Cooperation Agreement

between

Charité – Universitätsmedizin Berlin
represented by the Financial Director Faculty,
Charitéplatz 1, 10117 Berlin, Germany

Performing department:
Institute for Hygiene and Environmental Medicine

Person responsible for project management:
Dr. med. Brar Piening

- hereinafter referred to as "Charité" -

and

Department of Health Promotion, Mother and Child Care, Internal Medicine and Medical Specialities "G. D'Alessandro", PROMISE, Università degli Studi di Palermo
represented by Prof. Antonio Carroccio
Piazza delle Cliniche 2, 90127 Palermo, Italy

Person responsible for project management:
Prof. Mario Giuffrè

- hereinafter referred to as "PROMISE" -

- hereinafter all individually and collectively referred to as the "Contractual Partners" -

Preamble

The Contractual Partners intend to jointly implement the project entitled

"NeoIPC Surveillance"

(hereinafter referred to simply as the "Project").

The NeoIPC Surveillance is part of the NeoIPC project which is currently funded by the European Union's Horizon 2020 research and innovation programme under Grant Agreement No 965328.

While NeoIPC's overall goal "is to foster infection prevention and control research and implementation in the high risk setting of neonatal intensive care", the NeoIPC Surveillance (also "Work Package 5" or "NeoIPC-MEASURE") aims

1. to establish "surveillance participation as part of an IPC implementation strategy",
2. to perform an options "appraisal of currently available tools and platforms for neonatal intensive care IPC surveillance",

3. to capture “the diversity of the current state of IPC and hospital-acquired infection in neonatal intensive care”,
4. to establish an overarching IPC surveillance structure for neonatal intensive care”
5. and to develop and establish a “globally relevant surveillance toolkit and framework for key IPC process and outcome measures”.

Some of these objectives (1, 3, 4, and 5) will be addressed through the establishment of a database that will capture infections as well as the key risk factors of the patients treated in the participating NICUs and that will later be used to create the standardised and stratified reports based on which participating centres can assess their infection rates and plan interventions.

While the data contained in the planned reporting are primarily facility and/or case group related by their nature, the risk factors that must be entered for standardisation and stratification, e.g., a patient’s very low birth weight or the age in days on the day of admission, may well represent "individual cases" and thus "personal" data. Even though the participating hospitals will not provide any identifying data to Charité for the purpose of the NeoIPC Surveillance project, these before mentioned data must be considered as personal data under the European General Data Protection Regulation (GDPR), since the type of data transferred could, under certain circumstances, lead to a re-identification of the newborns. Therefore, the parties shall comply with applicable data protection laws and enter into a Joint Controller Agreement within the meaning of Article 26 GDPR, which is added to this contract and incorporated herein as Annex 2.

As there is currently no overview possible about how many hospitals can or will finally take part in this surveillance work program, we cannot generate one Consortium Agreement. Therefore, this cooperation will be set up via bilateral cooperation agreements, but which contain elements of a greater cooperation with more partners.

The Contractual Partners therefore conclude the following Cooperation Agreement:

§ 1 Subject of cooperation

(1) The subject of the Agreement is to cooperate with respect to establishing surveillance participation as part of an IPC implementation strategy and establishing an overarching IPC surveillance structure for neonatal intensive care. Parties will send in their data via an electronic data capture platform where they can also generate standard reports for their NICU. Charité will issue and publish aggregated reference reports based on this data on the NeoIPC website. There will not be any customized reports per Contractual Partner, but probably, due to the very different actual situation in the different participating countries or within a country, there will be some kind of “country-specific” or “region-specific” reports. Charité will ensure that reports are aggregated in a way that avoids identification of individual hospitals or patients.

(2) The respective contributions of the individual Contractual Partners and the schedule can be found in the project description (Annex 1).

(3) The project work is to be carried out in accordance with the relevant laws, guidelines, and other regulations, where applicable. Any necessary registrations and/or permits are to be obtained in good time and locally.

(4) The Contractual Partner also has to assure that there is a legal basis for the collection of the data, may it be a (local/national) law or any form of informed consent by the parents of the newborns.

(5) The Contractual Partners shall each appoint a project manager. The project managers shall be responsible for the proper execution of the work.

