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| DATA TRANSFER AGREEMENT |
| BETWEEN |
| [●] (hereinafter referred to as “Provider”), with Registered Office at [●], Fiscal Code and VAT No. [●], in the person of the Dr/Prof. [⚫] as the Legal Representative |
| AND |
| UNIT OF BIOSTATISTIC, EPIDEMIOLOGY AND PUBLIC HEALTH with registered office in via L. Loredan, 18 35128 - Padua, Fiscal Code 80006480281/ VAT number 00742430283 (hereinafter referred to as “Recipient”), in the person of Prof. Dario Gregori, as UBEP Director; |
| Hereinafter also collectively referred to as the "Parties” |
| WHEREAS |
| * The Provider is a participating site of the CRICKET Study: “Critical events in anaesthetised kids undergoing tracheal intubation – a prospective, multi-centre observational study”, hereafter referred to as the “Study”. * The Provider is the controller of the study data, (hereinafter referred to as the “Data”), as set forth in Annex I of this Agreement; |
| By this Agreement, the Parties wish to establish conditions for the transfer of the Data and specify the aspects of confidentiality, protection and ownership as follows: |
| ART. 1  INTRODUCTION |
| The introduction is an integral part of this Agreement. |
| ARTICLE 2  OBJECT |
| This Agreement is aimed at regulating the transfer of the Study Data between the Provider and the Recipient, for implementation and development of the Study.  **Study IT structure**  The Study will involve the use of the web-based REDCap platform for entering, recording, and updating patient clinical data. Recipient will be responsible for migrating the data and structuring a related database, to be hosted at its IT facility. Specifically, the Study involves:  - The creation of a centralized multicenter database using the REDCap software provided and managed by the Recipient, with the provision of shared electronic forms among all centers for the collection and monitoring of patient data.  - The setup of database access;  - The handling of problem-solving requests from users entering Data, with communication via e-mail;  - The possibility of independent correction of Data entered by users, with tracking of corrections; |
| ARTICLE 3  COMMITMENTS OF THE PROVIDER |
| 3.1 The Provider agrees to make the Data available to the Recipient, on a royalty free and on a non-exclusive basis, for the Study only and on the terms and conditions set forth herein. The Data will only be made available in a pseudonymised form, after all direct and indirect personnel identification has been replaced by a code.  3.2 The Data collected and entered into the system will be at the disposal of the individual participating centers, through the local Study managers, who will be responsible for acquiring from the patients, who are and remain the owners, or from those who exercise parental authority or guardianship over them, the consents required by current regulations.  3.3 The Provider warrants that it is entitled to supply the Data and that all necessary consents and/or authorizations for the transfer and/or use of the Data to/by the Recipient have been obtained. |
| ARTICLE 4  COMMITMENTS OF THE RECIPIENT |
| 4.1 The Recipient will provide the necessary IT infrastructure to host the databases and related management security (daily backup of data and disaster recovery procedures) including the processing of data that will be entered into it in particular the management of personal and health data in accordance with the General Data Protection Regulation (hereafter the “GDPR”), regarding the processing of sensitive data as provided in Article 5 of the Agreement. In this regard, subjects will be identified with a code and only the person in charge of the center responsible for data entry will maintain the relevant decryption key. The IT infrastructure made available (REDCap) provides high security with the use of personal username and password. Different access profiles will be created detailed below:  - standard user users: for the investigator of the Study with only the possibility of entering or editing data of patients treated in the respective Center.  - superuser users: in this case the Recipient who will have the possibility of full data visualization and editing of the collection forms necessary for possible quality control and for the realization of statistical analysis  The servers used for Data storage will be owned by the Recipient. The Recipient is committed to ensuring the uninterrupted maintenance of the web hosting service and the security of the interconnection. It also agrees to address any problems that cause erroneous data transmission, keeping the Provider indemnified and held harmless from any damages that may be caused to it by its own employees.   * 1. the Data shall not be duplicated, transferred, distributed or supplied to any third party, whether with or without consideration, for any purpose or use without the prior written consent of the Provider and provided that the terms of this Agreement are maintained ;   2. the Data shall be processed and/or used only within the Recipient computational infrastructure and handled in accordance to the GDPR including GDPR Art. 5: Principles relating to processing of personal data.   3. The Recipient agrees to immediately report to the Provider any actual or suspected Data protection breach, including a breach against applicable Data protection regulation, Data protection section of this Agreement, any actual or suspected impairment or inadequacy of the Recipient in fulfilling Data protection section of this Agreement, and any application to receive or any actual access to Data by an authority, unless such reporting is not admissible under statutory provisions. |
| ART.5  OBLIGATION OF CONFIDENTIALITY, DATA PROCESSING AND PRIVACY PROTECTION |
