

2021 CORE FUNDING PROGRAMS THERAPEUTIC PIPELINE PROGRAM AN EDMOND J. SAFRA CORE PROGRAM FOR PD RESEARCH

BACKGROUND

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 (MJFF) funds research to better define, measure, and treat Parkinson's disease as well as critical tools and other resources to advance that research. The purpose of this Request for Applications (RFA) is to support the development of new treatments and interventions with potential for significant impact for people with Parkinson's.

DEADLINES & REVIEW SCHEDULE

- Pre-proposals Due: October 22, 2020, 5 p.m. US ET
- Full Proposal Invitations: December 21, 2020
- Full Proposals Due (by invite only): March 18, 2021, 5 p.m. US ET
- Anticipated Award Announcement: Week of May 31, 2021
- Anticipated Funding: July 2021

Applicants are encouraged to apply early to allow adequate time to correct errors found during the submission process.

FUNDING AVAILABLE

Duration: One- to two-year grants for preclinical programs; two- to three-year grants for clinical programs.

Award Amount:

- Up to \$500,000 for Pre-clinical Program
- Up to \$2,000,000 for Clinical Program

Final budgets will be determined based on review of proposed work and MJFF role. MJFF may not be able to support all costs for a proposed therapeutic development plan and applicants are encouraged to leverage additional sources of funding and resources. These 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 [FAQs](#).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by researchers or clinicians in:

- U.S. and non-U.S. biotechnology/pharmaceutical 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.
- Post-doctoral fellows are **not** eligible to apply as principal investigators.

As therapeutic programs may require many kinds of expertise, MJFF encourages industry and academic collaborations when appropriate.

PROGRAM GOAL

The Therapeutic Pipeline Program seeks to speed the development of Parkinson's disease therapeutics with potential for fundamentally altering disease course or significantly improving treatment or management of non-motor or motor symptoms beyond current standards of care. Proposals should focus on strategies with clear impact for people with Parkinson's and well-defined development plans. Programs developing novel approaches as well as those seeking to repurpose or reposition approved or clinically safe therapies from other disease indications are appropriate for this RFA. MJFF will prioritize clinical and pre-clinical approaches built on strong scientific and biological rationale for targeting fundamental processes underlying Parkinson's cause, progression and/or non-motor and motor symptom expression.

Applications must address one of the following treatment challenges:

- Protection or restoration of degenerating and/or dysfunctional neurons affected in Parkinson's
- Alleviation of non-motor or motor symptoms of Parkinson's not well managed by current treatments
- Reduction of complications and side effects of current Parkinson's treatments.

This cycle, MJFF is particularly interested in efforts focused on **developing therapeutics that alleviate non-motor symptoms** and on **developing telehealth-based therapeutic interventions** that alleviate motor and/or non-motor symptoms (see details below).

PROGRAM PRIORITIES

Applicants may apply to any of the following two tracks.

The **TPP Pre-clinical Track** supports work in the following areas:

- Assay development, early screening campaigns, hit-to lead and lead optimization to identify approaches to selectively target disease features and mechanisms with strong and compelling rationale for PD,
- Proof-of-concept studies validating the potential benefits of a therapeutic strategy in pre-clinical models of PD and/or PD-relevant pathogenic mechanisms, and
- Characterization of promising therapeutic approaches to obtain data on PD-relevant pharmacokinetics, pharmacodynamics, safety, and other features critical for progress into future clinical testing stages.

The **TPP Clinical Track** supports work in the following areas:

- Phase I trials including first-in-human, pharmacokinetic/pharmacodynamic and early safety/tolerability studies,
- Phase II trials seeking early proof-of-concept clinical and biological efficacy data, and
- Phase III trials seeking pivotal demonstration of clinical efficacy.

This cycle, MJFF is particularly interested in:

- Efforts focused on developing treatments with acute therapeutic ability to alleviate non-motor symptoms (e.g., sleep disturbances, fatigue, pain, depression, anxiety, cognitive dysfunction, GI problems).
- Efforts that prioritize telehealth-based therapeutic interventions that aim to address motor and/or non-motor symptoms. Proposals to test remote monitoring that do not have a treatment focus (e.g., wearable activity trackers) should apply for funding consideration to the [2021 RFA for the Development and Validation of Improved Outcome Measures](#).

Note: Although MJFF believes that exercise, rehabilitation and other (e.g., meditation/mindfulness) approaches offer benefits to people with PD, proposals seeking to test these interventions are not appropriate for this program cycle.

Successful applications will provide strong and compelling data supporting the biological and clinical rationale for the proposed therapeutic and a clear plan, including essential “Go/No-Go” decision milestones for moving the approach through the essential stages of development. Investigators new to PD are encouraged to collaborate with experienced PD scientists, clinicians and/or industry professionals.

For clinical programs, given higher budgetary needs, MJFF funding should ideally leverage other funding sources with MJFF support focusing on activities that can, for example, support collection of critical PD-relevant outcome measures, targeted recruitment needs and/or other challenges that can help ensure faster and more informative results. Please also note that MJFF prefers to work closely with study sponsors to ensure trial protocols and plans are designed and executed with the greatest chance for success. Moreover, MJFF looks for studies that have developed a thorough recruitment and retention plan to meet the study goals on time. For further information, please consult our available recruitment and retention resources at [Trial Resource Pack](#).

ADDITIONAL INFORMATION

Our [Application Guidelines](#) provide general guidance about applying for funding from MJFF, though the RFA always supersedes information contained in the Application Guidelines. Please note that MJFF updated our publication and indirect costs policies in early 2020. The new [open access publication policy](#) requires articles resulting from MJFF-funded work publish in a preprint repository then in an open access forum with free and immediate readership rights.

DIVERSITY, EQUITY, AND INCLUSION

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.
- All applicants are encouraged to provide information about the steps they will take to carry out their investigations in diverse clinical populations.

INFORMATIONAL WEBINAR

MJFF will host an informational webinar on September 3, 2020, at 12 p.m. ET to clarify and explain the goals of MJFF funding opportunities and answer applicant questions. The webinar will be available to view on-demand after the live airdate. [Register now.](#)