



Process for Requesting an Exception to the PPMI Intellectual Property (IP) Policy

Investigators should read all of the following information prior to submitting a request for an exception to the PPMI IP Policy.

PPMI IP Policy Background

PPMI is a pre-competitive, public-private partnership established with the goal of verifying progression markers of Parkinson's disease. PPMI is governed by an open access philosophy—data collected in PPMI are made available to the research community in near real-time, biospecimens collected in PPMI are made available for request by qualified researchers, and all data from use of PPMI biospecimens are incorporated into the PPMI database. Given the pre-competitive nature of PPMI and the goal of sharing resources and findings to advance the field at large, no researcher or institution may claim any Intellectual Property (IP) rights to any PPMI study materials or inventions arising out of the PPMI study materials (see [PPMI Data Use Agreement](#) for further details). However, in response to the generation of broad profiling data on PPMI samples (e.g. whole genome sequencing, RNA sequencing), the PPMI Steering Committee does not want to discourage the development of IP that could lead to improved Parkinson's disease diagnostic tools or therapies. Therefore, the PPMI Steering Committee will consider granting investigators an exception to the standard PPMI IP Policy under extraordinary circumstances.

PPMI IP Policy Exception Review Committee

The [P Policy Exception Review Committee has been established to review requests for an exception to the PPMI IP Policy detailed in the PPMI Data Use Agreement. Following evaluation of a request, this committee will grant or decline an exception to the PPMI IP Policy. This committee will meet every other month to review all requests received in time for the meeting. All applications submitted to this committee will be treated confidentially. Please email ppmi@michaeljfox.org for instructions on how to submit an application to the PPMI IP Policy Exception Review Committee.

[Click here to read our Conflict of Interest statement.](#)

Evaluation Criteria

Applications for exceptions to the standard PPMI IP Policy must 1) clearly outline why a company or institution's business model impedes the company or institution from conforming to the standard PPMI IP Policy and 2) explain how a successful outcome of the proposed plan and, therefore, the development of IP from use of PPMI data would lead to a better understanding of Parkinson's disease and an improvement of the lives of patients living with Parkinson's today. In addition, applicants must confirm that they will agree to the IP Policy Exception terms (see below).

Please note that the scope of research proposals eligible for an exception to the PPMI IP Policy will be extremely limited. Current examples of scenarios that may be eligible for an exception to the PPMI IP Policy include computational model, algorithm, and diagnostic panel development. Please direct questions regarding eligibility to ppmi@michaeljfox.org.

PPMI IP Policy Exception Terms

Any investigator granted an exception to the PPMI IP Policy will be required to agree to the following standard terms:

1. No researcher or institution/company may claim any intellectual property ("IP") rights to any data, information, biospecimens, materials or results provided by or through PPMI ("Study Materials"). For clarity, data, information, materials and results generated by recipient through use of the Study Materials shall not be subject to the foregoing prohibition.
2. Researchers and institutions/companies may claim IP rights arising from or related to their use of the Study Materials, provided that (i) any researcher and institution/company claiming such IP rights ("Rights Holder") shall promptly report any such claim of IP rights to MJFF in writing and (ii) MJFF hereby does have a non-exclusive, sublicensable license to use and/or disclose such IP rights at no charge only for non-commercial research, which 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 rights at no charge only for non-commercial research.
3. "Non-commercial 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.
4. A Rights Holder shall promptly provide materials and/or access necessary to effectuate the license set forth in subsection b. 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 the Rights Holder'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.
5. Researchers who publish or present analyses of Study Materials will make these freely available without charge to the research community through the PPMI website, when not prohibited by journal copyright terms and conditions.

Confidentiality

MJFF and the PPMI IP Policy Exception Committee treat all requests for an exception to the IP Policy and associated research information (collectively, "Confidential Information") in confidence using no less than reasonable care in protecting such Confidential Information from disclosure to third parties who do not participate in the request review process and MJFF assessments. All Confidential Information will be used by the PPMI IP Policy Exception Committee and MJFF ("Reviewers") only internally for the purposes of reviews and assessments and will be shared only in accordance with its sharing policy stated herein. Notwithstanding Reviewers' obligations regarding such Confidential Information, such obligations cover any information retained in their unaided memories and may not be used without the permission of the disclosing party.

Notwithstanding the foregoing, the obligations governing the disclosure and use of Confidential

Information do not apply with respect to Confidential Information that it can be demonstrated:

- a) was generally known to the public prior to the effective date when the request was submitted;
or
- b) becomes generally known to the public through no unlawful or unauthorized act of omission by any recipient of Confidential Information, or in violation of this review process; or
- c) was independently developed by any recipient prior to the effective date of this review process; or
- d) was disclosed to a recipient by a third party who has the right to make such disclosure.

If any recipient of Confidential Information is requested to produce any of the Confidential Information pursuant to a legal or governmental proceeding, such recipient shall give the applicant or other owner of such Confidential Information (the "Discloser") as much prior notice of such requirement as is reasonably practicable under the circumstances and shall use its reasonable efforts to assist the Discloser of such Confidential Information in objecting to such request. If a recipient is compelled to disclose any of the Confidential Information pursuant to such legal or governmental proceeding, such recipient shall use its reasonable efforts to assist Discloser in obtaining confidential treatment for such Confidential Information, will disclose only that portion of the Confidential Information which is responsive to the order, and will provide the Discloser with any copies of Confidential Information so disclosed; provided that such Confidential Information shall remain confidential until it falls into one of the categories specified in this Section entitled "CONFIDENTIALITY".

Questions

Please direct any questions on the PPMI IP Policy or applying for an exception to the PPMI IP Policy to ppmi@michaeljfox.org.