

Pre-clinical Therapeutics Pipeline Program Request for Applications

- This pre-clinical program aims to accelerate the therapeutic pipeline
- Accepting applications on a rolling basis to allow for faster feedback from MJFF on proposed projects
- Open to industry and industry + academia partnerships
- Office hours available on a weekly basis to discuss scientific topics, address questions and partnerships before LOI submission and after full proposal invite



Parkinson's disease (PD) affects nearly 1 million people in the US and over 6 million worldwide, and those numbers are expected to rise over the coming decades. PD is highly heterogeneous: individuals experience a wide array of motor and non-motor symptoms, many of which depend on disease severity and duration. Though our understanding of PD and its causes is growing, many questions remain. There are no drugs available for Parkinson's that alter the progression of the disease, and current symptomatic treatments provide limited relief but come with complications and side effects.

The Michael J. Fox Foundation for Parkinson's Research (MJFF) is dedicated to finding a cure for Parkinson's disease (PD) through an aggressively funded research agenda and to ensuring the development of improved therapies for those living with Parkinson's today. Key to our mission is supporting the accelerated validation and de-risking of PD understanding into promising therapies. Strategic MJFF funding to date has fostered a robust pipeline that includes treatments for improved symptoms management as well as those that may modify disease course. Beyond funding, additional resources such as research tools, open access data sets and connection to MJFF's broad network of scientists, clinicians and the patient community offer added opportunities to enable a program's success.



The Pre-clinical Therapeutics Pipeline Program seeks to accelerate the path of the therapeutic pipeline towards the clinic through the support of ambitious and scientifically robust pre-clinical studies aiming at developing and/or testing treatments and/or interventions that can address the unmet needs of people with PD. To meet this goal, we are currently only accepting applications from industry groups and academia-industry partnerships.

This program currently accepts pre-clinical studies only. New MJFF funding programs for clinical-stage therapeutics are in development. Please check our **website** or **subscribe** to our email list for updates on new funding opportunities. If you are new to MJFF and would like to explore other partnership opportunities, please contact our Research Alliances team at **researchpartnerships@michaeljfox.org** to learn more.

When considering applications submitted to this program, MJFF is interested in programs that aim to:

- Identify, validate or develop novel pharmacological and non-pharmacological therapies through any of the pre-clinical stages of the therapeutics discovery and development process (from early screening campaigns to pre-clinical characterization and testing). Therapies can address any PD motor or non-motor symptoms or could be aimed at preventing, stopping or delaying disease progression.
- Test repurposed/repositioned therapies hitting priority PD pathways/targets in preclinical PD models.

For this program, MJFF will not consider proposals focused on the following:

- Applications for target identification, proposing early discovery studies to identify new targets (e.g., large-scale screening or genomic/transcriptomic analyses).
- Applications proposing genetic model systems and/or genetic manipulation to validate biological targets, except if used as therapeutic approach(es).
- Clinical trials

If you are developing a therapy for people with Parkinson's and your program aligns with the Foundation's priorities described above, we want to hear from you.

Please submit a letter of intent (LOI) via the **MJFF Grant Portal** to see if your idea is appropriate for this call.



When considering proposals submitted to this program, MJFF prioritizes those with the strongest preclinical-to-clinical translational potential, fulfilling the following criteria:

- The selected therapeutic target/pathway or mechanism shows a strong biological rationale to be pursued as a therapeutic target in PD.
- The proposal includes a translational biomarker development plan, including biomarkers to monitor target engagement/modulation, mechanism of action biomarkers, patient enrichment biomarkers, etc. to de-risk clinical development.
- You are either a company or an academic group in collaboration with an industry partner
 whose overall business plan aligns with the proposed research plan or has the ability and
 capacity to develop the potential therapeutic.



Duration: Up to 24 months

Award Amount: MJFF has a flexible approach to funding translational work that is guided by novelty, the stage of development and the overall priority of the unmet medical need for people with PD. The scope and budget for your study may be discussed with MJFF staff if invited to submit a full proposal and should be commensurate with the work proposed.

Budgets include direct and indirect costs. For academic and for-profit institutions, no more than 15% or 10%, respectively, may go to indirect costs. Additional details about MJFF's indirect cost policy can be found in the **Application Guidelines** and **FAQ**.