Charité hereby appoints the following person as project manager: Dr. med. Brar Piening

PROMISE hereby appoints the following person as project manager: Prof. Mario Giuffrè

Should a project manager resign during the term of the Agreement or for any other reason relinquish the project management, a staff member equally qualified to carry out the research work can be appointed as successor after informing the other Contractual Partner. If this is not possible or if the other Contractual Partner does not agree with the appointed successor for a justified reason, the Contractual Partners shall mutually agree to terminate the Agreement. Should this also not be possible, the Agreement may be terminated prematurely for cause.

(6) The Contractual Partners shall undertake to fulfil the coordinated areas of responsibility and subtasks. The Partners shall discuss among themselves the task descriptions, schedules, and all information necessary for the execution of the Project.

(7) Each Partner shall be responsible for the performance of the tasks it has taken on.

§ 2 Funding

Each Contractual Partner shall bear its own costs incurred in connection with the implementation of this Agreement. Claims for payment of any kind whatsoever cannot be established by this Agreement.

§ 3 Existing intellectual property

(1) Each Contractual Partner is and shall remain the owner of its intellectual property (protected and unprotected) existing at the time of conclusion of this Agreement.

(2) Due to the very nature of the collected data in this programme there is no expectation at all to discover any inventions or other intellectual property which can possibly be protected.

(3) If needed, each Contractual Partner shall grant the other Contractual Partner a free, non-exclusive, non-transferable, and non-sub-licensable right of use for this pre-existing intellectual property for the duration of the Project, in so far as this is necessary for the performance of this Agreement and provided there are no conflicting third-party rights. In particular, a right of use granted hereunder shall not give rise to any entitlement to process or modify the invention and the intellectual property right.

(4) Each Contractual Partner acknowledges that acts of use within the scope of the Project that concern the information and objects obtained from the other Contractual Partner shall not give rise to a right of prior use.

§ 4 Rights to the work results

(1) No inventions are expected due to the nature of the project. Still the Contractual Partner from whom the work results (patentable and non-patentable) developed within the scope of the Project originated shall be entitled to these results. And he/she will inform the other partner about these results without delay. Jointly developed work results belong jointly to the Contractual

Partners in proportion to the shares to be allocated according to their respective contributions to each Contractual Partner.

(2) Work results are all results, including reports and documents prepared, that are obtained by the Contractual Partners in the course of carrying out their work within the scope of the Project (e.g., expertise, inventions, works protected by copyright, software).

§ 5 Rights of use of non-patentable work results

(1) Each Contractual Partner shall receive a free, non-exclusive, non-transferable, and non-sub-licensable right of use for the non-patentable work results to which the other Contractual Partner is entitled for the duration and purposes of the Project. In so far as the non-patentable work results of a Partner are required for commercial exploitation or for purposes outside of the Project or after the end of the Project, the other Partner may receive a non-exclusive right of use for this at standard market conditions. Further details shall be mutually agreed between the Contractual Partners in a contract entered into separately from this Agreement.

(2) All Contractual Partners shall receive, free of charge, a non-exclusive, non-transferable right of use for non-commercial research and teaching activities for non-patentable work results, in so far as this is legally permissible.

§ 6 Patentable work results

(1) Each party will proceed with inventions according to its own standards and the local law.

(2) Regulation in case of joint inventions: The Contractual Partners involved shall immediately agree on the further course of action, in particular the protection under property law, and shall record the results in a written report or agreement. In the case of joint inventions, industrial property rights will be applied for in the name of the Contractual Partners involved; for this purpose, each Contractual Partner shall make unlimited use of the inventor's share of its employees notified to it. In the case of joint inventions, each of the Contractual Partners involved may only dispose of the invention or joint property right with the prior written consent of the other Contractual Partner (e.g., licence, sale). Such consent may not be unreasonably withheld. If a Partner of a joint invention wants to waive the application and/or maintenance of an industrial property right or industrial property right share, it shall first offer this to the other Contractual Partner for takeover. That Contractual Partner shall declare no later than eight (8) weeks after receipt of the takeover offer whether it will accept the offer. All costs arising from the takeover, including inventor's remuneration, shall be borne solely by the party taking over.

(3) Freelance inventors involved in the Project (e.g., students, doctoral candidates) must be obligated in writing to report and transfer their rights to any inventions prior to the start of their participation in the Project.

§ 7 Publications

(1) Charité will publish the results of this research after the termination of this common project in due time together with the participating sites and according to scientific standards. This may also happen as a report to the Founder of this programme. Parties will abstain from own publications until this planned common publication was approved fit to print or that 18 months have passed by since termination of this project.

