

MATERIAL TRANSFER AGREEMENT

This agreement is made by and between

Provider Institution (please complete fully name and place of business of Legal Entity) represented by Representative of the Recipient Institution (including title)

- hereinafter referred to as "**PROVIDER**" – and

the **University of Luebeck**, Ratzeburger Allee 160, 23562 Luebeck, Germany, represented by the President Prof. Dr. Gabriele Gillessen-Kaesbach, and the **University Hospital Schleswig-Holstein**, Ratzeburger Allee 160, 23538 Luebeck, Germany, represented by the Chairman of the Board Prof. Dr. Jens Scholz and the Finance Director Peter Pansegrau; performing department: **Institute of Neurogenetics, represented by Prof. Dr. Christine Klein**

- hereinafter referred to as "**RECIPIENT**".

1. Definitions

- 1.1 Upon request the PROVIDER shall provide to the RECIPIENT the material as described and quantified in Annex 1, hereinafter referred to as the "ORIGINAL MATERIAL". Annex 1 constitutes an integral part of this Agreement.
- 1.2 "Recipient" is the legal entity as identified in Annex 1.
- 1.3 "Recipient Scientist" is the scientific employee of RECIPIENT performing the intended experiments with MATERIAL as identified in Annex 1.
- 1.3 "Progeny" is defined as unmodified descendant from the Original MATERIAL including, but not limited to, virus from virus, bacterium from bacterium, cell from cell, or organism from organism.
- 1.5 "Unmodified Derivatives" are substances created by the RECIPIENT which constitute an unmodified functional subunit or product expressed by the Original MATERIAL, e.g. subclones of unmodified cell lines, purified or fractionated subsets of the Original MATERIAL, proteins expressed by DNA/RNA, or monoclonal antibodies secreted by a hybridoma cell line.
- 1.6 "Modifications" are substances created by the RECIPIENT which contain/incorporate the MATERIAL, e.g. crosses, breeding varieties, cell fusions, subcloning etc.

1.7 The "MATERIAL" which, regarding the inherent intellectual property rights, is and remains the exclusive property of PROVIDER, comprises the Original MATERIAL, any Progeny, Unmodified Derivatives, the Original MATERIAL contained in Modifications and proprietary information concerning the Original MATERIAL.

2. Use of the MATERIAL

2.1 PROVIDER will transfer to RECIPIENT the following materials:

Biospecimen

- DNA
- Whole blood
- Saliva
- Other: _____

Data

- Genetic data (*sequencing, array, summary statistics, etc.*):
-

- Clinical data:

- a. **Minimum data elements (required for all cohorts):** gender, age, age at onset, case/control status, family history, self-report race and ethnicity
- b. **Data dictionaries (field names, field types, and data coding)**
- c. **All available Serial Core data elements:** diagnostic checklist (*MDS-UPDRS or UKBB*), primary diagnosis, PD associated diagnoses (e.g. depression, dementia etc.), PD history (*age at motor symptom onset and first motor symptom type, diagnosis, medication initiation, vital status [i.e. age at last assessment when alive/age at death], wearing-off, dyskinesia, and reaching HY3 and HY4*), General status evaluation (*CISI-PD*), behavioral/environmental history (*PD-RFU-Q [smoking and alcohol history, caffeine consumption, concussion], medical history [metabolomic syndromes, CVDs, cancer, depression]*), current medication status (*drugs for Parkinson's disease and other diseases*), nM-EDL (*UPDRS1*), M-EDL (*UPDRS2*), motor (*UPDRS3 & HY*), complications (*UPDRS4*), cognitive assessment (*MoCA, MMSE, SCOPA-Cog*), autonomic function assessment (*SCOPA-Aut*), pRBD (*screening questionnaire*), clinical diagnosis of complications (*MCI/dementia, constipation, hyposmia, RBD and other sleep problems, depression and apathy*), years of education or educational level
- d. **All available Serial Extended data elements:** daytime sleepiness assessment (*ESS*), depression assessment (*GDS15, DBI, HAM-D*), orthostatic hypotension (*BP/HR in standing and sitting/supine*), olfactory function (*UPSIT, OSIT, Sniffi' stick*), general ADL (*Schwab & England*), PD EQL (*PDQ39*), pain (*King's PD pain scale*), vitals (*HR, BP*), blood/CSF data (*individual-level availability of plasma, serum, RNA, fibroblasts, autopsy with histological diagnoses, autopsy with frozen material*), imaging data (*individual-level availability of routine diagnostic MRI, research-based MRI sequences*)
- e. **Additional clinical data elements upon request from GP2 Monogenic Hub** (*e.g. data from future study visits*)

