

Annex No. 8 to the Draft Agreement – Data Processing Entrustment Agreement

Personal data processing entrustment agreement
concluded on between:
(hereinafter referred to as the “Agreement”)

Gdańsk Medical University with its registered office in Gdańsk (80-210) at ul. M. Skłodowskiej-Curie 3a, NIP: 584-09-55-985, REGON: 000288627, BDO: 000046822, hereinafter referred to as the “Data Administrator” or “Administrator”, represented by:

1. Acting Chancellor – prof. dr hab. Jacek Bigda
with the countersignature of the Deputy Chancellor for Finance – Bursar
2. mgr Zbigniew Tymoszyk

and:.....
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§1

Entrustment of personal data processing

1. In order to perform the main contract, the subject of which is Supervision of the comprehensive implementation of a clinical trial (CRO) in Great Britain as part of the project: Efficacy and safety of metoprolol as a complementary treatment to standard therapy in the prevention of the development of cardiomyopathy in patients with Duchenne muscular dystrophy aged 8-17 years. A randomized, double-blind, parallel-group study with placebo in the control group", application number: 2019/ABM/01/00026 -

in IT systems The Controller entrusts the Processing Entity in accordance with Art. 28 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ EU L 119 of 04.05.2016, p. 1, OJ EU L 127 of 23.05.2018, p. 2 and OJ EU L 74 of 4.03.2021, p. 35), hereinafter referred to as the GDPR, the processing of personal data contained in the Administrator's IT system, and the Processor undertakes to process the entrusted personal data for the above purpose, to the extent and in the manner necessary to perform the contract.

2. The Processor is obliged to provide, at each request of the Controller, information and documents which, in the opinion of the Processor, confirm that the Processor provides sufficient guarantees for the implementation of appropriate technical and organizational measures.

3. Unless otherwise provided in this Agreement, the terms used in this Agreement shall have the meanings given to them in the GDPR.

§2

Scope and purpose of data processing

1. The Processor will process the personal data entrusted under the agreement in electronic form within the scope of:

1). Scope of processed data:

- a. Name and surname
- b. Date of birth
- c. Residential address
- d. Telephone number
- e. E-mail address
- f. Medical information related to the clinical trial
- g. History of diseases and treatment
- h. Diagnostic test results

2). Purpose of data processing:

The Processor will process Personal Data in order to perform the subject of the Main Agreement, which means:

- a. Maintaining clinical trial documentation
- b. Monitoring and analyzing the progress of trial participants
- c. Ensuring compliance with legal and regulatory requirements for clinical trials
- d. Communicating with trial participants and other entities involved in the implementation of the trial
- e. Conducting statistical analyses and reporting trial results
- f. Ensuring the security and integrity of trial participant data
- g. Other purposes related to the implementation and supervision of the clinical trial in accordance with the agreement

§3

Obligations of the processor

1. The Processor undertakes to fulfil the obligations related to securing personal data. In particular, it undertakes to:

- 1) processing the data entrusted to him only in accordance with the documented orders or instructions of the Administrator;
- 2) obtaining from the persons engaged and authorized by him to process the data entrusted to him a documented commitment to maintain secrecy both during the period of their employment by the Processor and after its termination;

- 3) cooperation with the Administrator in the performance by the Administrator of the obligations referred to in Articles 32-36 of the GDPR, including informing the Administrator of any suspicions of violations in accordance with the procedure described later in the agreement;
- 4) limiting access to the personal data entrusted to him only to persons whose access to such data is necessary for the proper performance of the subject matter of the agreement and who have the appropriate authorization;
- 5) providing persons authorized to process the data entrusted to him with appropriate training in the field of personal data protection;
- 6) providing the Administrator with all information necessary to demonstrate compliance with the obligations provided for in this agreement, in accordance with the GDPR and other Data Protection Regulations;
- 7) maintaining a register of the categories of processing activities referred to in the GDPR in the scope of the entrusted data
- 8) if applicable, notifying the Controller of the appointment of the Data Protection Officer, as well as the name and contact details of such person;
- 9) applying technical and organizational measures ensuring the protection of the processed personal data appropriate to the threats and categories of data subject to protection, and in particular undertakes to take all measures required under Articles 32 and 24 of the GDPR, including securing personal data against accidental or unlawful destruction, loss, modification, unauthorized disclosure, unauthorized access, processing in violation of the GDPR and other data protection regulations;
- 10) ensuring control over the correctness of data processing and providing the Controller with all information necessary to demonstrate compliance with the obligations specified in the Agreement and Article 28 of the GDPR;
- 11) making the entrusted personal data available only to bodies or entities authorized under the provisions of applicable law.
- 12) After the completion of the provision of data processing services, the Processor, depending on the Controller's instructions:
 - a) deletes all personal data processed on behalf of the Administrator, including copies from all media and data processed by further processors, and confirms their deletion to the Administrator in the form of a written statement
 - b) returns to the Administrator all personal data processed on its behalf on the basis of the handover-acceptance protocol.

2. In the case of processing personal data outside the European Economic Area (EEA), the processor undertakes to comply with the legal requirements for the transfer of data outside the EEA provided for in the regulations on personal data protection, e.g. on the basis of standard contractual clauses based on European Commission Decision 2021/914 or standard data protection clauses adopted in accordance with Article 46 paragraph 2 letters c and d of Regulation (EU) 2016/679.

§4

The right to control

1. The Data Controller, in accordance with Article 28, paragraph 3, point h) of the Regulation, has the right to check whether the measures used by the Data Processor in the processing and securing of the entrusted personal data meet the provisions of the agreement.
2. The Data Controller will exercise the right to check during the working hours of the Data Processor with a minimum of 3 days' notice.

