

**MATERIAL TRANSFER AGREEMENT
FOR THE TRANSFER OF HUMAN MATERIALS
FOR RESEARCH PURPOSES**

This Human Material Transfer Agreement ("Agreement") is between _____ ("Provider") and the National Institute on Aging ("Recipient"), part of the National Institutes of Health (NIH), a component of the United States Department of Health and Human Services (HHS), 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. Provider and Recipient may each be referred to as a Party or collectively as Parties. This Agreement will become effective on the date of the last authorized signature below ("Effective Date").

Recipient and Provider agree as follows:

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:

- Biospecimen QC data: _____
 Other: _____

(collectively "Human Material").

2. Recipient will only use the Human 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) (www.g2.org); and

- b. Data generated or derived using Human Materials 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.
3. Recipient agrees not to do any of the following:
- (a) **Use the Human Material in humans or for any diagnostic, prognostic, or treatment purposes;**
 - (b) Use the Human Material for any commercial purposes, including selling, commercial screening, or transferring Human Material to a third party for commercial purposes;
 - (c) Transfer the Human Material to anyone who is not under the Recipient Investigator’s (as listed on the signature page of this Agreement) direct supervision unless advanced, written approval of Provider is obtained before any transfer.
4. If Recipient receives:
- (A) Information from Provider, or information ascertained through Recipient’s use of the Human Material, that can be used to determine a Human Subject’s identity, either alone or when combined with other personal or identifying information; or
 - (B) The coded Human Material with the key to such information in 4(A) above; or
 - (C) Identifiable, sensitive information (“ISI”), as defined in the Public Health Service Act at 42 U.S.C 241(d)(4), regarding the Human Material (see <https://humansubjects.nih.gov/coc/faqs>);

Then Recipient agrees to:

- (a) Abide by all applicable human subjects and other regulations and guidance, which may include:
 - (i) The Privacy Act of 1974, as amended, at 5 U.S.C. §552a (“Privacy Act”), the Health Information Portability and Accountability Act of 1996 (HIPAA) or other equivalent privacy regulations; and
 - (ii) 45 C.F.R. Part 46, 21 C.F.R. Parts 50 and 56, and FDA Good Clinical Practice Guidelines (ICH E6 Good Clinical Practice: Consolidated Guidance, 62 FR 25692 (1997)); and
 - (iii) A certificate of confidentiality issued by NIH in accordance with 42 U.S.C 241(d) of the Public Health Service Act.
- (b) Maintain any transferred information in a secure manner that restricts access by any individual not involved in the Research Project (e.g., for paper records – locked file cabinets or continual physical presence in a room that locks, or for electronic records – encryption and password protection); and

- (c) Remove or destroy any information that may be used to identify the Human Subject at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the Research Project; and
 - (d) Make no further use or disclosure of the information, except as described in Article 2, unless approved by the Provider, or as required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments).
Notwithstanding the foregoing, ISI is immune from the legal process, and will not, without the consent of the Human Subject, be admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.
- 5. Recipient agrees not to contact or make any effort to identify Human Subjects.
- 6. Recipient represents that it has obtained Institutional Review Board approval, as appropriate, to use Human Material.
- 7. 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. Notwithstanding any other provision of this Agreement, the obligation to not disclose ISI to any other party will extend indefinitely.
- 8. For the purposes of this Agreement, Confidential Information will not include information that:
 - (a) Has been published or is otherwise publicly available at the time of disclosure to the receiving Party or was in the possession of or readily available to the receiving Party without being subject to a confidentiality obligation from another source prior to the disclosure;
 - (b) Has become publicly known, by publication or otherwise, not due to any unauthorized act of the receiving Party; or
 - (c) The receiving Party can demonstrate it developed independently, or acquired without reference to, or reliance upon, such Confidential Information.
- 9. If the receiving Party becomes legally required to disclose any of the Confidential Information, the receiving Party will take all reasonable measures to disclose only that Confidential Information legally required and will notify the disclosing Party as soon as practicable. In all instances, the receiving Party will only disclose that portion of the disclosing Party's Confidential Information which is obliged to be disclosed. The disclosing Party is free to seek any remedies at law or in equity to limit or prevent the disclosure of the disclosing Party's Confidential Information.
- 10. The Parties will comply with all laws, rules, regulations and policies applicable to the handling, use and disposal of the Human Material.

11. When data generation is completed or upon the termination of this Agreement, whichever comes first, any unused Human Material will be returned to the Provider unless the Provider gives Recipient directions for disposing of the Human Material by another means.
12. Either Party may terminate this Agreement by providing sixty (60) days prior written notice to the other Party, subject to the terms of Articles 10 and 11, above.
13. In all oral presentations or written publications concerning the use of Human Material, Recipient comply with the publication guidelines set for by the GP2 Steering Committee (https://www.parkinsonsroadmap.org/gp2/wp-content/uploads/sites/2/2020/10/GP2-publication-policy_October2020.pdf)
14. Any Human Material delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. **Provider makes no representations and extends no expressed or implied warranties of any kind, including warranties of merchantability, quality, or fitness for a particular purpose, or that the use of Human Material will not infringe any patent or other proprietary rights.**
15. Provider will not be liable for any loss, harm, illness or other damage or injury arising from Recipient's handling, use or disposal of the Human Material. No indemnification for third party claims is intended, implied, or provided by either Party.
16. This Agreement will be construed in accordance with United States Federal law as applied by the Federal courts in the District of Columbia.
17. 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.

Signatures Appear on the Next Page

SIGNATURE PAGE

FOR PROVIDER:

(Signature of Authorized Official)
Name:
Title:

Date

Provider Investigator:

I represent that the Human 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.

(Signature of Providing Investigator)
Name:
Title:
Address:
Phone:
Email:

Date

FOR RECIPIENT:

(Signature of Authorized Official)
Name:
Title:
Address:
Phone:
Email:

Date

Recipient Investigator:

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 Human Material.

(Signature of Investigator)
Name:
Title:
Address:
Phone:
Email:

Date