PPMI cell lines INSTRUCTIONS & APPLICATION

THE MICHAEL J. FOX FOUNDATION GRANT PORTAL REGISTRATION GUIDE

All pre-proposals must be submitted through the new [MJFF Grant Portal](https://mjff.smartsimple.com/s_Login.jsp).



**Getting Started: New Users**

If you have never applied to an MJFF RFA, click the Register Here button.

1. Search for your organization in the Organization Name field. If your organization is not found, click Add New Organization and complete the organization registration.
2. Complete the Contact Information fields. Be sure to use an active email address.
3. Click the Submit button.
4. You will receive an email to the provided email address.
5. Follow the instructions in that email to set a password and log in to the Grant Portal.

**Getting Started: Returning Users**

If you have applied to an MJFF RFA in the past, click the Returning User button.

1. Input the email address associated with your MJFF account.
2. If the email you entered is in our system, you will receive an email instructing you to reset your password and log in to the Grant Portal.
3. If you do not receive an email, you may try a different email address. If you still do not receive an email, please register as a new user.

Once you have logged in to the MJFF Grant Portal, click the Funding Opportunities button to view open funding opportunities. Select PPMI Cell Lines and proceed to start your proposal.



**Changing Your Organization**

You can access your profile and information by clicking on your initial on the top right of the page and then selecting My Profile. If you notice your organization is incorrect you may request an organization change by following the below steps:

1. Navigate to the Organization Change Request tab in your profile.



1. Check the Request a Change to Primary Organization or Associated Organization checkbox.
2. After reading the instructions on the page and determining your change type, select the appropriate option from the Change Type drop down menu.
3. Search for the new organization in the Organization search bar. If it does not currently exist in our database, click the Add Organization if Not Found Above button and follow the steps to register the new organization.
4. In the Notes/Description box, please briefly explain the need for the change.
5. Click the Request Organization Change button at the bottom of the page.



You can begin an application before the organization change is made. Once you request an organization change, a member of MJFF staff will promptly review your request and send you a confirmation email.

SUBMISSION INSTRUCTIONS

* Please review the instructions and requirements below. Please note that proposals will only be accepted through the MJFF Grant portal (<https://mjff.smartsimple.com/>).
* 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.**
* If you are interested in applying for both cell lines and other biospecimens, please submit two separate applications.
* 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 [Application Guidelines](https://www.michaeljfox.org/page.html?administrative-guidelines) while preparing your application.
* If the review committee preliminarily approves your application, full approval will be subject to execution by you and your institution, as applicable, of a Cell Line Use Agreement and Material Transfer Agreement.
* All questions about the application submission should be directed to ppmi@michaeljfox.org.

APPLICATION checklist & proposal instructions

### **Summary of Application Requirements**

* Online Application: Complete the online application tabs with the following information:
	+ Project Information & Description tab: Please enter basic information about your proposed project, including title, project duration, and whether this proposal is a resubmission of a previously submitted proposal.
	+ 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 who is NOT the main applicant 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, budget template (if you are requesting funds from MJFF for this study), and Sample Type Worksheet. 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. These documents are described below.
	+ Project Proposal Template tab: Complete the Project Proposal Template and Use Agreement, described below, and upload. 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: Download the Cell Lines Sample Type Worksheet from the Documents section toward the top of the online application, fill out, and upload in the Sample Type Worksheet field on the **Attachments** tab. On the Cell Lines Sample Type Worksheet, you will find a different chart for each sample type available (fibroblasts and IPSCs). For each sample type you wish to request, select a Study Arm from the drop down, then fill in the number of subjects you are requesting, the number of aliquots per subject, and the number of clones per subject (if IPSCs). More information about cell line availability can be found on the [PPMI website](https://www.ppmi-info.org/access-data-specimens/request-cell-lines/) and associated [Cell Lines Inventory Catalogue](http://www.ppmi-info.org/access-data-specimens/download-data/).
	+ Project Proposal Template (3 pages maximum not including supporting data/literature citations page): Using page 7 of this document as a template, combine the following sections as **one** 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 7 for more information about what each section entails.
* Rationale
* Biosamples Requested
* Project Details
* Project Timeline
* Preliminary Data
* Submission of Data
* Impact
* Collaborative Team & Environment
* Project Support
* 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 3-page limit)
	+ Use Agreement: Download the Use Agreement from the Documents section toward the top of the online application, fill out, and upload in the Use Agreement field on the **Project Proposal Template** tab.

