

Parkinson's Progression Markers Initiative

<u>PPMI Biospecimen Full Proposal</u> <u>Instructions & Application</u>

Submission Instructions

Please review the instructions and requirements below. Please note that **proposals will only be accepted through the MJFF Grant portal** (https://grants.michaeljfox.org/s_Login.jsp).

- Once you begin an online application, you may save and return to it before final submission. You can access it through your portal homepage under Applications in Progress. When ready to submit, please click Submit at the bottom of the application to ensure that your submission is delivered promptly to MJFF.
- A notice of proposal receipt is automatically sent by email upon online submission. If you do not receive this automatic notification within one hour of submission, please contact MJFF at ppmi@michaeljfox.org to check on the status of your proposal.
- All proposals are treated as confidential and will be reviewed by PPMI Biospecimen Review Committee (BRC) and The Michael J. Fox Foundation in collaboration.
- Please refer to the <u>Application Guidelines</u> while preparing your application.
- Please consult PPMI's <u>Biospecimen Request</u> page and the <u>Biosample Inventory</u> for more information on the number and type of biospecimens available

Application Checklist & Proposal Instructions

Summary of Application Requirements

Online Application: Complete the online application tabs with the following information:

- Project Information & Description tab: Information entered during the pre-proposal stage will populate on this tab. You may adjust any information.
- Team Information tab: The main applicant will default to the Principal Investigator role on the Research Team Members grid, but this can be changed if necessary. Please fill in required information for the main applicant, including ORCID, and add other members of the team if applicable (including Co-Principal Investigators, Consultants, etc.) For each team member listed, you will need to note their first and last name, institution, position title, email, role on the project, career stage, and ORCID. An NIH biographical sketch must be uploaded for every team member (see Personnel Requirements below).
 - We require that every team member <u>who is NOT the main applicant</u> listed with the role of Co-Principal Investigator, Principal Investigator, Paid Collaborator, and Unpaid Collaborator be invited to collaborate on the application. Please refer to the section below entitled Personnel Requirements for more information.
- Attachments tab: Here you will upload the main applicant's Institutional Approval and budget template (if you are requesting funds from MJFF for this study). The Sample Type

Worksheet you included with your pre-proposal will be available on this tab should you need to make any adjustments based on reviewer feedback. On this tab you must also fill in the Total Requested Amount, which should equal the grand total in the budget template. If you are NOT requesting funds from MJFF for this study, you need not upload a budget but simply enter 0 on the Total Requested Amount field.

• Project Proposal Template tab: Complete the Project Proposal Template and upload in the Full Proposal field on this tab. Complete the Budget Narrative and Funding Sources template and upload in the Full Proposal Other Attachments field. In the Confirmation section of the Project Proposal Template tab, please confirm your submission and input your initials.

Documents

- Applicant's Institutional Approval: The main applicant should upload their institutional approval on the **Attachments** tab using the provided template. Institutional approvals for other team members should be uploaded to their Collaboration and Institutional Approval activity that will be created when they are invited to collaborate on the proposal (see the Personnel Requirements section below).
- Budget Template: Only required if you are requesting MJFF funds for this study. If applicable, download the MJFF budget template, complete, and upload to the **Attachments** tab of the online application.
- Sample Type Worksheet: You may make changes to the worksheet you uploaded at the preproposal stage.
- Project Proposal Template (5 pages maximum not including supporting data/literature citations page): Using page 4 of this document as a template, combine the following sections as <u>one</u> PDF document and upload in the Full Proposal field on the **Project Proposal** Template tab of the online application. You may delete instructional text, but all narrative headings in the left column must be intact for review. Please refer to the template on page 4 for more information about what each section entails.
 - Project background, goal, and hypothesis
 - Rationale and impact
 - Biomarker assay validation information
 - Preliminary data
 - Sample request
 - Project plan
 - Timeline and milestones
 - Optional: 1 additional page of figures/supporting data and highly relevant articles references in the proposal that are published or "in press" at application submission (not counted toward the 5-page limit)
- Budget Narrative and Funding Sources: Using page 6 of this document as a template, complete the questions (budget narrative is only required if you are requesting funding from MJFF) and upload to the Full Proposal Other Attachments field on the **Project Proposal Template** tab.

Personnel Requirements

Any additional (<u>not the main applicant</u>) research team members added to the Team Information tab in the roles of Co-Principal Investigator, Principal Investigator, Paid Collaborator, or Unpaid Collaborator must be invited to collaborate on the application. The applicant can invite these team

members to collaborate on the application by clicking the "Send Invitations" button. When this button is clicked, the applicant will be prompted to re-enter the information of each team member before the invitation is sent. **Please note that the application cannot be submitted** unless every <u>non-main applicant</u> team member with the role of Co-Principal Investigator, Principal Investigator, Paid Collaborator, and Unpaid Collaborator is invited to collaborate, accepts the invitation, and completes the required activities upon accepting the invitation (Collaboration and Institutional Approval and Biosketch). Once the invitation is accepted, these team members can also access the proposal.

