LITE Biospecimen Use Agreement

This Agreement governs access to and use of biospecimens collected by the LRRK2 Investigative Therapeutic Exchange (LITE) initiative ("LITE"). I request access to biospecimens collected by the LRRK2 Investigative Therapeutic Exchange (LITE) initiative for the purpose of scientific investigation and agree to the following terms:

1. I will receive de-identified biospecimens and will not attempt to establish the identity of or attempt to contact any LITE study participants.
2. I will not share or use these biospecimens beyond the uses outlined in this agreement and my approved proposal for access. I will not transfer these biospecimens or their derivatives to any third party for profit.
3. I will require anyone on my research team who utilizes these biospecimens to comply with this Biospecimen Use Agreement.
4. I will not, and will not allow others to, use LITE biospecimens or materials derived directly from them in humans for diagnostic purposes involving human subjects, for the manufacture of any products except in connection with my approved research project, or for any therapeutic use.
5. This restriction does not preclude the development, validation, or regulatory approval of diagnostics, biomarkers, or therapeutics that may ultimately be used in patients, provided that such activities use only de-identified biospecimens in accordance with this Agreement and all applicable ethical and regulatory requirements.
6. If I receive peripheral blood mononuclear cells (PBMCs) and use them to generate induced pluripotent stem cells (iPSCs), I will not directly or indirectly use the iPSCs to derive or generate human gametes or germline cells.
7. I will accurately provide the requested information regarding the individuals who will use these biospecimens and the analyses that are planned using these biospecimens. I will respond promptly (within 15 days) and accurately to requests to update this information.
8. I will comply with any rules and regulations imposed by my institution and its Institutional Review Board or Ethics Committee in requesting and using these biospecimens and will share relevant documentation ahead of receiving the biospecimens.
9. I acknowledge that certain LITE biospecimens represent limited or specialized resources (e.g., including but not limited to CSF, skin biopsies, immune cell populations, lysosomal fractions, breath, sebum, and iPSC lines). LITE may prioritize requests and limit sample quantities to preserve these resources and ensure alignment with the scientific objectives of the program.

10. Release of LITE biospecimens is subject to review and approval by the LITE Biospecimen Access Committee, appointed by the LITE Steering Committee. Requests that overlap with ongoing or planned consortium analyses may be deferred or modified to ensure completion of the core scientific objectives of the LITE program.

11. I acknowledge that research performed using LITE biospecimens may lead to discoveries, assays, biomarkers, or therapeutic approaches that are intended for future use in patients. I may pursue such clinical or commercial development in accordance with my institutional policies, applicable laws and regulations, and the LITE Intellectual Property Policy, while maintaining all protections and restrictions regarding LITE biospecimens described in this Agreement.

12. I will comply with the LITE Intellectual Property Policy that states:

    (a) Rights to pre-existing IP or that were conceived outside of the LITE study ("Background IP") which a researcher uses in analyzing or manipulating LITE data, information, biospecimens, materials or results, remain with the investigator or institution;

    (b) Intellectual property arising from discoveries made using LITE biospecimens may be pursued under institutional policies;

    (c) The Michael J Fox Foundation for Parkinson's Research, as implementer of LITE, retains a non-exclusive, perpetual, sublicensable, royalty-free license for research use of IP and results discoveries arising from the use of LITE biospecimens;

    (d) Access to LITE biospecimens or derived data shall not, confer any ownership interest, intellectual property rights, or exclusive rights in or to LITE biospecimens, LITE data, derived datasets, or any portion thereof. In the event that the LITE biospecimens and data considered are primarily collected and made available under the Parkinson's Precision Medicine Initiative (PPMI) for which there is co-enrollment in LITE, the terms of the PPMI Biospecimen Use Agreement and PPMI Data Use Agreement shall govern and shall prevail in the event of any conflict with this Agreement.

18. If I seek to publish manuscripts or abstracts describing analyses of LITE biospecimens, I will comply with the LITE Publications Policy, which provides that: (a) manuscripts will be submitted to the LITE Steering Committee prior to submission; (b) LITE and its funding partners will be acknowledged; and (c) copies of accepted manuscripts will be provided to LITE.

19. "Data and biospecimens used in the analyses presented in this article were obtained from the LRRK2 Investigative Therapeutic Exchange (LITE) initiative (https://www.michaeljfox.org/lrrk2-investigative-therapeutics-exchange-lite). Investigators within LITE contributed to the design and implementation of LITE and/or provided data and collected biospecimens but did not necessarily participate in the analysis or writing of this report.

For up-to-date information on the study, please visit https://www.michaeljfox.org/lrrk2-investigative-therapeutics-exchange-lite. LITE is supported by The Michael J. Fox Foundation for Parkinson's Research and collaborating partners. We thank the LITE study participants and participating clinical sites for their contributions."

20. If I generate experimental data from analyses of LITE biospecimens, such data may be required to be submitted to LITE via a designated mechanism
21. I will ensure that investigators who utilize LITE biospecimens implement appropriate administrative, physical, and technical safeguards to prevent misuse.
21. I will report any use or disclosure of biospecimens not provided for by this agreement within 15 days of becoming aware of such use or disclosure
22. I understand that failure to abide by these guidelines may result in termination of my privileges to access LITE biospecimens.
24. Biospecimen Return or Destruction: Upon completion of the approved research project, or upon termination of access to LITE biospecimens, any remaining biospecimens or derived materials must either be returned to LITE or destroyed in accordance with institutional policies, as directed by LITE.

The Michael J. Fox Foundation and the LITE Steering Committee maintain the right to modify this policy by posting notice of such modifications on this page. Any modification becomes effective immediately upon posting the modification unless otherwise stated.