(2) Work results that are attributable to one Contractual Partner alone may be published by this partner. For these "Single-"publications, the Contractual Partner shall submit the manuscripts of planned publications and presentations to the other Contractual Partners possibly involved for review at least thirty (30) days prior to the planned publication in order to give the other Contractual Partner the opportunity to comment. Proposed amendments by the other partners will be taken into account, provided that they do not negatively impact upon the scientific character or neutrality of the publication. If, after thirty (30) calendar days from the date of delivery, no written and substantiated objection has been raised, the consent to publication shall be deemed to have been granted.

(3) Any publication of results out of this cooperation shall always include a reference to the NeoIPC project which is currently funded by the European Union's Horizon 2020 research and innovation programme under grant agreement No 965328.

§ 8 Trademark protection

(1) The Contractual Partners shall mutually acknowledge all other party's trademark rights and rights to the use of a name. Neither Contractual Partner shall use the other Contractual Partner's name or trademarks, in whatever form and for whatever purpose and regardless of the medium, without the other Contractual Partner's prior written consent.

(2) This does not include the naming of names within the scope of the usual naming of authors in scientific journals or official study registers (such as www.clinicaltrials.gov). For the avoidance of all doubt, it is clarified that, for example, mentioning the name on one's own homepage or in so-called popular science media does not constitute naming within the meaning of this paragraph.

§ 9 Confidentiality

(1) **Duty of confidentiality.** The Contractual Partners undertake to keep confidential all work results, trade secrets, expertise, technical descriptions and evaluations, inventions as well as other information and data requiring protection (hereinafter referred to as "Confidential Information") belonging to the other Contractual Partner and made available to one another or that they otherwise become aware of within the scope of this cooperation, and to refrain from making them available to third parties either directly or indirectly and to use them exclusively for the execution of this Agreement and the Project.

(2) **Scope of Confidential Information.** The above duty of confidentiality shall include all information that is designated as such verbally or in writing, or the confidentiality of which is readily apparent to the receiving Contractual Partner from the circumstances.

(3) **Effectiveness of the duty of confidentiality.** The foregoing obligation to maintain the confidentiality of Confidential Information shall extend beyond the term of this Agreement for five (5) years, regardless of whether the Agreement is terminated ordinarily or for cause.

(4) **Exceptions.** The following shall not be covered by the duty of confidentiality:

(a) information that was generally known at the time of signing of this Agreement or that becomes generally known at a later date without any breach of this Confidentiality Agreement having taken place,

(b) information that the recipient has already obtained knowledge of in a lawful manner prior to the conclusion of this Agreement,

(c) information that the recipient has received from a third party authorised to disclose the information,

(d) information that must be disclosed on the basis of a statutory, judicial, or official order,

(e) information that has been developed by the receiving Contractual Partner independently of the information received on the basis of this Agreement, or

(f) information that the Contractual Partners agree in writing is not to be treated as confidential.

The burden of proof for the non-existence of Confidential Information as described in § 9(4) lies with the Contractual Partner who invokes this. In the event of a statutory, judicial or official order pursuant to § 9(4)(d), the recipient shall – to the extent permitted by law – notify the Contractual Partner that provided the information of this without undue delay, support the measures put in place by the latter to protect the Confidential Information to the reasonable extent permitted by law, and limit disclosure to that which is absolutely necessary to fulfil the obligation.

(5) Technical/organisational confidentiality measures. Each Contractual Partner shall ensure confidentiality by technical means and through other measures that are appropriate under the circumstances.

§ 10 Data protection

The parties agree that all data protection regulation is to be followed within this project. The regulations concerning the processing of personal data within the scope of the Project are laid down in a separate Joint Controller Agreement based on Article 26 of the GDPR attached to this Agreement as Annex 2Errore. L'origine riferimento non è stata trovata.. Annex 2 also contains an explanation to the kind of data used within the project.

§ 11 Liability

(1) The Contractual Partners shall carry out the work carefully and in accordance with recognised scientific standards. The Contractual Partners are aware of the success risk associated with the research work. Due to the research character of the work, the Contractual Partners do not guarantee that a specific work result will be achieved or that the work result can be used or commercially exploited for a specific purpose or that it is free of third-party property rights. Where conflicting property rights become known, the Contractual Partner getting to know this fact shall immediately inform the other Contractual Partners of this.