| The Parties consider the program of activities confidential and mutually agree, using the best diligence, to observe and have their respective collaborators observe confidentiality regarding facts, information, knowledge and documents.  The Parties in the execution of the activities provided for in this agreement shall provide for the processing, dissemination and communication of personal Data in compliance with laws as applicable for each Party and the provisions of this contract, in accordance with EU Regulation 2016/679.  Pursuant to Data Protection Laws, the Parties will be required to comply with the regulatory provisions operating in full respect for the confidentiality and privacy of the Data, as well as any internal regulations in force.  The database contains no encrypted Data, so no data is traceable to the identification of the patient, in compliance with the regulations mentioned above.  The Recipient agrees:   * that the Data: (a) is to be used only for the academic purposes as described in Study protocol; (b) may not itself be commercialized and (c) shall not be transferred to or accessed by any third party, for any purposes whatsoever, without the prior written agreement of the Provider and in compliance with the informed consent of the subject; * to restrict disclosure of the Data solely to those employees or individuals working within the Recipient’s institution who require such access to the Data in order to conduct the Study; * make sure that the Data is protected from unauthorized access, promptly inform and assist the Provider immediately and in writing about any deviation concerning access to the Data (both accidental and unauthorized), and, if necessary, take any reasonable steps to regain access control and confidentiality; |
| ART. 6  DATA OWNERSHIP AND PUBLICATIONS |
| Ownership and all property rights and economic use of the database are the exclusive property of the Provider and will remain in the exclusive possession of the Provider, with access available, during the term of this Agreement to both the Provider and the Recipient. The data entered into the databases are and remain in each case of the patients who have given consent to the individual centers to acquire them and who may at any time request and obtain from the Provider the clearing of their data from the databases.  The Recipient warrants to the Provider that the contents of the information system it creates will not violate in any way the intellectual property rights of third parties and will hold it harmless and unharmed from any claim or action made by third parties and based on alleged violations of intellectual property rights arising from the structure and/or use of the information system. The results of the research and shared scientific projects will be the property of both parties.  The publication and dissemination of results of the Study is defined by the publication policy outlined in the Study protocol.  In the case of the achievement of patentable results, the possible patenting of the results will be the subject of a specific agreement between the Parties, in compliance with the relevant regulations.  In any case, the rights due to the inventors under the relevant legislation in force remain unaffected. |
| ART. 7  PERIOD OF AGREEMENT AND TERMINATION |
| This Agreement shall be effective from the date of last signature and for the period of 5 (five) years, with the possibility of extension for the time necessary for the completion of the Study, and further possibility of extension for subsequent periods, upon written agreement between the parties.  Each party has the right to terminate the Agreement by giving at least 60 days' written notice.  Il Provider may withdraw early from the agreement in the case of suspension of the web hosting service protracted for more than 30 days.  In the event of termination of the agreement and withdrawal there is an obligation on the part of Recipient to make available the database and software configuration documentation as of that date existing to the extent necessary or appropriate to allow the Provider to migrate the information system avoiding loss of data or compromise of databases. |
| ARTICLE 8  CHANGES |
| This agreement may be integrated, modified or amended, upon agreement between the Parties, only in writing, by persons with appropriate powers of representation on behalf of the Parties. |
| ART. 9  INDEPENDENCE OF THE PARTIES |
| This Agreement does not create any relationship of dependence of one party on the other, nor does it otherwise limit the legal autonomy of the parties, which remain fully distinct and independent subjects. |
| ART. 10  ANTICORRUPTION |
| The Parties mutually recognize each other's right to terminate this Convention: (a) if a Party or its Representatives fail to comply with the Anti-Corruption Laws or this provision, or (b) if there are reasonable grounds to believe that a Party has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. |
| ARTICLE 11  DISAGREEMENTS |
| For all disagreements that may arise in connection with the interpretation, validity and execution of this agreement that cannot be settled amicably, the parties, as of now, hereby now, elect as the place of jurisdiction the Court at the place of business of the defending Party. |
| ART. 12  REFERRAL RULES |
| For matters not expressly provided for, reference is made to the relevant provisions of the law |
| Read, approved and signed. |
| For [⚫]  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  [⚫] *(place) \_\_\_\_\_\_\_\_\_\_\_\_\_\_* |
| For the Unit of Biostatistics, Epidemiology and Public Health of the University of Padua, the Head Prof. Dario Gregori  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­  Padova\_\_\_\_\_\_\_\_\_\_\_\_ |