LRRK2 COHORT CONSORTIUM BIOSPECIMENS USE AGREEMENT
(“Biospecimens Use Agreement”)

I request access to biospecimens collected by The MJFF LRRK2 Cohort Consortium (“LCC”) for the purpose of scientific investigation and agree to the following terms of the LRRK2 Biospecimens Use Policy:

LRRK2 Cohort Consortium Biospecimens Use Policy
Access to biospecimens collected by the LCC (“Biospecimens”) will be granted according to procedures set forth by the LRRK2 Cohort Biospecimens Steering Committee (“LCB”) and in compliance with this LRRK2 Biospecimen Use Policy (“Policy”):

1. All access to Biospecimens must be approved in advance by the LCB. Such approval will be granted to scientific researchers, including employees or independent contractors working under the direction of such scientific researchers, and the (non-profit or for-profit) institutions at which approved scientists will conduct their research (“Recipients”).

2. Recipients will be required to agree to the terms and conditions of this Policy prior to receiving access to Biospecimens.

3. Access to Biospecimens will be granted by the LCB only for scientific research purposes, which may include testing research tools, therapies or cures for commercialization. Requestors will complete a form requesting access to Biospecimens which will include, among other things, a description of the intended research use of the Biospecimens.

4. Recipients must agree to comply with all rules and regulations imposed by institutions at which Recipients will use the Biospecimens, including institution review board (“IRB”) policies and procedures.

5. Biospecimens will be shipped from the LCC biorepositories to the receiving investigator in a blinded fashion. The samples are matched to a unique identification number (“ID”). When the analyses are completed the investigator will submit a report of the analyses by subject to the LCB. Upon approval, the LCB will provide a “code” that will match the unique ID with the LCC ID so the specimens can then be unblinded and investigators can match the Biospecimens data to the clinical data in the LCC database. Within two months of unblinding, all investigators who use LCC samples must resubmit his/her data/analyses to the LCB. Upon submission, the LCB has the right but not the obligation to deposit these analyses in the LCC study database for use by the Research Community.
6. Data associated with Biospecimens are deidentified. Access to Biospecimens will be granted only on the condition that Recipients will not attempt to establish the identity of, or attempt to contact, study subjects participating in the LCC.

7. Biospecimens may not be used: (a) for any purpose other than as outlined in a Recipient’s proposal for access; or (b) in any way that conflicts with this Policy or the guidelines established by the LCB. During any time that Recipient is in possession of one or more Biospecimens, Recipient must report (i) any important changes to the research purpose or (ii) changes to the principal investigator in charge of the Biospecimens included in an application for access to Biospecimens (each a “Material Change”), which Material Change will require advance approval from the LCB.

8. Biospecimens may not be shared by Recipients with anyone not affiliated with the Recipient institution (each, a “Third Party”), unless advance approval is obtained from the LCB, the proposed Third Party is participating in the research identified in the Recipient’s application for access to the Biospecimen(s) and the Third Party agrees in writing to be bound by this Policy.

9. Recipients must respond promptly and accurately to annual requests for updates on use of Biospecimens and the progress of the research for which any Biospecimen is used.

10. No Recipient or institution receiving Biospecimens may claim any intellectual property rights, including, without limitation, patent, copyright, trademark or trade secrets (“IP”) in Biospecimens or data associated with Biospecimens. Neither MJFF nor the LCB may claim IP rights in any Biospecimen.

11. No Recipient or institution using Biospecimens may claim any IP rights for any invention or new work created in whole or part from Recipient’s use of Biospecimens or associated data. Recipients will agree to use their best efforts to publicize to the research community any invention or new work useful to Parkinson’s disease researchers created in whole or part from Biospecimens or associated data, including contacting MJFF for assistance in publicizing such invention or new work. This Section 11 shall not preclude any Recipient from claiming IP rights to any invention or work not involving in any way Recipient’s use of Biospecimens (“Background IP”), even if the Biospecimens are used to test or analyze the Background IP. Any such Background IP should be identified on Recipients’ proposal requesting access to Biospecimens.