(2) Mutual liability shall be limited to intent and gross negligence.

(3) Liability for consequential damages shall be excluded, except in the case of intent and gross negligence.

(4) In so far as liability is excluded or limited, this shall also apply to the Contractual Partner's employees, legal representatives, vicarious agents, and assistants.

(5) If necessary, the Contractual Partners shall support one another in defending claims by third parties by providing the necessary declarations and/or documents.

§ 12 Limits of the cooperation

(1) The Contractual Partners confirm that the conclusion of the Agreement shall have no influence on either Contractual Partner's sales transactions, in particular procurement processes/pricing, and that there are no expectations in this regard.

(2) The Contractual Partners undertake not to provide any gift, payment, or other form of advantage to any person directly or indirectly involved in the execution of the Agreement without legal grounds, which could be seen as an incentive or reward for the conclusion or execution of any part of the Agreement.

(3) No Contractual Partner shall be entitled to represent individual Contractual Partners or all Contractual Partners together. The Contractual Partners shall not use the Project title or a comparable sign describing or indicating the association of the Contractual Partners in legal transactions in such a way as to create the impression that the said Contractual Partners jointly represent individual or all Contractual Partners.

(4) No Contractual Partner shall be entitled to assign or transfer obligations arising from this Agreement in whole or in part.

§ 13 Term of the Agreement

(1) This Cooperation Agreement shall enter into force upon the last signature and shall end at the latest upon achievement of the project objective or upon the preparation of a joint final report.

(2) Termination for cause shall remain unaffected. Cause shall be deemed to exist in particular if the terminating Contractual Partner cannot reasonably be expected to continue the contractual relationship until the agreed termination or until the expiry of a notice period, taking into account all circumstances of the individual case and weighing the interests of both parties.

(3) Notice of termination must be in writing.

(4) Those provisions of this Agreement that the Contractual Partners wish to continue beyond the end of the Agreement, in particular § 3 - § 9, shall continue to apply in the event of termination.

§ 14 Applicable law and place of jurisdiction

(1) The Agreement shall be governed exclusively by Belgian law to the exclusion of conflict of law provisions.

(2) The place of jurisdiction shall be Berlin.

§ 15 Final provisions

(1) The following documents form an integral part of this Cooperation Agreement. The contents are binding for all Contractual Partners:

Annex 1:	Project description
Annex 2:	Data protection/data explanations

(2) Any changes and additions to this Agreement must be made in writing. No subsidiary agreements have been made; should these be made, they must also be in writing. This requirement for the written form can also only be amended in writing.

(3) Should individual provisions of this Agreement be invalid, the validity of the remaining provisions shall not be affected. In place of the invalid provision, a provision shall apply that comes closest to what the Contractual Partners intended or would have intended if they had been aware of the invalidity of the provision. The same shall apply to any contractual loopholes.

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On behalf of Charité

Berlin, on

Town/city, date

Dr. Katharina Flemming

Head of GB Research Services

Acknowledged:

Berlin, on

Town/city, date

Dr. med. Brar Piening

Project manager

On behalf of PROMISE

Palermo, on

Town/city, date

Prof. Antonio Carroccio

Director of Department PROMISE

Acknowledged:

Palermo, on 13th November 2023

Town/city, date

Prof. Mario Giuffrè

Project manager

Annex 1

Project description

Surveillance of hospital-acquired infections and the occurrence of multi-drug-resistant pathogens and comparing their occurrence-rates from a single centre to a benchmark generated from a reference database is a widely accepted means of infection prevention and control (IPC) and continuous quality improvement in hospitals. In neonatology there currently is a lack of reference databases and applicable benchmarking information in many European countries and worldwide. The NeoIPC Surveillance project aims to change this by providing surveillance tools and methods, and benchmarking information, which are applicable in a wide variety of settings.

Starting in 2023 the project will provide a toolkit for surveillance, including a reference database from which benchmarking information will be generated on a yearly base until at least 2025.

Charité will develop and improve the surveillance methods and tools, run the reference database, and generate reference reports for benchmarking, while individual hospitals (contract partners) adopt the methods and use the tools to perform ongoing surveillance as part of their continuous quality improvement that is integrated into regular patient care. The reference reports provided by Charité will help them and other hospitals to assess their situation regarding IPC.