Inviting consultants to collaborate on the proposal is optional. The applicant may also invite other non- team members to collaborate (such as a Grants Manager). These roles can be invited as Contributors. If invited, Contributors do not have to complete the required activities but can still access the proposal.

When **non-main applicant** Co-Principal Investigators, Principal Investigators, Paid Collaborators, and Unpaid Collaborators are invited to collaborate on the proposal, they will be required to complete two activities. First is a Collaboration and Institutional Approval activity and second is a Biosketch activity.

- Collaboration and Institutional Approval: Each invited team member with one of the above roles must acknowledge their collaboration on the proposal and, if applicable, upload an institutional approval. One institutional approval is required for each unique collaborating institution on the proposed project so only one team member per institution will need to upload the institutional approval. After the activity is completed, the acknowledgement and institutional approval, if applicable, for each required team member will appear on the Collaboration and Institutional Approval section of the **Team Information** tab. The main applicant's institutional approval should be uploaded on the **Attachments** tab.
 - o **A note about institutional approval:** Institutional approval can be given by an official of the institution, such as the Office of Sponsored Research or Office of Grants & Contracts, but NOT the Chairperson or Head of Department. A CEO, CFO, or legal advisor may serve as the authorized signer of the institutional approval for for-profit applicants.
- Biosketch: A biosketch is required of every team member listed. Invited team members can
 upload their biosketch when they complete their required biosketch activity upon logging into
 the Grant Portal. The main applicant can upload their biosketch directly on the Team
 Information tab. Since it is not a requirement to invite consultants to collaborate on the
 application, the main applicant can upload the biosketches of any consultants on their behalf on
 the Team Information tab. Please limit each biosketch to five pages.



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<u>PPMI Biospecimen Project Proposal</u> <u>Template (Full Proposal Stage)</u>

Application Information

Principal Investigator Institution Project Title Email

General Formatting Guidelines

- Use letter-size pages (8.5 x 11 inches), minimum 11-point font
- Minimum of one-inch margins on the top, bottom, and both sides of every page

Please use the following template to create an executive summary of your research plan and upload as <u>one</u> PDF (5 pages maximum) to the Full Proposal field on the **Project Proposal Template** tab of the online application. Figures, supporting data, and citations of relevant primary literature supporting the proposal are encouraged and do not count against the 5-page limit. You may delete instructional text, but all narrative headings in the left column must be intact for review.

Project background, goal, and hypothesis	Do not include background information on Parkinson's disease.
Rationale and impact	Given that PPMI is a study ideally reserved for verification of progression biomarkers, provide compelling rationale for assessing the biomarker in this cohort and explain how a successful outcome could impact the field.
Biomarker assay validation information	Provide information on key assay validation parameters on the biospecimens being requested. These include, but are not limited to, the dynamic range, precision, sensitivity, specificity, test/retest reliability, effect of pre-analytical variables, etc.
Preliminary Data	Include preliminary data on the requested biospecimens of human origin, preferably collected under the same conditions as in the PPMI cohort.
	Specifically, include all pertinent data indicating the utility of the biomarker to monitor PD progression, such as longitudinal assessment, correlation with disease severity/duration measures, or compelling scientific rationale implicating the biomarker to pathogenesis/pathophysiology of PD.

Sample Request	Justify the number and type of samples requested (including any relevant clinical characteristics, etc). Please include power calculations that are informed by prior data. If no prior data exist, provide the justification for the assumptions underlying proposed power calculations.
Project plan	Outline the proposed studies and associated data analysis plan. PPMI requires that investigators deposit data back to the PPMI study database for use by the wider research community. Describe the data and results that will be returned.
Timeline and milestones	Provide a summary table and/or description of the anticipated timeline for completion of major study milestones, including any 'go/no-go' decision points where progress and data could impact the direction of the project and deposition of data/results.



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Application Information

Principal Investigator Click here to enter text

Email Click here to enter text

Institution Click here to enter text

Project Title Click here to enter text

General Formatting Guidelines

- Use letter-size pages (8.5 x 11 inches), minimum 11-point font
- Minimum of one-inch margins on the top, bottom, and both sides of every page

Please use the following template and upload as <u>one</u> PDF to the Full Proposal Other Attachments field on the **Project Proposal Template** tab of the online application. The Budget Narrative question is only required if you are requesting funding from MJFF. The Funding Sources question is required for all applicants. You may delete instructional text, but all narrative headings in the left column must be intact for review.

BUDGET NARRATIVE	Only required if you are applying for funding from MJFF. Provide a brief description of the role and responsibility(s) of each research team member on the project. Provide justification of key budget items, specifying their relevance to the project.
FUNDING SOURCES	Required regardless of whether you are applying for funding from MJFF. Include current and pending funding sources for the Principal Investigator. For each grant, include the title, a brief abstract, annual amount of grant, funding period, and percentage effort of the investigator. Applicants whose total time commitment exceeds 100% must explain in detail. Specifically, state whether or not there is scientific overlap with the current application; and where there is overlap, please explain the rationale for requesting MJFF funding. If an individual has no other funding (current or pending), a statement should be included to specify this.