisational measures as proof of proper processing (Art. 24 (1))	x	x
Review and update of appropriate technical and organisational measures as necessary (Art. 24 para. 1)	x	x
Contact point for the data subjects (Art. 26 (1) sentence 3)	x	x
Making the essence of the agreement available to the data subjects (Art. 26 para. 2)		x

Involvement of processors or sub-processors and their verification (Art. 28)	x	x
Maintenance of the records of processing activities (Art. 30)	x	x
Notification of personal data breaches to the supervisory authority (Art. 33)	x	x
Notification of the data subject of a personal data breach (Art. 34)	x	x (only for study team members)
Data protection impact assessment (Art. 35)	x	x
Appointment of a data protection officer (Art. 37)	x	x
Ensuring the conditions for transfer of personal data to third countries (Art. 44 ff.)		x (only for study team members)

Annex B

Information on joint responsibility according to Art. 26 (2) sentence 2 of the General Data Protection Regulation (GDPR)

Research project:

Left Atrial Appendage closure in patients with non-valvular atrial fibrillation and end-stage chronic KIDNEY disease (LAA-KIDNEY).

The Sponsor and the Study Centre are legally obligated (Art. 26 (2) p. 2 GDPR) to explain the data protection responsibilities to you in a comprehensible manner. As you have signed up as a participant in the LAA-KIDNEY study, we are therefore providing you with this information sheet.

What is the reason for the joint responsibility?

The Sponsor (University Hospital Schleswig-Holstein) and your responsible Study Centre work closely together within the scope of the In LAA-KIDNEY project. This also concerns the processing of your personal data. The parties have jointly determined the order of processing of this data in the individual process stages. They are therefore jointly responsible for the protection of your personal data within the process stages described below (Art. 26 DS-GVO).

Description of the joint processing of personal data

The implementation of the study is described in the so-called protocol. Among other things, it specifies which personal health data must be collected from you. Your data will be collected by the Study Centre and stored in an electronic database of the Sponsor. From the time you as the patient are informed and included in the study until the final closure of the database, after which the Study Centre no longer has write access to the eCRF, there is joint responsibility. The Sponsor and Study Centre have access to the database for this period and can read, rectify and erase data.

Subject of the processing	*LAA-KIDNEY*
Nature and purpose of the processing	Medical research
Legal basis of the processing	Article 6(1)(a), 1(b), 1(c) and 1(f) GDPR Article 9(2)(a), 2(g), 2(h) and 2(i) GDPR Section 22 BDSG
Type of personal data	Surname, first names, health data
Categories of data subjects	Patients (health data) Other parties involved in the study at the Study Centre, Sponsor and involved processors
Description of the actual function and relationship of the joint controllers	The respective processing and mutual transmission of personal data by the joint controllers shall be carried out on the basis of the above-mentioned legal bases in each case exclusively for the purpose of fulfilling the contract for the research project, of which the joint controllers are the contracting parties.

What have the parties agreed?

As part of their joint responsibility under data protection law, the Sponsor and the Study Centre have agreed on which of them fulfils which obligations under the GDPR. This in particular concerns the exercise of the rights of the data subjects and the fulfilment of the information obligations pursuant to Articles 13 and 14 of the GDPR.

This arrangement is necessary because personal data are processed in different process stages and systems are operated either by the Sponsor or Study Centre within the scope of the implementation of the ***LAA-KIDNEY*** study.
In the following, you will find an overview showing which party is primarily responsible for which processing activity. The basis for data processing is your specific and express declaration of consent.

Process stage, if applicable IT system		Obligations to be fulfilled by:
Provision of the documentation system (eCRF) and the data privacy statement and declaration of consent documents for the study participants		Sole responsibility of the Sponsor
Obligation to provide information when collecting personal data from the data subject (using the information sheet provided by the Sponsor) (Art. 13) and obtaining the Study participant's declaration of consent under data protection law		Study Centre
Collection of personal data (health data) according to the specifications in the investigation plan via the locally used system (electronic patient file or paper-based)		Study Centre
Documentation of the collected health data in the eCRF (documentation system for secure data storage) provided by the Sponsor.		Study Centre
Checking the data provided for plausibility and completeness. Regular exchange with the Study Centre for the purpose of "cleaning up" the data.		Sponsor
Rectification of the documented data in the eCRF if errors are found during a plausibility check (manual or automated/programmed)		Study Centre
Analysis of the data provided with the statistical programme SAS and subsequent publication after anonymisation of the data.		Sole responsibility of the Sponsor
Over the course of the study: If necessary, forwarding of individual safety-relevant reports to participating ethics committees in anonymised form.		Sole responsibility of the Sponsor
Over the course of the study: Reporting of breaches in the handling of personal data		Sponsor and Study Centre, depending on who is acting as controller where the data protection breach occurred.

What does this mean for data subjects?
Even if there is joint responsibility, the parties shall fulfil the data protection obligations in accordance with their respective responsibilities for the individual process stages as described above.
The Sponsor shall make the information required under Articles 13 and 14 of the GDPR available to you free of charge in a precise, transparent, comprehensible and easily accessible form and in clear and simple language. This information will be provided to you by the Study Centre.
The Sponsor and the Study Centre shall inform each other without delay of any legal positions asserted by you and shall provide each other with all information necessary to respond to requests for access to information.
Data protection rights can be asserted both with the Sponsor and the Study Centre. Since the Sponsor only receives encrypted (pseudonymised) data from you, the Sponsor may not be able to process your request due to lack of attribution. In this case, the Sponsor will immediately forward your request to the Study Centre so that your request can be answered within the legal time limits. You will find the respective contact details in the consent form. In all other cases, you will always receive the requested information from the Study Centre.

If you have any questions, please directly contact your physician attending to your case within the context of the LAA-KIDNEY Study.