- Biospecimen QC data: _____
- Other: _____

(collectively "ORIGINAL MATERIAL").

2.2 The Parties will comply with all laws, rules, regulations and policies applicable to the handling, use and disposal of the MATERIAL.

2.3 RECIPIENT will only use the MATERIAL for the following research project: the Global Parkinson's Genetics Program (GP2) ("Research Project"). PROVIDER understands and agrees that in accordance with this Research Project:

- a. Information and data provided to RECIPIENT under this Agreement may be shared with members of the Global Parkinson's Genetic Program (GP2) (<https://www.parkinsonsroadmap.org/gp2/>);
- b. MATERIAL provided to RECIPIENT under this Agreement may be shared with GP2-designated genetic data generation centers, including, but not limited to, the National Institute on Aging (part of the National Institutes of Health, a component of the United States Department of Health and Human Services) and Psomagen, Inc.
- c. Data generated or derived using MATERIAL provided to RECIPIENT under this Agreement will be deposited into a data repository such as the Accelerating Medicines Partnership – Parkinson's Disease ("AMP-PD") data portal (<https://amp-pd.org/>), which approved researchers can gain access to. The MATERIAL being experimental in nature must not be used in humans, in clinical trials, for diagnostic, prognostic, or treatment purposes, purposes involving human subjects or animals unless - where applicable - explicitly admitted by an ethics committee or regulations on the treatment of laboratory animals.

2.4 The MATERIAL must not be used for any commercial purposes, including selling, commercial screening, or transferring MATERIAL to a third party for commercial purposes; Transfer the MATERIAL to anyone who is not under the RECIPIENT (as listed in the signature page of this Agreement) direct supervision unless advanced, written approval of PROVIDER is obtained before any transfer.

2.5 The RECIPIENT will store the ORIGINAL MATERIAL for the duration of the Research Project. When the Research Project is completed or upon the termination of this Agreement, whichever comes first, any unused ORIGINAL MATERIAL will be destroyed unless the PROVIDER gives RECIPIENT directions for disposing of the ORIGINAL MATERIAL by another means or permission to store the ORIGINAL MATERIAL indefinitely.