To ensure the successful creation of a reference database and the generation of valid benchmarking information, the contract partners must meet the following requirements

- Approval from the head of the neonatology department and the hospital administration to participate in the NeoIPC Surveillance
- Consent to apply the methods specified in the NeoIPC surveillance protocol as published on the NeoIPC website
- Participation of at least one representative in an introductory course (online webinar)
- Regular participation of at least one representative in annual meetings (online webinar); at least every second year
- Regular entry of surveillance data into the data collection platform and announcement of any interruption in continuous data collection.
- Approval for the publication of the anonymised (aggregated) reference data
- Willingness to participate in validation measures on the quality of the reported data (e.g. diagnosis of nosocomial infections).

Charité assures the departments involved

- To give them advice and professional support in carrying out the surveillance
- To treat their participation and their data strictly confidential
- To generate standardized and stratified reference data and to make them publicly available
- To provide contract partners with a means to generate standardized and stratified reports for their individual centre
- To provide assistance in the interpretation of surveillance results for quality management

While the Horizon 2020 programme requires open access to research data and Charité as member of the European University Hospital Alliance and signee of the Sorbonne Declaration on Research Data Rights is committed to making research data publicly available, there are currently open questions regarding safe anonymization of personal data of neonates and access to anonymized data stemming from routine patient care.

Since addressing these questions may be of high relevance for future research on neonatal infections, Charité will work together with stakeholders, experts in the field and individual hospitals to assess the options for public sharing of anonymized data. Nevertheless, due to the aforementioned problems, Charité will not disclose any unaggregated data from a contract partner without explicit written consent.

Annex 2

Agreement on joint control over the processing of personal data in accordance with Article 26 of the General Data Protection Regulation (GDPR)

between

Charité – Universitätsmedizin Berlin

Charitéplatz 1, 10117 Berlin, Germany

(Controller within the meaning of the GDPR, hereinafter referred to as "**Party 1**")

Implementing entity:

and

Party 2 which is the participating Hospital

(Controller within the meaning of the GDPR, hereinafter referred to as "**Party 2**")

(Party 1 and Party 2 hereinafter collectively referred to as the "**Parties**")

Preamble

The Parties intend to cooperate within the framework of the NeoIPC-Surveillance of nosocomial infections (hereinafter referred to as the "**Project**"). The cooperation in the context of the Project requires the processing of data, some of them personal data in respect of which the Parties – at least in part – jointly determine the purposes and means of the data processing and to that extent consider themselves as joint controllers within the meaning of Article 26 GDPR. For this reason, the Parties enter into the present agreement on joint control over the processing of personal data in accordance with Article 26 of the General Data Protection Regulation (hereinafter the "**Agreement**"):

General remarks

(1) This Agreement governs the rights and obligations of the Parties in relation to the joint processing of personal data. This Agreement applies to all activities in the course of which employees of the Parties or processors engaged by them process personal data in the context of the Project. The Parties have jointly determined the means and purposes of the processing activities described in more detail in 0.

(2) The subject matter of this Agreement is the processing of personal data by the Parties for the purpose of implementing the Project. The Parties hereby determine the processing steps in which personal data are processed under their joint control (Article 26 GDPR).

(3) For the avoidance of doubt, with respect to any processing that falls outside the scope of this Agreement, each of the Parties shall remain solely responsible and fully liable as controller within the meaning of Article 4 GDPR and, to that extent, no responsibilities or obligations of any Party towards the respective other Party shall arise under this Agreement.

(4) Unless otherwise specified in this Agreement, the terms used herein shall have the meaning ascribed to them in Article 4 GDPR.

Data processing operations, legal bases and tasks of the Parties

A) The responsibilities and competences in the context of the implementation of the Project are set out in Annex 2.1.

B) The subject matter of the processing, the type of data and categories of data subjects, and the purposes of the processing, are set out in Annex 2.2 and in the surveillance protocols as published on the NeoIPC website (https://neoipc.org/surveillance/resources/)

C) If necessary, because of a data processing operation, the Parties will adapt the provisions of this Agreement accordingly. In view of the obligations of the Parties as joint controllers, each of the Parties is responsible for informing the other Parties if it deems it necessary to adapt the Agreement.

Principles relating to the processing

(1) Each Party shall ensure compliance with the statutory provisions, in particular the lawfulness of the data processing operations it carries out, including in the context of joint control. The Parties affirm and shall ensure that all personal data will be collected and further processed in accordance with the provisions of this Agreement and applicable data protection laws.

