

PPMI Cell Line Use Agreement

I ("Recipient") request access to fibroblasts and/or induced pluripotent stem cell (iPSC) lines (fibroblasts and/or iPSC lines collectively referred to as "cell lines") collected by The Parkinson's Progression Markers Initiative (PPMI) for the purpose of scientific investigation and agree to the following terms:

1. Recipient will receive de-identified cell lines and will not attempt to establish the identity of or attempt to contact any of the PPMI subjects.
2. Recipient will require anyone on Recipient's team who utilizes these cell lines to comply with this PPMI Cell Line Use Agreement by signing this agreement.
3. Recipient will accurately provide the requested information for persons who will use these cell lines and the analyses that are planned using these materials.
4. Recipient will respond promptly and accurately to annual requests to update this information.
5. Recipient will comply with any rules and regulations imposed by Recipient's institution and its Institutional Review Board (IRB) in requesting these cell lines.
6. Recipient will use the cell lines and their derivatives solely for neurodegenerative disease research purposes which (a) are outlined in Recipient's proposal for access as approved by The Michael J. Fox Foundation for Parkinson's Research ("MJFF") and/or the PPMI Biospecimen Review Committee (BRC), and (b) in the case of a cell line and its derivatives, are (i) permitted in accordance with this agreement, (ii) are permitted in accordance with the PPMI Cell Lines Material Transfer Agreement approved by the cell line manufacturer, and, if applicable, (iii) are appropriately licensed by the cell line manufacturer and/or third parties.
7. The cell lines and their derivatives may not be used directly or indirectly to derive or make any human gamete or gamete precursor cell.
8. The cell lines and their derivatives may not be reverse engineered.
9. Recipient may not use the cell lines or their derivatives in humans, in clinical trials, for diagnostic purposes involving human subjects, or directly for any therapeutic use.
10. Recipient shall not sell or transfer the cell lines and/or their derivatives except (a) as outlined in Recipient's proposal for access as approved by MJFF and/or the PPMI BRC, (b) as permitted in accordance with this agreement, (c) as permitted in accordance with the PPMI Cell Lines Material Transfer Agreement approved by the cell line manufacturer, and, if applicable, (d) are appropriately licensed by the cell line manufacturer and/or third parties.
11. Cell lines and their derivatives may not be used in the manufacture or processing of any products or for any work for hire or other arrangement in which the fruits of work performed are owned by or pledged to a third party except as outlined in Recipient's proposal for access as approved by MJFF and/or the PPMI BRC and (i) as permitted in accordance with this agreement, (ii) as permitted in accordance with the PPMI Cell Lines Material Transfer Agreement approved by the cell line manufacturer, and, if applicable, (iii) as appropriately licensed by the cell line manufacturer and/or third parties.