2.6 Upon request, the RECIPIENT shall inform PROVIDER on the status of its research.

2.7 RECIPIENT agrees not to contact or make any effort to identify Human Subjects.

2.8 RECIPIENT represents that is has obtained ethical approval, as appropriate, to use ORIGINAL MATERIAL.

3. Confidentiality

- 3.1 All information to be deemed confidential that is transferred between the Parties under this Agreement will be clearly marked "CONFIDENTIAL" by the disclosing Party ("Confidential Information") and maintained in confidence by the receiving Party for a period of three (3) years from the date of receipt. Any Confidential Information that is orally disclosed must be reduced to writing and marked "CONFIDENTIAL" by the providing Party and such notice must be provided to the receiving Party within thirty (30) days of the oral disclosure. RECIPIENT shall hold the Confidential Information in strict confidence, and use the Confidential Information solely for the Purpose and shall not disclose or permit disclosure of the Confidential Information to anyone except if only to the extent that such disclosure is necessary to the Investigator's evaluation of his/her interest in participating in the study(ies) and unless otherwise permitted by PROVIDER. RECIPIENT will use best efforts to safeguard such Confidential Information. In the event PROVIDER permits RECIPIENT to disclose the Confidential Information for the Purpose to a third party, RECIPIENT shall ensure such third party is bound by confidentiality obligations similar to those contained herein prior to disclosure. If RECIPIENT is required by law, regulation, rule or order of any governmental authority or agency to disclose any Confidential Information, RECIPIENT may disclose such Confidential Information provided that RECIPIENT provide PROVIDER, as applicable, maximum prior written notice and an opportunity to file a protective order. Each party agrees that it will promptly notify the other should it conclude that it is no longer interested in pursuing the Purpose for which such Confidential Information was provided. Immediately following transmission or receipt by RECIPIENT of any such notice or upon request from PROVIDER, RECIPIENT shall return the Confidential Information; provided, however, that RECIPIENT may retain one (1) copy of Confidential Information for archival purposes and thereafter shall not use the Confidential Information for any purpose whatsoever.
- 3.2 The term "Confidential Information" shall not include information which: (i) at the time of disclosure is information published, generally known or available to the public, or after the time of disclosure becomes generally available through no wrongful act of RECIPIENT; (ii) was rightfully in RECIPIENT 's possession (as evidenced by written records) prior to being disclosed by PROVIDER; (iii) is obtained from any third party lawfully in possession of the information and not in violation of any legal obligation with respect to the information; or (iv) is independently developed by or for RECIPIENT without the use of PROVIDER's Confidential Information, as evidenced by written records.

4. Data Protection

The parties undertake to know and comply with the relevant national (federal and state) and international regulations in their current version, in particular

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 - GDPR)

5. Publications

In all oral presentations or written publications concerning the use of MATERIAL, RECIPIENT will comply with the publication guidelines set for by the GP2 Steering Committee: <https://parkinsonsroadmap.org/gp2/publicationpolicy/>.

6. Intellectual Property

The Parties agree to the GP2 policy that no intellectual property rights arising from participation in GP2, or use of GP2 resources (including without limitation MATERIAL), may be claimed by anyone, except if and to the extent that The Michael J. Fox Foundation for Parkinson's Research (MJFF) and the GP2 Steering Committee issue one or more GP2 policies allowing for claims of any such rights. For clarity, this Section 6 shall not apply to any MATERIAL retained by PROVIDER, even if the same MATERIAL is transferred to PROVIDER pursuant to this Material Transfer Agreement.

7. Warranties and Liability

- 7.1 Any MATERIAL provided to this Agreement is understood to be experimental in nature. It may have hazardous properties. The PROVIDER makes no representations and extends no warranties of, any kind, express or implied, as to the fitness of the MATERIAL for a particular purpose, or that the use of the MATERIAL will not infringe any patent, copyright, trademark, or other proprietary rights of a third party.
- 7.2 RECIPIENT assumes all and any liability for damages, which may arise from the use of the MATERIAL, its storage or disposal. The RECIPIENT shall hold harmless the PROVIDER and its researcher/s for any loss, claim or demand, which could be raised by the RECIPIENT, or made against the RECIPIENT by any other party, due to, or arising from, the use of the MATERIAL by the RECIPIENT, except to the extent caused by the gross negligence or wilful misconduct of PROVIDER.

8. Termination

Either Party may terminate this Agreement by providing sixty (60) days prior written notice to the other Party, subject to the terms of Articles 2.2 and 2.4, above.

9. Miscellaneous

- 9.1 The ORIGINAL MATERIAL is provided cost-free; however, a handling fee may be charged for its preparation and shipment to the RECIPIENT. As applicable, both items are specified in an accompanying letter to this Agreement.
- 9.2 The Parties agree to go silent on applicable law and court of jurisdiction.
- 9.3 This Agreement shall enter into force on the date of the last signature to it. It expires after five years or after conclusion of the experiments according to Annex 1, without prior notice by any of the parties. The provisions concerning Confidentiality, Publications, Intellectual Property and Liability shall survive this expiration.