**Personnel Requirements**

Any additional (**not the main applicant**) 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 **non-main applicant** 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.
	+ **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.

PPMI cell lines project proposal template

Applicant Information

PRINCIPAL INVESTIGATORClick here to enter text.EMAILClick here to enter text.

INSTITUTIONClick here to enter text.

PROJECT TITLEClick here to enter text.

Additional Information

Do you plan to seek funding from MJFF for this study? [ ]  Yes [ ]  No

*Please note that if you are requesting funding, you must upload a budget on the MJFF budget template to the Attachments tab of the online application.*

Do you plan to generate isogenic controls? [ ]  Yes [ ]  No

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* ***one*** *PDF (3 pages maximum) to 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 3-page limit. You may delete instructional text, but all narrative headings in the left column must be intact for review.*

|  |  |
| --- | --- |
| RATIONALE | Briefly describe the study plan and its significance. Include the rationale for studies on iPSCs specifically from the PPMI cohort.  |
| BIOSAMPLES REQUESTED | Briefly describe the requested number of samples (e.g., number of clones/line, number of donor lines), including descriptions of subject characteristics (e.g. PD, healthy control, genotype, any specific clinical parameters) and specific biosample parameters (e.g. cell line type, method of collection, QC), if relevant. An overview of available PPMI cell line resources can be found [here](https://www.ppmi-info.org/access-data-specimens/request-pbmcs-cell-lines/).* PBMC-derived iPSCs
	+ Please see the Blood Collection Manual (CDI Study) in the [Research Documents & SOPs section](http://www.ppmi-info.org/study-design/research-documents-and-sops/) of the PPMI website for details on the blood collection for PBMC-derived iPSCs. **PLEASE NOTE:** The goal of the iPSC Sub-Study was to generate multiple clones of PBMC-derived iPSCs from a subset of PPMI participants. For the latest numbers of available PBMC-derived iPSCs, please consult the Cell Line Catalog in the [PPMI database](http://www.ppmi-info.org/access-data-specimens/download-data/). If you would like to receive multiple clones for a given line, please include this information in your application.
* Skin biopsy-derived fibroblasts and matching iPSCs
	+ Please see the Skin Biopsy Manual (NYSCF Study) in the [Research Documents & SOPs section](http://www.ppmi-info.org/study-design/research-documents-and-sops/) of the PPMI website for details on the punch biopsy procedure for skin biopsy-derived iPSCs.
	+ Skin biopsy-derived fibroblasts and multiple clones of matching iPSCs were generated from 25 PPMI participants. For a detailed inventory of available skin biopsy-derived fibroblasts and matching iPSCs, please consult the [Cell Line Catalog](http://www.ppmi-info.org/access-data-specimens/download-data/) in the PPMI database.
* If results from the proposed study will be combined with those obtained from other samples, include an explanation of how the requested samples will fit in with the overall study design.
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| PROJECT DETAILS | * Define the study hypothesis and describe the study design, including detailed study methods, and descriptions of outcome measures and sample sizes.
* Please include detailed information associated with your sample size calculations (e.g., effect size of outcome measures considered). In addition, list the statistical methods that will be used to analyze the data from the proposed study.
* PPMI cell lines are provided blinded to diagnosis and mutation status, and unblinding is performed as part of the data return process. If your experimental design requires this information up-front, please provide compelling rationale for consideration.
 |
| PROJECT TIMELINE | Please provide a feasible timeline of milestones and their estimated completion dates demarcated in separate milestone periods. |
| PRELIMINARY DATA | If utilizing iPSCs, provide preliminary data demonstrating expertise in culturing iPSCs and differentiating iPSCs into desired cell-types (neurons, glia, etc.). Preliminary data should take the form of representative images demonstrating morphology and markers for phenotype or citations to prior work.  |
| SUBMISSION OF DATA | PPMI requires that investigators submit a report of completed analyses to MJFF and the Biospecimen Review Committee (BRC). In addition, all data using PPMI samples must be deposited in the PPMI study database for use by the research community. Describe what data and results will be returned to PPMI and specify timelines for key milestones, project completion and data return.  |
| IMPACT | Explain how a successful outcome of the proposed plan would lead to better understanding of PD and/or would address critical questions essential to development of PD therapies or biomarkers or future research pertinent to these. |
| COLLABORATIVE TEAM & ENVIRONMENT | Briefly describe your team and resources highlighting the expertise to conduct the research plan (ex. working with iPSCs, specific differentiation protocols, etc.) |
| PROJECT SUPPORT(Please complete if you are *not* requesting funds from MJFF) | If you are not requesting funding from MJFF to support this work, please indicate whether there is current funding to support the research project and, if so, provide the funding source(s) and grant number(s). If there is no funding currently in place, briefly describe the plan to apply for funding (if not through MJFF). Approval of access to samples will be conditional on successfully obtaining funding. Conditional approvals will be valid for a period of up to 12 months.  |

Notice of Not-for-Profit User Restrictions from iPS Academia Japan, Inc.