MJFF seeks ideas on a rolling basis through this open program. Applicants are encouraged to engage with MJFF to consult on program fit. MJFF is offering Office Hour timeslots for those interested in discussing their proposal with MJFF staff. To reserve a time, please email **grants@michaeljfox.org**.

Applicants are permitted to submit multiple and unique submissions throughout the program duration. Applicants are also permitted and encouraged to re-submit a revised LOI application that addresses feedback provided by MJFF, if applicable.

Applicants will be notified of a decision within two weeks of the letter of intent (LOI) submission. If the LOI review results in an invitation to submit a full proposal, the submission deadline will be noted and will be no sooner than six weeks from the date of invitation. Full proposals will be competitively reviewed 4 times per year (see table below). Applicants will be notified of a decision within 3 months of the full proposal submission period to which the proposal has been assigned.

Full Proposal Due Dates - 2023	Funding Decision Announced
January 12 th , 2023	April 2023
March 23 rd , 2023	July 2023
May 25 th , 2023	September 2023
July 27 th , 2023	November 2023



Applications may be submitted by researchers or clinicians in:

- U.S. and non-U.S. biotechnology/pharmaceutical/medical device companies, or other publicly or privately held for-profit entities; and
- U.S. and non-U.S. public and private non-profit entities, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government in collaboration with biotechnology/pharmaceutical/medical device companies, or other publicly or privately held for-profit entities.
- Post-doctoral fellows are eligible to apply as co-investigators with the designation of an
 administrative primary investigator who directs the laboratory in which the fellow will
 conduct research. The administrative co-PI will be responsible for assisting in providing
 all institutional documents required for the project and will be required to sign any
 award contract. Training or mentoring-only proposals will not be considered.



Investigators are encouraged to leverage MJFF-sponsored biospecimen and cell line collections for their studies. MJFF staff can assist with MJFF's biosample process at both the LOI and full proposal stage. To review MJFF's available biosample collections, refer to the MJFF biorepository **website**.

Investigators should indicate their intention to leverage MJFF's biosamples within their LOI. If invited to submit a full proposal, a formal biosample request will be reviewed in parallel. Requests to access MJFF-sponsored biosample collection(s) only (without funding) are also welcomed. Investigators should contact **resources@michaeljfox.org** to learn about the application process.



DIVERSITY, EQUITY AND INCLUSION (DEI)

In pursuit of our mission to accelerate the development of better treatments and a cure for Parkinson's disease, MJFF aims to support a rigorous research agenda reflecting a wide and diverse range of perspectives on Parkinson's disease and carried out in diverse populations. Diversity may refer to characteristics including, but not limited to, race, religion, ethnicity, sex, gender identity, sexual orientation, socioeconomic circumstance, nationality, geographic background, ability and disability, political ideology and age. Parkinson's is a complex problem; the more angles from which we attack, the greater the chances of finding innovative scientific solutions to benefit everyone living with the disease. As such:

- The Foundation encourages applications from diverse investigators representing groups historically underrepresented in the research enterprise.
- Because research shows that diverse teams outperform homogeneous ones, we urge applicants to share information about the composition of the team that will carry out the funded work.



The **Application Guidelines** provide general guidance on applying for funding from MJFF, though the RFA always supersedes information contained in the Application Guidelines.

MJFF holds an **open access publication policy** requiring articles resulting from MJFF-funded work to be published in a preprint repository, then in an open access forum with free and immediate readership rights.

MJFF requires that the Principal Investigator be the primary applicant (i.e., the person who initiates and takes primary responsibility for the application). All application-related correspondence will be sent to the Principal Investigator.

MJFF will hold office hours to discuss scientific topics and interests, as well as to answer questions, and address issues regarding the program. Office hours will be held on Fridays from 10am-11am EST. To sign up, please email **grants@michaeljfox.org** for availability.



MJFF has made available an informational video to clarify and explain the goals of our funding opportunities and answer applicant questions. The video is available to view **here.**

For questions about the application process or project suitability for this call for applications, please email **grants@michaeljfox.org**.

Thank you for your interest in collaborating with MJFF and your commitment to the Parkinson's community.