- 9.4 In the event the MATERIAL or part of it should be under physical control of the RECIPIENT before this Agreement is signed, the terms and provisions shall apply for this MATERIAL retroactively.
- 9.5 This Agreement may be executed in one or more counterparts, each of which together will be deemed original but all of which together shall constitute one and the same document. A Portable Document Format (PDF) or other common format electronic file or electronic signature will constitute valid execution and delivery of this Agreement. Any communication or notice to be given will be emailed via the contact information listed below.
- 9.6 Should any provision of this agreement be invalid or unenforceable or should the contract contain an omission, the remaining provisions shall be valid. In the place of an invalid provision, a valid provision is presumed to be agreed upon by the parties, which comes economically closest to the invalid provision. The same shall apply in the case of an omission. This wording contains the entire agreement between the parties; any changes of the agreement have to be made in writing. The representatives hereby expressly certify and affirm that they are authorised to sign this Agreement on behalf of their institution.

For RECIPIENT, On behalf of the
University of Luebeck and the University
Hospital Schleswig-Holstein:

Legal Department

Third-Party Funds Department

Recipient Scientist

**I have read and understood the terms
and conditions of this Agreement, and I
will abide by them in the receipt and use
of the ORIGINAL MATERIAL.**

Prof. Dr. Christine Klein
Institute of Neurogenetics

Luebeck, Germany

Date:

For the PROVIDER:

Representative of the Provider Institution /
Legal Entity; including academic and
employment title(s)

Provider Investigator:

**I represent that the ORIGINAL MATERIAL
(including any data) that I am providing
under this Agreement has all the necessary
approvals required (including informed
consent forms, Institutional Review Board
etc.) to be transferred to RECIPIENT for the
uses contemplated in the Research Project.**

Provider Investigator

complete name and address; including
academic and employment title(s)

Date:

Annex 1

The MATERIAL:

for the transfer of 1) material isolated from individuals who have participated in clinical research (each a "Human Subject"), with or without accompanying data, 2) data derived from material isolated from individuals who have participated in clinical research, with or without accompanying data, or 3) protected summary statistics derived from material isolated from individuals who have participated in clinical research, with or without accompanying data to be used for research purposes as further defined below.

Recipient Scientist:

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Abstract:

Supported by the Aligning Science Across Parkinson's (ASAP) Initiative, the Global Parkinson's Genetics Program (GP2) is an international collaborative effort aimed at making transformational progress in Parkinson's disease (PD) genetics.

The vision of GP2 is to improve our understanding of the role genetics plays in PD and further, to make this knowledge globally available and actionable. Bringing together researchers from all over the world and forming a cohesive group of collaborators, GP2 will collect and generate critical clinical and genetic data, harmonize data, train clinicians and analysts around the world, and develop a portal that democratizes data and analytical resources. Using these data and resources, the aim is to identify novel risk loci and monogenic causes of the disease, as well as genetic modifiers, to fine map risk loci, and to understand population differences in PD genetics.

The monogenic disease genetics arm of GP2 aims to create an efficient infrastructure to accelerate the identification of novel genetic causes of apparently monogenic PD. Leveraging the above-described global network of researchers and adding further already existing resources from the monogenic field, the monogenic arm will collect > 10.000 PD patients from families and singleton cases, as well as trios, in whom a monogenic cause may be suspected. All collected patients will be prioritized for whole genome sequencing

(WGS) or long-read sequencing based on a number of different criteria: family history and availability of samples from several affected (and unaffected) family members, age at onset (AAO), consanguinity, ethnicity (with a particular emphasis on families from underrepresented populations) and level of available genetic pre-screening.

All patients enrolled in the monogenic arm of GP2 will also undergo GDA genotyping which, based on its PD-related custom content, will result in the identification of a sizable number of patients with pathogenic risk variants or mutations in known PD genes.