(2) The Parties shall at all times ensure that they comply with the principles relating to the processing of personal data under Article 5 GDPR.

(3) If any of the Parties considers that, in the course of the performance of the present Agreement, any/the other Party is in breach of the provisions of this Agreement or of the applicable data protection laws, it shall immediately notify the other Party/Parties of this.

Expediency and data minimisation

(1) The Parties shall store the personal data for which they are responsible in a structured, commonly used, and machine-readable format, as agreed in the Main Agreement.

(2) Each Party that collects data shall ensure that only those personal data are collected that are consistent with the specified, clear, and legitimate purposes for the implementation of the Project and are strictly necessary.

(3) None of the Parties shall make copies or duplicates of the personal data processed under this Agreement unless necessary for the implementation of the Project (including data backups) or for the purpose of complying with legal retention obligations.

Location of the data processing

(1) Party 1 will process personal data in the course of the implementation of the Project exclusively in Germany

Information to be provided to data subjects

(1) If necessary, in the country of Party 2, Party 2undertakes to provide data subjects free of charge with the information required under Articles 13 and 14 GDPR in a concise, transparent, intelligible, and easily accessible form, using clear and plain language. This information shall inform the data subjects about the allocation of responsibility for the processing of the personal data. In particular, information shall be provided on which Party is responsible for the identifying data or the process of re-identification. This Party should also be named as the contact person for safeguarding the rights of data subjects.

(2) The Parties agree that the Party collecting the personal data from the data subjects (Party 2) shall provide the information referred to in paragraph 1.

Contact point for data subjects and reciprocal information requirement

(1) The Parties shall take all necessary technical and organisational measures to ensure that the rights of the data subjects, in particular under Articles 12 to 22 GDPR, can be or are guaranteed at all times within the statutory time limits, in so far as these rights are not restricted by statutory provisions.

(2) The Party that is to process the identifying data (Party 2) in accordance with the Agreement shall be responsible for responding to requests from data subjects for the purpose of asserting their rights under Articles 15 to 22 GDPR. The Parties agree that in each case this Party shall be named as the contact point for the data subjects. Data subjects may assert the rights to which they are entitled under Articles 15 to 22 GDPR against all Parties. Data subjects shall be informed of the contact point responsible for them and of their rights by the responsible Party in accordance with 0.

(3) The Parties will assist each other in responding to requests and giving effect to data subject rights. If a Party receives a complaint, request, or notice from a data subject whose data it did not collect, it will promptly notify the Party that collected the data of the data subject's request. If a data subject contacts one of the Parties regarding the exercise of his or her data subject rights, in particular for information or the rectification or erasure of his or her personal data, the Parties undertake to forward this request without delay to those Parties whose sphere of activity is affected by the request, irrespective of the obligation to ensure the data subject right.

(4) The Parties' responsible contact persons are:

Function	**Surname, first name**	**Email**	**Telephone**
Party 1 (Charité – Universitätsmedizin Berlin)			
Project manager	Herr Dr. med. Brar Piening	brar.piening@charite.de	+49 30 450 577616
Data Protection Officer	The Data Protection Officer of Charité – Universitätsmedizin Berlin Campus Charité Mitte Charitéplatz 1 10117 Berlin	datenschutzbeauftragte@charite.de	+49 30 450 580015

Function	Surname, first name	Email	Telephone
Party 2 (Participating Hospital)			
Project manager	Prof. Mario Giuffrè	mario.giuffre@unipa.it	+39 91 6555452 - +39 328 0410496

The other Parties shall be notified without delay of any change to the respective contact person.

(5) If a Party uses a processor and the processor receives a complaint, request or notice from a data subject, the Party that engaged the processor shall ensure that the processor notifies the Party that collected the data subject's data of the request.

Erasure of personal data

(1) If personal data are to be erased, the Parties shall inform each other in advance. The Parties may object to the erasure for a legitimate reason, for example if they have a legal obligation to retain the data or if the right to erasure is restricted by law.

(2) Regardless of a request for erasure, the Parties shall erase the data when the project objective has been achieved and if there is no right to further retention.

(3) Each Party shall keep a record of the erasure of personal data, which is to be provided to the other Parties upon request.

(4) Paragraphs 1 and 3 shall apply accordingly in the event of requests for rectification or restriction of processing from data subjects.

