
CONSORTIUM AGREEMENT

on Joint Research Project

(hereinafter referred to as "Agreement")

by and between

The Governors of the University Of Calgary

2500 University Drive NW
Calgary, Alberta T2N 1N4
Canada
(hereinafter referred to as "UCalgary")

and

Goethe University

represented by the President
Theodor-W.-Adorno-Platz 1
60323 Frankfurt
(hereinafter referred to as "UGoethe")

executing departments:

1. Department of Child and Adolescent Psychiatry, Psychosomatics and Psychotherapy
Molecular Genetics Laboratory
Responsible Director of Department: Prof. Dr. med. Christine M. Freitag
Mailing address: University Hospital Frankfurt, Deutschordenstr. 50, 60528 Frankfurt a.M.

2. Department of Neurology
Epilepsy Center Frankfurt Rhine-Main
Responsible Director of Department: Prof. Dr. med. Felix Rosenow
Mailing address: University Hospital Frankfurt, Schleusenweg 2-16. 60528 Frankfurt a.M.

and

University of Eastern Finland

Yliopistoranta 1
70210 Kuopio
Finland
(hereinafter referred to as "UFinland")

and

Université libre de Bruxelles, teaching and research institution registered under Belgian laws, to which legal personality has been assigned by the law of 12 August 1911 modified by the law of 28 May 1970, registered under the company number 0 407 626 464 and located at Avenue Franklin Roosevelt 50, 1050 Brussels, Belgium, hereby duly represented by Mr. Daniele Carati, Head of the Research Department pursuant to the delegation of authority and signature granted by the Academic Board, in presence of Prof. Dr. Massimo Pandolfo ((hereinafter referred to as "ULB"))

Together UGoethe, UFinland and ULB are called Partner Institution (s).

PREAMBLE:

Whereas UCalgary and the Partner Institutions have applied for and received funding for a project as detailed below (the "Research Project");

Whereas UCalgary and the Partner Institutions each have specific areas of specialization that will contribute to the successful completion of the Research Project;

And Whereas the Parties wish to enter into this Agreement to clarify their respective obligations in connection with the Research Project.

1. BASIS FOR THE AGREEMENT

1.1 'Party and Parties' shall mean UCalgary and the Partner Institutions individually and collectively.

1.2 This collaboration shall be governed by this Agreement and the additional appendices mentioned below.

2. PURPOSE

2.1 The purpose of the collaboration is to analyze the clinical, raw EEG, raw MRI and genetic data in order to provide insights into fundamental principles of antiepileptic drug response and development of decision support tools allowing a rational individualized selection of antiepileptic drugs in epilepsy patients.

2.2 In order to achieve the Purpose, the Parties have described the contents of and the framework for the collaboration in Appendix 1 which is attached to and forms a part of this Agreement.

2.3 Each Party undertakes to take part in the efficient implementation of the Research Project, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under this Agreement in accordance with applicable professional standards and best practices within the field and in compliance with any applicable laws and regulations, as may be reasonably required from it and in a manner of good faith. However, no Party gives any warranty or makes any representations that its work will lead to any particular result, nor does it guarantee a successful outcome of the Research Project.

3. DURATION

3.1 The Research Project shall commence on June 1, 2019 and shall continue until the Research Project are fulfilled according to Appendix 1 or terminated by either Party according to section 9 or 10. It is expected that the final analysis of the data will be finished by the end of 2022.

4. PUBLICATION

4.1 The Parties shall enjoy the unrestricted right to publish their own data created through the performance of their portion of the Research Project in scientific works and journals and pursuant to the traditions of the area of research in question. Publication of another Party's Confidential Information (as defined below) requires that Party's consent. The final data analysis of the entire Research Project will be published through the collaborative efforts of all of the Parties.

4.2 Before any publication, e.g. submission for review in connection with a conference, scientific journal or publishing company, the other Party or Parties shall receive a draft for review for thirty (30) days. The non-publishing Party is entitled to comment on the academic contents of the draft as well as suggest specific amendments, provided however, that the publishing Party alone shall decide the final wording and content of the text. If the non-publishing Party discovers that the draft contains Confidential Information demonstrably controlled by the non-publishing Party and disclosed to the Publishing Party in the course of the performance of the Research Project, such Confidential Information shall be removed by the publishing Party prior to publication. In the event of the preparation and submission of a patent application or an application for

registration as a utility model, each Party may demand any publication be postponed for an adequate period of time, which, however, may not exceed four (4) months from the date of receipt of the draft for review.