12. Any IP claim in violation of Sections 10 or 11 of this Policy shall be void, and Recipient agrees to withdraw any improperly filed IP claim, whether such claim is filed in a court, to a government agency, and/or with a private party.

13. Any publication, presentation or analysis using Biospecimens and/or data associated with Biospecimens shall be made freely available to the scientific research community without charge, including, at MJFF’s election, through a website maintained by MJFF, unless accepted for publication by a journal of established reputation in the scientific community not controlled by Recipient whose publication policies conflict with this Section 13, in which case such publication may be in accordance with the policies of the journal.
14. Any publication, presentation or analysis using Biospecimens by Recipient will cite the LCC as the source of the Biospecimens and MJFF as funder and coordinator of the LCC. Acknowledgements shall include language similar to the following:

“The MJFF LRRK2 Cohort Consortium is coordinated and funded by The Michael J. Fox Foundation for Parkinson’s Research.”

14.1 Any manuscripts published using Biospecimens will include the following on the author line of the manuscript, after the named authors, “and the MJFF LRRK2 Cohort Consortium*” with an asterisk referring to the following statement and list of LCC investigator names (found on the LCC website - https://www.michaeljfox.org/page.html?lrrk2-cohort-consortium):

“*Biospecimens used in the analyses presented in this article were obtained from the MJFF LRRK2 Cohort Consortium (LCC) (https://www.michaeljfox.org/page.html?lrrk2-cohort-consortium). The investigators within the LCC contributed to the design and implementation of the LCC and/or provided data and collected biospecimens but did not necessarily participate in the analysis or writing of this report. LCC investigators include [names of LCC investigators].”

14.2 Within the methods section of any manuscripts published using LCC biospecimens, language similar to the following will be included. Depending upon the length and focus of the article, it may be appropriate to include more or less than the example below, however, inclusion of some variation of the language shown below is mandatory.

“Biospecimens analyzed for this article were obtained from the MJFF LRRK2 Cohort Consortium (LCC) (https://www.michaeljfox.org/page.html?lrrk2-cohort-consortium). For up-to-date information on the study, visit https://www.michaeljfox.org/page.html?lrrk2-cohort-consortium.”

15. Any publication, presentation or analysis using Biospecimens will be submitted to MJFF in advance so that MJFF may verify that Recipient has complied with these Sections 13 and 14. MJFF may share the publication, presentation or analysis with the LCB. MJFF and the LCB will maintain confidentiality of the manuscript and will complete its review promptly.

16. Any raw data generated from analyses of LCC Biospecimens will be submitted to the LCB upon completion of analyses. The LCB may choose to incorporate the raw data into the LCC database.

17. Unused Biospecimens or portions thereof will at the election of the LCB be returned to the Biorepository or destroyed. Recipients must notify the LCB promptly upon completion of the research identified in the application or any amendments thereto.

18. Recipients will use appropriate administrative, physical and technical safeguards to prevent use or disclosure of the Data other than as provided for in this Biospecimens Use Agreement.
19. Any violation of this Policy by a Recipient must be promptly reported to the LCB and may at MJFF’s election result in termination of Recipient’s access to Biospecimens and the return of such Biospecimen to the Biorepository.

I agree to report any use or disclosure of the Biospecimens not provided for by this Policy of which I become aware within 15 days of becoming aware of such use or disclosure.

I will ensure that any Recipients who utilize Biospecimens use appropriate and administrative, physical and technical safeguards to prevent use of the Biospecimens other than as provided for by this Biospecimens Use Agreement and as outlined in the application protocol.

I agree to the terms of this Policy as well as any changes to this Policy that the LCB may adopt, unless such changes hamper my work. If that is the case, I agree to contact the LCB to discuss such changes to understand the best way to proceed without violating terms of the Policy as amended.

I understand that failure to abide by this agreement will result in termination of my privileges to access LCC data and/or biospecimens.

____________________________________
(Signature)

____________________________________
(Print Name)

____________________________________
(Date of signature)