3. The Data Processor undertakes to remove any deficiencies identified during the check within the period indicated by the Data Controller, no longer than 7 days.

4. The Data Processor shall provide the Controller with all information necessary to demonstrate compliance with the obligations specified in Article 28 of the Regulation.

§5

Further entrustment

1. The Processor is obliged to process the personal data indicated in §2 exclusively on the territory and using technical means located in the European Union.

2. In connection with the performance of the Agreement, the Processor declares that it will not further entrust the processing of personal data to other entities.

3. In the event of the intention to further entrust the processing, the Processor shall provide the Administrator with information regarding the name of the further processor, the scope and place of further entrustment of processing in the table below. In the event of failure to fulfill the above obligations specified in paragraphs 1 and 3 above, the Administrator reserves the right to withdraw from the agreement.

No.	Name of the sub-processor	Scope of further entrustment	Place of processing of personal data in (country/address) with the type of processing infrastructure (physical servers, virtual, cloud ¹ , backup)

4. The Processor undertakes to submit a declaration of deletion of the entrusted personal data.

§6

Reporting and cooperating in the management of violations

1. The Processor undertakes to notify the Controller of any breach of security of the entrusted personal data no later than 24 hours after the discovery of the breach of data protection, by telephone and in the form of e-mail, fax or written correspondence, and to cooperate to the full extent in order to enable the performance of the data controller's obligations specified in legal regulations, good practices or codes of conduct. Such notification should include all relevant details regarding the personal data affected by the event, including, among others:

¹ Cloud data processing, understood as a network of external servers (also applies to creating backup copies of data entrusted by the Administrator)

- the nature of the personal data breach, including, to the extent possible, the categories affected by the event and the approximate number of data subjects, as well as the categories and the approximate number of personal data entries affected by the event,
- a description of the likely consequences of the personal data breach, and recommended methods for reducing potential damage.

2. The Processor shall ensure the possibility of the Controller's participation in explanatory activities and shall inform him of the findings at the time of their making, in particular of the finding of a breach in the event of suspicions. The Controller's notification should be sent together with all necessary documentation concerning the breach, and if the Controller finds deficiencies, supplemented at his request within no more than 24 hours. In the event of breaches, the Processor is obliged to notify:

1) position: personal data protection inspector, e-mail: iod@gumed.edu.pl

and

2)position:organizational unit, tel. +48
..... e-mail:²

3. The Processor must promptly, in order to secure the data and mitigate the effects of the breach, at its own expense, analyse and assess such data protection breach and identify and implement adequate measures, subject to prior approval by the Controller.

4. The Processor undertakes to cover or reimburse the Controller for all costs, value of the damage incurred, losses and expenses, as well as any penalties or fines incurred by the Controller as a consequence of the breach of personal data protection referred to in paragraph 2 above of this agreement or in the regulations on data protection by the Processor, including civil law claims of persons resulting from the damage suffered as a result of the breach of personal data protection due to the fault of the Processor

5. The Processor undertakes to notify the Administrator of significant activities involving its own participation in matters concerning the protection of personal data entrusted under the Agreement, conducted in particular before the Office for Personal Data Protection, state offices, the police or before the court;

6. The Parties undertake to cooperate with each other, as well as with a state body or an international institution, in the event of an inspection or other proceedings concerning the processing of personal data of either Party, to the extent that it concerns processing in connection with the Agreement. Cooperation includes, in particular, providing information, answers to questions and providing explanations in a form and within a time limit enabling the execution of the authorities' requests.

§7

Liability of the Processor

The Processor is liable for damages incurred by the Administrator as a result of failure to perform or improper performance of the Agreement, in particular as a result of making personal data available or using it in a manner that is not in accordance with the provisions

² Please enter the owner of the contract/process responsible for handling the whistleblower procedure.

on the protection of personal data, the GDPR Regulation or the Agreement. The Processor is liable for damages caused by its actions in connection with failure to comply with the obligations that the GDPR directly imposes on it, in particular in the event of failure to provide appropriate personal data security measures, further entrusting data processing without the required consent of the Administrator, or when it acted outside the Administrator's lawful instructions or contrary to these instructions. The Processor undertakes to cover or reimburse the Administrator for all costs, value of the damage incurred, losses and expenses, as well as any penalties or fines incurred by the Data Administrator as a consequence of breach of the above obligations. The Administrator reserves the right to immediately terminate the Agreement in the event of the occurrence of the liability for damages referred to above.

§8

Czas obowiązywania umowy

This contract is valid for the duration of the conclusion of the main contract.

§9

Termination of the contract

1. The Data Controller may terminate this Agreement with immediate effect if the Processor:
 - a) despite being obliged to remove the deficiencies identified during the inspection, fails to remove them within the agreed deadline, despite a prior written request (under penalty of nullity) to remove the violations, in which the request will indicate specific deficiencies together with the relevant provisions of law or the Agreement, and an additional, appropriate deadline for removing the deficiencies will be set, which will not be shorter than 7 days;
 - b) processes personal data in a manner inconsistent with the Agreement and the GDPR, despite a prior written request (under penalty of nullity) to remove the violations, in which the request will indicate specific deficiencies together with the relevant provisions of law or the Agreement, and an additional, appropriate deadline for removing the deficiencies will be set, which will not be shorter than 7 days;
 - c) has entrusted the processing of personal data to another entity without the consent of the Data Controller.

§10

Final Provisions

1. The agreement has been drawn up in two identical copies for each party.
2. In matters not regulated, the provisions of the Civil Code and the Regulation shall apply.
3. The court competent to hear disputes arising from this agreement shall be the court competent for the Data Administrator.
4. Amendments to this agreement must be made in writing.

Data Administrator

Processor