5. CONFIDENTIALITY

5.1 'Confidential Information' shall mean information disclosed between the Parties as part of the Research Project and is clearly marked 'confidential', or if disclosed orally, is written down by the controlling Party, marked 'confidential' and sent to the receiving Party within thirty (30) days after the time of disclosure, together with information that is obviously of a confidential nature.

5.2 Confidential Information shall be kept confidential by the receiving Party, and may not be disclosed to any third party without the prior written consent of the controlling Party. Each Party shall endeavour to keep to a minimum the amount of information that is disclosed to the other upon which restrictions are imposed.

5.3 Confidential Information does not comprise information, that:

- at the time of receipt was published or in any other way made available to the public,
- after the time of receipt has been published or made available to the public other than by neglect of this obligation of confidentiality,
- already at the time of receipt was in the rightful possession of the receiving Party without any restrictions,
- rightfully has been disclosed by a third party, or
- is generated by the receiving Party independently of the Research Project.

5.4 This obligation of confidentiality shall cease no later than three (3) years from the time of termination of the Research Project.

5.5 The Parties fully accept that the Agreement does not prevent the receiving Party from disclosing Confidential Information to the extent that the receiving Party is required to do so according to statute, judicial order or binding legislation act. Confidential Information covered by this section 5.5 shall still be considered Confidential Information to the extent that it does not become public as a result hereof. The receiving Party shall as soon as possible notify the controlling Party of disclosure in accordance with this section to enable the controlling Party to protect its interest to the maximum feasible extent.

6. RIGHT AND TITLE

6.1 Background Information

'Background Information' shall mean technology, know-how, materials and information, including inventions, improvements, discoveries, Software, etc., whether patentable, registerable or protected by copyright or not, that are generated or controlled by the Parties before the beginning or outside of the Research Project.

6.1.1 All rights and title to Background Information shall remain with the Party that owns or controls such Background Information at the time of entering into this Agreement.

6.1.2 The necessity of the Background Information for the Research Project, submitting the Background Information shall be in the sole discretion of the Party owning the Background Information or having the Background otherwise in its possession. The Parties are not obliged to submit any Background Information to be used by the other Parties in the Research Project, unless otherwise agreed in writing.

6.1.3 Background Information shall be made available for the performance of the Research Project on a free of charge, non-exclusive basis. If Background Information is not publicly available or its use is protected by law it may only be used in accordance with the Purpose of the Research Project. The Party receiving the submitting Party's Background Information shall not be entitled to assign the Background Information further to a third party.

6.1.4 To the extent that Background Information is considered Confidential Information, such Background Information shall be treated in accordance with the provisions of section 5.

6.2 Foreground Information

'Foreground Information' shall mean technology, know-how, materials and information, including inventions, improvements, discoveries, software, etc., whether patentable, registerable or protected by copyright or not, that are generated as part of the Research Project.

'User Right for Research Purposes' shall mean to a non-exclusive right to use the Foreground Information in internal research and development purposes of a Party as well as in teaching or for scientific research purposes. User Right for Research Purposes does not include a right to sub-license the Foreground Information or otherwise assign the Foreground Information or a part thereof to third parties, nor a right to sell services conducted by using the Foreground Information or a right to otherwise commercially exploit the Foreground Information.

6.2.1 Rights and title to Foreground Information shall be vested solely in the Party who has generated such Foreground Information.

6.2.2 Rights and title to Foreground Information that has been generated jointly by the Parties shall be vested jointly in the Parties with shares equivalent to each Party's intellectual contribution. The joint owning Parties shall agree separately on detailed conditions for the exploitation of their jointly owned Foreground Information. Should the joint owners fail to reach an agreement as regards their jointly owned Foreground Information, each joint owner shall be entitled to use the jointly owned Foreground Information independently as it sees fit.

6.2.3 The Parties not owning the Foreground Information shall have a royalty-free User Right for Research Purposes to Foreground Information generated by the other Parties, excluding patentable inventions and software, as well as first right of refusal to negotiate on the purchase of other rights before third parties as regards the Foreground Information owned by the other Parties.

6.2.4 The Parties are obliged to inform each other within a reasonable time if Patentable Foreground Information has been generated.

6.3 Non-commercial Exploitation of Patentable Foreground Information

6.3.1 The Parties reserve the right to use their own Patentable Foreground Information, including Patentable Foreground Information vested in the Parties jointly, for non-commercial purposes, including for educational purposes, patient treatment and care as well as for research.