Communication and notification obligations

The Parties shall inform each other without delay if they discover errors or irregularities with regard to data protection provisions when reviewing the processing activities within the scope of the Project.

Procedure in the event of data protection incidents

(1) The Parties are responsible for the notification and communication obligations resulting from Articles 33 and 34 GDPR vis-à-vis the supervisory authority and the data subjects affected by a personal data breach under their respective responsibility. Any required notification to the supervisory authority shall be the responsibility of the Party under whose responsibility the personal data breach occurred. If the breach occurs under the responsibility of more than one Party, the Parties shall consult with each other on how to proceed.

(2) The Parties shall notify each other without delay, and in no circumstances more than 24 hours, after becoming aware of a possible personal data breach under their responsibility. If possible, this notification should already contain the information required under Article 33(3) GDPR.

(3) Any required notification to the supervisory authority shall be the responsibility of the Party under whose responsibility the personal data breach occurred. If the breach occurs under the responsibility of more than one Party, the Parties shall consult with each other on how to proceed. The Parties shall comply with the statutory time limit for notification within 72 hours. Any deviation from the time limit must be justified and documented.

(4) If, due to a risk to the rights and freedoms of natural persons, data subjects are to be informed pursuant to Article 34 GDPR, the Party that collected the personal data (Party 2) shall be responsible for this. The respective other Parties shall assist the Party responsible under the first sentence to the best of their abilities in fulfilling its notification obligations and shall forward the information required to carry out the notification to the Party in question without delay.

(5) Where possible, the Parties shall coordinate with each other on any communication with the competent supervisory authority and/or the data subjects relating to a personal data breach before it is sent. The Parties shall promptly take all measures within their areas of responsibility that are necessary to address or prevent data protection breaches and violations.

Data protection impact assessment (DPIA)

If a DPIA is required pursuant to Article 35 GDPR, the Parties shall assist each other and provide each other with the information necessary for its preparation. Projects for which a DPIA is to be carried out may only be started once the DPIA has been completed.

Documentation/accountability

Documentation within the meaning of Article 5(2) GDPR which serves to demonstrate proper data processing shall be prepared by each Party in accordance with its legal powers and obligations and, if necessary, shall be retained beyond the end of this Agreement.

Confidentiality, retention, state of the art, protection

(1) The Parties shall ensure, within their area of responsibility, that all employees involved in data processing maintain the confidentiality of the data in accordance with Articles 28(3), 29 and 32 GDPR for the duration of their employment as well as after termination of the employment relationship and that these persons have committed themselves to confidentiality and been informed of the data protection provisions relevant to them prior to commencing their employment.

(2) The Parties shall independently ensure that they comply with all statutory retention obligations existing in relation to the data. To this end, they shall take appropriate data security precautions (Article 32 et seq. GDPR). This applies in particular in the event of termination of the cooperation.

(3) The implementation, pre-setting and operation of the systems shall be carried out in compliance with the requirements of the GDPR and other legislation, in particular in compliance with the principles of data protection by design and by default, as well as using appropriate technical and organisational measures in line with the state of the art.

Record of processing activities

Each Party shall, in accordance with Article 30(1) GDPR, keep a record of the processing operations it carries out, including and in particular a note on the nature of the processing operation under its joint or sole control.

Audit rights

(1) Each Party shall have the right to audit the compliance of the other Party/Parties with this Agreement if this is necessary in order to fulfil an obligation vis-à-vis a supervisory

authority or to satisfy itself that the other Party/Parties has/have adapted its/their operations to the provisions of this Agreement following a data protection incident.

(2) If and to the extent that such an audit requires the performance of on-site inspections, such inspections shall ordinarily take place during normal business hours and without unnecessary disruption to operations. The Party conducting an audit shall give reasonable advance notice to the other Parties of all circumstances related to the audit.

(3) A Party may engage a third party to carry out the audit. In such a case, the third party must be bound in writing to maintain secrecy and confidentiality, unless the third party is subject to a professional duty of confidentiality.

Liability

(1) Without prejudice to the provisions of this Agreement, in the event of unlawful data processing, the Parties shall, in accordance with Article 82(4) in conjunction with the first sentence of Article 82(2) GDPR, in relation to third parties, be jointly liable vis-à-vis the data subjects for any damage caused by processing which infringes the GDPR, unless any of the Parties can prove that it is not in any way responsible for the event giving rise to the damage (Article 82(3) GDPR).