12. If approved to receive cell lines, Recipient acknowledges that his or her institution must sign and agree to all terms outlined in the PPMI Cell Lines [Material Transfer Agreement](#) approved by the cell line manufacturer before the PPMI repository will release the cell lines.
13. Recipient will prepare “lay” abstracts to be posted on the PPMI and/or MJFF websites of analyses that Recipient is performing with PPMI cell lines and/or their derivatives.
14. Recipient acknowledges that researchers who receive approval to access PPMI cell lines will be granted an exception to the standard PPMI Intellectual Property (IP) Policy that prohibits claiming of new IP generated through use of PPMI samples. Further:
 - a. Any user of cell lines may generate and claim proprietary IP rights on research tools developed there from (“Inventor”).
 - b. IP on compounds developed and/or tested with any research tool created through or from PPMI cell lines in conformity with the PPMI IP Policy may remain with the Inventor.
 - c. Recipient hereby grants to MJFF a non-exclusive sublicensable license in and to any IP and results generated through use of the cell lines at no charge only for internal non-commercial scientific research, which sublicensable license includes the right of MJFF to designate one or more third party researchers, whether or not such researchers are employed by or affiliated with for-profit or non-profit entities, to receive and use such IP and results at no charge only for non-commercial scientific research. “Non-commercial scientific research” shall include preclinical research and clinical research up to and including a phase 3 clinical trial, even if such preclinical or clinical research involves investigation of a product that may be commercialized.
 - d. Recipient shall promptly report results and any claim of IP rights to MJFF in writing and shall promptly provide materials and/or access necessary to effectuate the license set forth in subsection c. upon request of MJFF but may delay providing such materials and/or access only upon reasonably asserting that exercise of the license will materially compromise Inventor’s ability to obtain IP protection from a government agency or first publish the IP rights; in such event, MJFF will limit or refrain from exercising such license so that filing for IP protection and/or first publication, whichever is applicable, is not materially compromised.
 - e. Nothing herein shall be construed as granting any right in or license under any intellectual property owned or controlled by the cell line manufacturer or its licensors and embodied in cell lines or their derivatives and nothing herein shall be construed to allow the Inventor or any Recipient to claim any IP rights on or in relation to the cell lines.
15. Recipient will comply with all provisions described in the [PPMI Publications Policy](#), including the following:
 - a. If Recipient publishes abstracts on analyses of PPMI cell lines and/or their derivatives, Recipient agrees to the following:
 - i. Recipient will cite PPMI as the source of the cell lines and the PPMI funding sources in the abstract as space allows.
 - ii. Unless the abstract is identified as a Primary Publication (see [PPMI Publications Policy](#), group authorship of PPMI will not be cited in the authorship line of the abstract.
 - iii. Recipient will upload abstracts onto the PPMI website for registered users to see either as they are accepted or after they are presented.

- b. If Recipient publishes manuscripts using PPMI cell lines and/or their derivatives, Recipient agrees to the following:
- i. Unless manuscript is identified as a Primary Publication (see [PPMI Publications Policy](#)), group authorship of PPMI will not be cited in the authorship line of the manuscript.
 - ii. Recipient will include language similar to the following in the methods section of the manuscripts in order to accurately acknowledge data gathering by the PPMI personnel. 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:

"Cell lines used in the analyses presented in this article were obtained from the Golub Capital iPSC Parkinson's Progression Markers Initiative (PPMI) Sub-study (<https://www.ppmi-info.org/access-data-specimens/request-cell-lines>). As such, the investigators within PPMI contributed to the design and implementation of PPMI and/or provided data and collected samples but did not participate in the analysis or writing of this report. For up-to-date information on the study, visit [PPMI-info.org](https://www.ppmi-info.org)."
 - iii. Recipient will acknowledge funding by PPMI in the support acknowledgement section of the manuscript using language similar to the following:

"PPMI – a public-private partnership – is funded by The Michael J. Fox Foundation for Parkinson's Research and corporate sponsors, including [list all PPMI Industry Partners found at <https://www.ppmi-info.org/about-ppmi/who-we-are/study-sponsors>.]"
- c. Recipient will submit all abstracts and manuscripts to the PPMI Data and Publications Committee (DPC) *prior* to submitting to a journal. This review will not be a scientific review but is intended to ensure that all items in this Section 16 above are correctly implemented. The DPC will maintain confidentiality of the manuscript and will complete its review within two weeks.
- d. Researchers who publish or present analyses of cell lines and/or their derivatives will make these freely available without charge to the research community through the PPMI website, when not prohibited by journal copyright terms and conditions.
16. Recipient will submit a report of completed analyses using PPMI cell lines and/or their derivatives to the PPMI Biospecimen Review Committee (BRC). Recipient understands that the BRC reserves the right to deposit these analyses in the PPMI study database for use by the research community 45 days after the report of completed analyses is submitted.
17. Recipient will report any use or disclosure of the cell lines and/or their derivatives not provided for by this Agreement of which Recipient becomes aware within 15 days of becoming aware of such use or disclosure.
18. Recipient agrees that MJFF owns the PPMI cell lines and their derivative cells, and that their use by Recipient does not constitute a transfer of ownership rights.

I understand that failure to abide by these guidelines will result in termination of my privileges to access PPMI data and/or cell lines.