6.4 Other exploitation rights

6.4.1 The Parties shall have a non-exclusive, perpetual, worldwide right to utilize, free of charge, any Foreground Information that cannot enjoy protection under applicable law for commercial and non-commercial purposes.

6.4.2 The Parties may not without the prior written consent of each other either directly or indirectly refer to each other or each other's employees in connection with any marketing activities, or generally exploit each other's name.

7. DATA

During the performance of the Research Project, the Parties shall create information and data in connection with such performance (herein "Data")

7.1 All Parties agree to limit the use and disclosure of Data to the conduct of the Research Project.

7.2 All Parties represent and certify that they have, or will have prior to commencing the Research Project, the approval of all Partner Institutions compliance offices relevant to the conduct of the Research Project.

7.3 All Parties shall allow access to the Data provided pursuant to this Agreement only the individuals, who have a need to access the Data to perform their duties as described herein and are bound by the terms of this Agreement.

7.4 All Parties shall not use or further disclose the Data other than to carry out the Research Project or as otherwise required by law.

7.5 All Parties shall use appropriate safeguards to prevent use or disclosure of the Data other than as permitted by this Agreement and shall return the Data and all derivatives to the party who has created it upon the expiration or termination of this Agreement. A copy of the Data will remain at UCalgary for the purposes as laid out in 7.7.

7.6 All Parties shall report to the other Party any use or disclosure of the Data not provided for by this Agreement of which that Party becomes aware.

7.7 At the conclusion of the Research Project, the Parties intend to establish a repository in order to make the Data available to other researchers. The Parties shall, through the Steering Committee (defined below) develop the processes and resources to create and manage the Data repository.

7.8 Where applicable, the Parties shall follow European Code of Conduct for Research Integrity in the Research Project (<http://www.allea.org/publications/joint-publications/european-code-conduct-researchintegrity/>).

7.9 During the Research Project, each Party may as part of its activities individually or jointly with other Parties collect or process personal data, as defined in Article 4(1) of Regulation (EU) 2016/679 of 27 April 2016 (the General Data Protection Regulation, hereinafter referred to as the "GDPR"). In such event, the Party shall be individually (or collectively with other Parties and/or third parties as the case may be) responsible for ensuring that the personal data is processed in accordance with GDPR and other applicable EU/EEA data protection legislation ("Data Privacy Legislation"). In addition, for the purpose of ensuring compliance with the GDPR, each Party agrees to comply with the supplementary terms and conditions set out in Appendix 2 concerning processing of personal data.

8. ECONOMICS

8.1. With the exception of the ERAPerMed funding that shall be distributed amongst the Parties, the Parties acknowledge and agree that no further payments will be provided from one Party to the other to compensate the Party for conducting activities related to the Research Project. Accordingly, each Party may secure additional funding for the activities contemplated under this Agreement that are not covered by the ERAPerMed funding. At all times during the Term of this Agreement, each Party must provide the other Party with prompt written notice to identify any source of funding used to support the Research Project which may contain provisions inconsistent with the terms of this Agreement.

9. DURATION AND TERMINATION

9.1 The Agreement shall enter into force by the Parties' last signature to the Agreement with effect from the beginning of the Research Project and shall expire when the Research Project expires as stated in section 3 of the Agreement.

9.2 The Agreement may be terminated by any Party with ninety (90) days written notice. The validity of the termination is subject to the condition that it is submitted in writing and signed by an authorized person of the terminating Party. The Parties have no claims against each other as a result of the termination.

9.3 Each Party shall be entitled to terminate the Agreement with thirty (30) days written notice in the event that the employee(s) of such Party allocated to the Research Project, due to long-term illness or the like, become(s) unable to perform his/her/their tasks connected to the Research Project or in the event that his/her/their employment(s) terminate(s), no matter the reason. The right to terminate the Agreement is subject to the condition that the terminating Party is not able to allocate other competent employees to the Research Project.

9.4 Notwithstanding the termination of the Agreement, the sections that explicitly given their content are expected to survive the termination of the Agreement shall remain in full force and effect, including but not limited to relevant parts of sections 4-13.

10. BREACH OF AGREEMENT

10.1 In the event that a Party materially breaches its obligations according to the Agreement, the other Party may terminate the Agreement. The breach must be substantial. However, the Agreement may only be terminated if the breaching Party has not remedied such breach within thirty (30) days after receipt of a written demand.

11. LIABILITY

11.1 The Parties shall be liable for any and all claims, demands, actions and costs whatsoever to the extent that may arise, directly or indirectly, out of their negligent or wrongful act or omission. Apart from breach of confidentiality, cf. section 5, the Parties shall however not be held liable for any indirect losses, consequential damages, operating losses, lost earnings or other economic consequential losses, including claims of a third party.