**Definitions:**

1. MJFF: The Michel J. Fox Foundation for Parkinson’s Research
2. iPS-AJ: iPS Academia Japan, Inc.
3. Project iPS Cells: iPS cells which MJFF transfers or delivers under Parkinson’s Progression Markers Initiative (PPMI) project
4. Project Differentiated Cells: iPS cell-derived differentiated cells which MJFF transfers or delivers under Parkinson’s Progression Markers Initiative (PPMI) project
5. Project Cells: Project iPS Cells and Project Differentiated Cells
6. Not-for Profit User: not-for-profit organization, including academia, governmental body and other not-for-profit organization who are transferred or delivered Project Cells by MJFF
7. Pluripotent Cells: Project iPS Cells transferred or delivered to Not-for Profit User by MJFF
8. Progeny: Cells derived by the Not-for Profit User from the Pluripotent Cells which retain the ability to self-replicate, retain ability to differentiate into cell types from all three germ layers and remain in an undifferentiated state whether or not said cells are genetically modified and further including cell lines cloned from such cells so long as the cells retain the ability to self-replicate, retain ability to differentiate into cell types from all three germ layers and remain in an undifferentiated state
9. Modification: Cells which are created by the Not-for Profit User through the use of the Pluripotent Cells or Progeny, but which (i) do not differentiate into cell types from all three germ layers and (ii) are in a partially or terminally differentiated state
10. Materials: Project Cells, Pluripotent Cells, Progeny and Modification
11. Commercial Use: any activity by the Not-for Profit User including at least one of the following activities:
	1. use of Materials for manufacturing process of related products distributed and/or sold to a third party including but not limited to culture media and equipment;
	2. use of Materials to provide a service, information or data to a third party for Financial Gain; or
	3. sale, lease, distribution or transfer of Materials to third parties for Financial Gain.

For clarity, “Financial Gain” means any financial benefit or gain earned by the Not-for Profit User which consideration or revenue of a transaction exceeds its Cost of operating the transaction, and “Cost” means a direct material cost of Pluripotent Cells, Progeny or Modifications to the Not-for Profit User.

1. Drug Screening: any activity using Materials to select chemical compounds, antibodies, proteins, peptides, nucleotides, and others as candidate active ingredients (including leading compounds) of products for humans and animals, which is carried out through the evaluation of bioactivities, pharmacological activities, toxicities, ADME, and so on, and where the products include those for use mainly in therapy, prophylaxis, diagnosis, or in the maintenance or improvement of health conditions, regardless of the number of candidate active ingredients to be tested.

**Not-for Profit User Restrictions**:

1. Not-for Profit User may use Materials for its internal research for academic, educational or other non-commercial purposes, and may transfer Materials to other not-for-profit organizations for non-commercial purposes.
2. Not-for Profit User may carry out Drug Screening using Materials, however, the Not-for Profit User is required to obtain prior written approval of iPS-AJ when the rights of results obtained through the Drug Screening are transferred from the Not-for Profit User to any other party, except for the transfer to other not-for-profit organizations for non-commercial purposes.
3. Not-for Profit User is required to obtain prior written approval of iPS-AJ when it starts Commercial Use of Materials.

1. Not-for Profit User agrees to use Materials in compliance with all applicable statutes and regulations, but not to use Materials for (i) any administration or introduction of Project Cells, Pluripotent Cells, Progeny or Modifications into humans and (ii) any human clinical or veterinary use of Project Cells, Pluripotent Cells, Progeny or Modifications for therapeutic, diagnostic or prophylactic purposes, the use including, but not limited to, clinical applications, cell therapy, transplantation and regenerative medicine
2. The transfer or distribution of Project Cells from MJFF to Not-for Profit User does not mean a grant of license, and no rights are conveyed to the Not-for Profit User whether expressly, by implication, by estoppel or otherwise for any other purpose.
3. For information on taking a license to the patent rights for purposes other than those permitted above, please directly contact with License Division, iPS-AJ.

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