

## Fall 2022 Request for Applications Biomarkers to Support Therapeutic Trials



### BACKGROUND

Parkinson's disease (PD) is an age-dependent, relentlessly progressive and heterogeneous neurodegenerative disorder associated with accumulation of increasingly disabling symptoms impacting daily function and quality of life for nearly one million people in the U.S. and more than six million globally. Unfortunately, there are no drugs available for PD that can alter the progression of the disease - only symptomatic treatments to provide limited relief.

The Michael J. Fox Foundation (MJFF) aims to foster and advance a diverse therapeutic pipeline to target critical PD symptoms, pathology and stage. Although this pipeline continues to expand at an exciting rate, trials are hampered by a lack of robust, reliable and objective biomarkers for use as primary or secondary endpoints. *Establishing a clear link between outcome measures and the therapeutic pipeline to enable more informative trials remains a critical unmet need.*



### PROGRAM GOAL

The goal of this Request for Applications (RFA) is to fund outcome measures which will directly *inform* and *transform* therapeutic development. This may include:

- Biomarkers to facilitate subject selection by enabling more accurate diagnosis or predicting which patients may benefit from an intervention
- Markers to identify susceptibility risk
- Biomarkers to stratify subjects based on prognosis
- Measures to demonstrate proof of efficacy through monitoring changes in the degree or extent of disease
- Outcome measures to evaluate pharmacodynamic response

Funding will support development, optimization or analytical validation of new or existing outcome measures for all intended uses (diagnosis, prognosis, monitoring or pharmacodynamic response) towards deployment of these tools in clinical trials.

The main focus of this RFA is on *molecular bioassays* which have the potential to *directly serve* clinical trials. Biomarker work as a tool to understand the role of a particular pathway in PD without a clear link to therapeutics will not be considered.

For this program, MJFF will **not** consider proposals on the following topics (please browse our other open programs that may encompass these topics):

- Unbiased discovery work (ex. proteomics, genomics, transcriptomics, etc.)
- Clinical scales
- Patient reported outcomes
- Neuroimaging
- Target validation, drug discovery, or therapeutic development



## PROGRAM PRIORITIES

The Outcome Measures to Support Therapeutic Trials Program will consider applications across various intended uses, including diagnosis, prognosis, monitoring and pharmacodynamic response. Proposals may span all stages, including development, optimization and analytical validation.

The Outcome Measures to Support Therapeutic Trials RFA will fund proposals for measures related to:

- known PD targets (which might require additional refinement, validation and/or assessment in diverse PD populations)
- related neurodegenerative diseases (for which rationale to evaluate in a PD cohort can be demonstrated)
- emerging pathways strongly linked to PD (ex. lysosomal, mitochondrial, neuroimmune and glucose metabolism). Note: successful proposals must not merely probe the role of a pathway in PD but have potential to directly inform clinical trials
- prodromal risk and/or phenoconversion markers



## FUNDING AVAILABLE

**Duration:** 12 to 24 months

**Award Amount:** Up to \$300,000. Requested support should be commensurate with work proposed.

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 [FAQ](#).



## DEADLINES & REVIEW SCHEDULE

- Pre-proposals Due: April 26, 2022, 5 p.m. US ET
- Full Proposal Invitations: Week of June 6, 2022
- Full Proposals Due (by invite only): August 11, 2022, 5 p.m. US ET
- Anticipated Award Announcement: Week of November 14, 2022
- Anticipated Funding: November 2022

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



## 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 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.



## BIOSAMPLE REQUESTS

Applicants may propose studies designed to evaluate biomarkers in human biospecimens. Investigators are encouraged to leverage existing tissue and biosample resources if possible. New recruitment should be limited to studies where clinical biosamples are unavailable for the intended purpose (ex. different collection protocol required, specific cohort required or novel biomatrix proposed). Studies requesting access to biosamples available through MJFF-sponsored biospecimen and cell line collections are eligible to apply to this initiative. In these cases, access to samples will be reviewed in parallel to funding requests by the committees overseeing the biospecimen collection(s) requested. To review MJFF's available biosample collections, please consult the MJFF biorepository [website](#) and biorepository inventory catalog. Groups requesting access to samples only (without funding) should contact [resources@michaeljfox.org](mailto:resources@michaeljfox.org).



## 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.
- Specific DEI aspects which are relevant for this program include consideration that cohort(s) are representative of *all* people with Parkinson's (ex. for recruitment of new subjects and reporting of demographics for existing samples)
- Note: Proposals to validate know/existing outcome measures in underrepresented groups will be considered.



## ADDITIONAL INFORMATION

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.

For questions about the application process or project suitability for this call for applications, please email [grants@michaeljfox.org](mailto:grants@michaeljfox.org).