11.2 The Parties shall not be held contractually liable in the event that the Research Project does not lead to the expected or desired results, that the Foreground Information cannot be used or that the time schedule is exceeded.

11.3 The Parties shall not assume any liability with regards to the other Party's exploitation of Foreground Information. Thus, the Parties shall not be held liable in the event of product liability or infringement of the rights of any third party caused by the other Party's commercial exploitation. Furthermore, the exploiting Party shall indemnify the other Party against any claims from a third party resulting from such exploitation. Such indemnity is not limited by the liability cap in section 11.1.

11.4 Neither Party guarantees that any Foreground Information will not infringe any rights of a third party or that Foreground Information in the form of software is not based entirely or partly on open source Software.

11.5 The liability of a Party shall in all cases be limited to 100.000 euro. The limitations of liability set out herein shall not apply if the damage is caused by a willful act or gross negligence.

12. FORCE MAJEURE

12.1 None of the Parties is responsible for non-fulfilment of their obligations in accordance with this Agreement where fulfilment is prevented by extraordinary circumstances which the Party in question has no control over and which the Party neither could nor should properly have foreseen when signing the Agreement and neither should have avoided nor overcome. These extraordinary circumstances include for example changes to public regulation.

12.2 If the above-mentioned force majeure event lasts for more than sixty (60) days, the other Party is entitled to terminate the Agreement with immediate effect.

13. STEERING COMMITTEE

13.1 The Parties shall establish a Steering Committee which shall be responsible for the coordination of the Research Project as set out herein. The Parties shall determine the frequency of Steering Committee meetings. The Parties shall be entitled to join the meetings by teleconference or other telecommunication means. The Parties agree to abide by all of the decisions of the Steering Committee.

13.2 The Steering Committee will consist of all the partners as listed in the Proposal.

13.3 The decisions of the Steering Committee shall be made unanimously.

13.4 Each Partner shall have one vote. A Party which can show that its own work, time for performance, costs, liabilities, intellectual property rights or other legitimate interests would be severely affected by a decision of a

Steering Committee may exercise a veto with respect to the corresponding decision or relevant part of the decision.

13.5 The Steering Committee will be responsible for coordinating the performance of the Research Project and shall also create procedures and requirements for the management, data security and subsequent disclosure of data arising from the Research Project to researchers. The Steering Committee will also coordinate procedures for the resolution of any issues or conflicts arising between the Parties including, without limitation any ethical issues related to the performance of the Research Project.

14. TRANSFER OF THE AGREEMENT TO A THIRD PARTY

14.1 Rights and obligations in accordance with this Agreement cannot be transferred to a third party without the written consent of the other Party.

15. SUBCONTRACTING

15.1 The Parties are entitled to use subcontractors. The Parties shall be liable for the work of the subcontractors as for its own.

16. CHOICE OF LAW AND VENUE

16.1 This Agreement shall be construed and interpreted in accordance with the laws of the province/state of the Party defendant in litigation is located. The Parties further acknowledge that the courts of the home province/state of the Party defendant in the litigation shall have exclusive jurisdiction to entertain any complaint, demand, claim or cause of action whatsoever arising out of this Agreement and hereby irrevocably submit to the exclusive jurisdiction of said courts.

[Signature page follows]

15. SIGNATURES

THE GOVERNORS OF THE UNIVERSITY OF CALGARY

Name: Dr. Robert Ian Thompson

Title: Associate Vice President (Research)

GOETHE UNIVERSITY FRANKFURT

AS Sabine Monz

Name: Dr. Sabine Monz
Title: Head of Research Service Center



JOHANN WOLFGANG GOETHE-UNIVERSITÄT
Die Präsidentin
Theodor-W.-Adorno-Platz 1
60629 Frankfurt am Main

Read and Acknowledged:

Name: Prof. Dr. med. Christine M. Freitag
Title: Responsible Director of Department

Read and Acknowledged:

in

Name:
Title: Responsible Director of Department
Prof. Dr. med. Felix Rosenow

Prof. Dr. med. Felix Rosenow
Leiter, Epilepsiezentrum Frankfurt Rhein-Main
Zentrum der Neurologie und Neurochirurgie
Universitätsklinikum Frankfurt
Schleusenweg 2-16, 60528 Frankfurt a. M.

