**PARKINSON’S DISEASE THERAPEUTICS PIPELINE PROGRAM**

**Request for Applications**

**Clinical Development Track**

#### **Pre-Proposal**

*Please use the template below to create your pre-proposal and upload a single PDF copy with your online submission. Instructions to submit online are linked* [*here*](https://app.getguru.com/card/TyKRznoc/Instructions-for-Submitting-a-Proposal-to-The-Michael-J-Fox-Foundation-for-Parkinsons-Research)*.*

Principal Investigator:

Institution/Company:

Project Title:

**TEMPLATE**

 *Text should be no smaller than 11-pt font and not exceed* ***2 pages. Please, carefully read the instructional text within each box. If desired, you may delete it to save space, but make sure headings are kept and all instructional text is addressed.*** *We encourage the use of bullet points, when appropriate, as well as the submission of schematics, images and/or graphs accompanying any unpublished preliminary data. Optional literature references as well as schematics, images and/or graphs are excluded from the 2-page counting.*

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| --- | --- |
| MEDICAL NEED | What patient need are you seeking to address and in what target population? What is the novelty of approach and patient value proposition?  |
| TARGET/PATHWAY/CIRCUITRY | Please identify the target indication and presumed mechanism of action for the therapeutic being proposed for testing. For pharmacologic interventions, please detail compound composition of the proposed therapeutic. What molecular target, biologic pathway or neurocircuitry is your intervention targeting and how is it linked to PD? How and in which PD models have the functional role of your target/pathway/circuitry been validated?  |
| EXPERIMENTAL PLAN | What stage of development are you at (e.g. Phase 1, Phase 2, etc.)? Please provide a summary of the proposed clinical study design, including the route of administration and relevant data (preclinical and/or clinical) that justifies the progression of the therapeutic through clinical trials. |
| BIOMARKERS PLAN (as relevant) | Which biomarkers or other measures will you use to establish target engagement/modulation of the therapeutic? How will you establish PK/PD relationship and blood-brain-barrier penetration if your therapeutic is CNS-penetrant?  |
| FUTURE DEVELOPMENT PLAN | Please provide insights on how the proposed clinical study will inform subsequent studies. Outline future clinical development and commercialization strategies following this study, including what additional funding sources you will seek (e.g., government, private/VC, industry partners, etc.). Describe what role patients, care partners and health care professionals will have in these next steps.  |
| INTELLECTUAL PROPERTY | Describe any intellectual property considerations and/or restrictions (i.e. freedom-to-operate) that may impact further advancement of the proposed therapy. For industry/academia collaborations, please describe in a few words your plan to co-advance the therapeutic program, if successful. |
|  PROGRAM NEEDS | How can MJFF support your efforts? Please provide a high-level description of resource needs for your proposed study including a budget estimate. Is there specific access to expertise, advice or reagents that MJFF can help facilitate? |