(2) In their internal relationship, the Parties shall, without prejudice to the provisions of this Agreement, only be liable for damage that has occurred within their respective area of responsibility.

(3) If, pursuant to Article 82(4) GDPR, a Party has paid the entire compensation to a data subject for the damage suffered, that Party shall be entitled to recover from the other Parties that part of the compensation which corresponds to those other Parties' share in the responsibility for the damage.

(4) Paragraph 3 shall apply accordingly in the event that a supervisory authority has imposed a fine on a Party if and to the extent that the breach giving rise to the fine is based, in whole or in part, on a breach of this Agreement or the applicable data protection laws by one or more of the other Parties. Without prejudice to the foregoing, a Party may seek indemnification for a fine only if it has made all reasonable efforts to defend against or reduce that fine in the context of administrative proceedings.

Miscellaneous

(1) This Agreement shall remain in force, irrespective of the duration of the Project, until all data processed jointly by the Parties and/or any processors engaged have been erased, at which time it shall automatically cease to be in force.

(2) In all other respects, the final provisions of the Main Agreement shall apply accordingly.

Annex 2.1 (to 0: Responsibilities and competences of the Parties

Editing note: Please mark with [X] to indicate who is responsible for which tasks and with [Y] to indicate merely a support function.

Tasks according to GDPR	**Party 1** (Charité – Universitäts-medizin Berlin)	**Party 2** (Participating Hospital)
Determination of the purpose and means of data processing	**x**	**x**
Determination of the type of personal data	**x**	**x**
Article 26(2): Informing the data subjects about the essence of this Agreement*	**y**	**x**
Article 13: Information to be provided where personal data are collected from the data subject*	**y**	**x**
Article 14: Information to be provided where personal data have not been obtained from the data subject	**y**	**x**
Articles 15-18, 20: Data subject's rights of access, rectification and erasure/restriction of processing and data portability*	**y**	**x**
Article 19: Notification obligation regarding rectification or erasure of personal data or restriction of processing**	**y**	**x**
Article 21: Right to object, if applicable (not in case of consent)	**y**	**x**
Articles 24, 32, 35, 36: Determination/documentation of technical and organisational measures, risk assessment, data protection impact assessment, where applicable, and consultation with the supervisory authority	**x**	**x**
Article 28: Engaging processors	**x**	**x**
Article 30: Maintaining the records of processing activities	**x**	**x**
Article 33: Notification of personal data breaches*,**	**x**	**x**
Article 34: Communication of a personal data breach to the data subject*,**	**y**	**x**

* Communication with the data subjects shall be carried out exclusively by the body that may lawfully access identifying data, see §§ 7 to 10 of the Agreement.

** Communication between the Parties shall, where appropriate, take place in pseudonymised form, see §§ 7 to 10 of the Agreement.

Annex 2.2 (to 0 paragraph B)): Description of the processing activity and categories of personal data

NATURE AND PURPOSE OF PROCESSING	☒ Implementation of a research project as part of a specific project ☐ Processing for the purpose of future research ☒ quality assurance
CATEGORIES OF PERSONAL DATA	☐ Identifying data (*No identifying data will be transmitted to Charité*). ☒ Pseudonymized Data relating to health Specifically: ☒ Sex; Birth weight; delivery mode; gestational age; ☒ Admission on day of life, admission type; ☒ Multiple birth, number of siblings; ☒ Pathogen(s) detected; ☒ Symptoms and diagnoses (necrotizing enterocolitis, pneumonia, blood stream infections; surgical site infection); ☒ Information about surgical procedures ☒ Information about antibiotic treatment (medication) ☒ Event dates such as date of admission, date of infection; end of surveillance
CATEGORIES OF DATA SUBJECTS	☒ Patients/study participants ☐ Relatives of patients/study participants ☒ Employees ☐ Others (e.g., employees of contract processors)
DESCRIPTION of systems used for data processing	☒ Paper form ☒ Internal electronic database ☐ External electronic database ☒ Internal electronic data processing systems ☒ External electronic data processing systems (e.g., APP on terminal devices, survey tools, algorithms, software) ☐ Laboratory
Recipient of personal data	☒ Sponsor/research institution located in a country covered by the GDPR or with an adequate level of data protection ☐ Sponsor/research institution located in a third country without an adequate level of data protection