UNIVERSITY OF EASTERN FINLAND

Name:

Title:

UNIVERSITE LIBRE DE BRUXELLES

Name:

Title:

Appendix 1
Proposal

Appendix 2

Actions involving Personal Data

1. DEFINITIONS

- 1.1 "Data Controller" shall have the meaning given to it by Article 4(7) GDPR, which is the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the Processing of Personal Data, where the purposes and means of such Processing are determined by the European Union or Member State law.
- 1.2 "Data Processor" shall have the meaning given to it by Article 4(8) GDPR, which means a natural or legal person, public authority, agency or other body which processes Personal Data on behalf of a Data Controller.
- 1.3 "Data Subject" shall have the meaning given to it by Article 4(19) GDPR, which is an identified or identifiable natural person.
- 1.4 "Joint Data Controllers" shall have the meaning given to it by Article 26(1) GDPR, which means two or more controllers who jointly determine the purposes and means of Processing.
- 1.5 "Personal Data" shall have the meaning given to it by Article 4(1) GDPR, which is any information relating to a Data Subject.
- 1.6 "Processing" shall have the meaning given to it by Article 4(2) GDPR, which is any operation or set of operations which is performed on Personal Data or on sets of Personal Data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

2. SCOPE

- 2.1 The terms laid down in this Appendix 2 applies exclusively to those of the Parties who are Processing Personal Data under the Research Project.
- 2.2 The Research Project may consist of different tasks under which a Party may Process Personal Data. A Party Processing Personal Data shall be considered Data Controller, Joint Data Controller and/or Data Processor, as the case may be, in accordance with the definitions set forth above.

Personal Data may be Processed only by each of the Parties alone or together with other Parties or third parties. Furthermore, each Party is solely responsible for evaluating its role as Data Controller, Joint Data Controller or Data Processor.

3. ACTIONS INVOLVING PERSONAL DATA

- 3.1 Each Party are solely responsible for its own Processing of Personal Data (including its transfer to another Party or third party) in compliance with the Data Privacy Legislation.
- 3.2 **Controller to Controller**
To the extent a Data Controller Processes Personal Data in relation to the Research Project and enables other Parties to access and/or receive such Personal Data independent from specific instructions of the Data Controller regarding the Processing of Personal Data, the Data Controller undertakes to secure that all applicable Data Privacy Legislation have been observed in the collection and transfer of the Personal Data. This includes that the Data Controller undertakes to ensure that the Personal Data is lawfully collected and transferred allowing the Data Controller to share the Personal Data with other Parties in order for such Parties to perform their tasks in the Research Project.

The Parties to whom Personal Data is transferred shall be considered Data Controllers themselves and shall be solely responsible for compliance with the Data Privacy Legislation, including to only Process such Personal Data in accordance with the applicable legal basis.

The transfer of Personal Data on a Controller-to-Controller basis does not modify the acknowledgment and/or allocation of intellectual property rights of this Agreement. This transfer shall only be the consequence of honouring the rights (e.g., ownership, licenses or exploitation rights) that both the introducing Party and the accessing Party shall have on the relevant Background Information and Foreground Information according to this Agreement

3.3 Data Controller to Data Processor

To the extent a Data Controller in relation to the Research Project engages a Data Processor to Process Personal Data on behalf of and upon instruction from the Data Controller the Data Controller and the Data Processor are required to enter into a written data processing agreement as set forth in Article 28 GDPR. The Data Controller shall also conduct an assessment on the Processor according to art. 28(1) GDPR.

3.4 Joint Data Controllers

To the extent joint data controllership is established in relation to the Research Project, the Joint Controllers shall for the purpose of ensuring compliance with the Data Privacy Legislation execute a written arrangement setting out the respective responsibilities of such Parties vis-à-vis the relevant Data Subjects, cf. Article 26 GDPR in addition to complying with the relevant requirements applicable to any controller-to-controller transfer according to section 3(2).

3.5 Processing of Personal Data outside EU/EEA

To the extent Personal Data are transferred by a Data Controller or Data Processor to another Data Controller or Data Processor outside the European Economic Area or in another country which does not offer an adequate level of protection, said party is responsible for ensuring that such transfer is carried out in accordance with the requirements under GDPR. Unless otherwise provided for by GDPR (e.g. by a derogation under Article 49 GDPR) the legal basis for transfer of Personal Data to a country outside EU/EEA shall be based on the EU Standard Clauses or another appropriate safeguard considered adequate under the GDPR.

If the legal basis should at a later stage become suspended or invalid, for example due to a verdict from the ECJ, a suspension order by the competent data protection supervisory authority or changes in applicable legislation, the Parties shall work together in good faith to ensure a new legal basis without undue delay.