**Alpha-synuclein seed amplification assay (a-syn SAA) 2021 rfa**

APPLICATION INSTRUCTIONS AND CHECKLIST

**GRANT PORTAL INSTRUCTIONS**

All full proposals must be submitted through the [MJFF Grant Portal](https://grants.michaeljfox.org/).

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**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 “Winter 2021 RFA: Alpha-synuclein Seed Amplification Assay Program” and proceed to start your proposal.

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**APPLICATION INSTRUCTIONS**

On the application, you will be prompted to fill out required information. You can click the Save My Work button on the bottom left at any time to save your work to date and return to your application later through the Applications in Progress shortcut on your portal homepage.

### **TEAM STRUCTURE**

A note about the Principal Investigator role: In efforts to streamline administrative processes, MJFF now requires that the Principal Investigator be the primary applicant (i.e. the person who initiates the application and takes primary responsibility for the application), rather than a Co-Principal Investigator or Paid Collaborator, for example. **There should only be one Principal Investigator on the application (the primary applicant).** All application-related correspondence will be sent to the Principal Investigator. As described in the steps below, the Principal Investigator will invite other team members to collaborate on the proposal, and upon accepting the invitation those individuals will have access to the application.

Research team member information should be entered in the Research Team Members section on the **Team Information** tab in accordance with the below definitions. You may enter team members with the following roles: Co-Principal Investigator, Paid Collaborator, Unpaid Collaborator, and Consultant. Non-research team members (such as a Grants Manager) do not need to be added to the Research Team Members section.

* The **Principal Investigator** is the primary applicant and the person overseeing the project who has the appropriate level of authority and responsibility to direct the grant. The applicant will auto-populate under Research Team Members with the role of Principal Investigator. **There should only be one Principal Investigator on the application.**
* **Co-Principal Investigators** are other people who have the appropriate level of authority and responsibility to direct the grant and will do so in conjunction with the Principal Investigator.
* **Paid** or **Unpaid** **Collaborators** are other people working on the project who are affiliated with the institution of the Principal Investigator or Co-Principal Investigator(s).
* **Consultants** are people not affiliated with the institution of the Principal Investigator or Co-Principal Investigator(s) who will play a role on the project and receive a fee for their contribution (rather than a portion of their salary).

**We require that every research team member listed with the role of Co-Principal Investigator, Paid Collaborator, and Unpaid Collaborator be invited to collaborate on the application at the full proposal stage.**

### **INVITATIONS TO COLLABORATE**

At the full proposal stage, all team members listed in roles of Co-Principal Investigator, Paid Collaborator, and Unpaid Collaborator in the Research Team Members section on the Team Information tab must be invited by the Principal Investigator to collaborate on the proposal. Before you can submit your proposal, these team members must not only be invited but must also accept the invitation, create a contact profile in the Grant Portal if they do not already have an account, and then complete two activities related to the invitation.

For detailed instructions on how to invite team members, please see the [Inviting Team Members to Collaborate in the Grant Portal](https://michaeljfox.box.com/s/s7c8qim3ke19a9wmiqymoyomcvgoz1sj) document.

Two important things to note regarding invitations:

1. Inviting team members can be done in stages, so you can invite some team members now and then later go back and invite more team members. However, please note that **you** **do not need to delete already invited team members if sending invitations in stages—the system will only send invitations to newly added team members. Deleting team members that have already been invited will cause their activities to disappear on the invitations grid.**
2. Please also note that once you invite team members, **these invitations cannot be deleted even if you delete the invitation from the Inviting Project Team Members window**, as the invitation activities have already been created in their portal and must be completed in order for you to submit the application. Please plan to ensure that invited team members have enough time to complete their activities before the application is due.

**Please note that the application cannot be** **submitted** unless every team member under the Research Team Members section with the role of Co-Principal Investigator, Paid Collaborator, and Unpaid Collaborator is invited to collaborate, accepts the invitation, and completes the required activities upon accepting the invitation (Collaboration/Institutional Approval and Biosketch). Once invited, these team members can also access the proposal through the Applications in Progress shortcut on their portal homepage.

Inviting Consultants to collaborate on the proposal is optional. You may also invite other non-research team members to collaborate (such as a Grants Manager). If applicable, when you enter these non-research team members on the Inviting Project Team Members window, select the role of Contributor. If invited, Contributors do not have to complete the required activities but can still access the proposal through the Applications in Progress shortcut on their portal homepage.

The activities created for invited research team members will be described under Personnel Requirements in the next section.

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| --- | --- | --- | --- | --- | --- |
| **Summary of Invitation Requirements** | | | | | |
| **Role** | **Listed in Research Team Members section** | **Invitation?** | **Invited As** | **Must Complete Biosketch Activity and Acknowledgement of Collaboration/Institutional Approval Activity** | **Can Access Proposal if Invited** |
| Co-Principal Investigator | Yes | Required | Co-Principal Investigator | Yes | Yes |
| Paid Collaborator | Yes | Required | Paid Collaborator | Yes | Yes |
| Unpaid Collaborator | Yes | Required | Unpaid Collaborator | Yes | Yes |
| Consultant | Yes | Not Required | Contributor | No | Yes |
| Others (Grants Manager, Lab Techs, students, Administrative Assistant, etc.) | No | Not Required | Contributor | No | Yes |

### **SUMMARY OF APPLICATION REQUIREMENTS**

*General Application Requirements (one per application)*

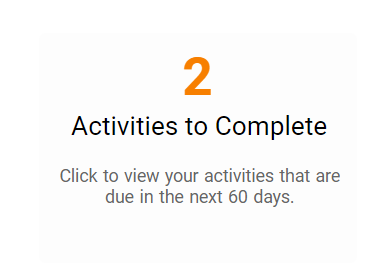
* Project Proposal Template: Combine the following bulleted sections as **one** PDF document and upload in the **Project Proposal Template** tab of the online application.
  + Scientific Narrative *(required)*
  + Budget Narrative *(required)*
  + Team Narrative (*required*)
  + Supporting Materials *(recommended)*
  + Project timeline and milestones *(required)*
* Biosample Request Forms: To request biospecimens download, complete, and upload the form in the Other Attachments field on the **Project Proposal Template** tab. The form template can be found near the top of the application under **Documents**.
* Budget Template: Download the budget template on the **Attachments** tab. Complete it and upload as an Excel spreadsheet to the **Attachments** tab of the online application. For detailed instructions on completing the budget template, along with information on allowable vs. unallowable costs and our indirect policy, refer to the [MJFF Team and Budget Guidelines](https://michaeljfox.box.com/s/cao0x68qu0uoaqn543tmcckslkrwda3s).
* Lay Abstract: Download the appropriate lay abstract template on the **Attachments** tab, complete, and upload as a Word document to the **Attachments** tab of the online application. Only one lay abstract is needed per proposal.
* Ethical Approval Letters: If currently available (and applicable), upload to the **Attachments** tab. If research is exempted from formal ethics review, provide an official document confirming exemption. **Note:** Ethical approval is not necessary at the application stage, but if awarded, please note that NO payments will be made until these approval documents have been received.
* Letter of Intent from Drug Suppliers: If applicable, upload to the **Attachments** tab a letter of support from the company supplying and packaging your drug product.
* Copies of Relevant FDA Meeting Minutes or May Proceed Letter: If your project requires an Investigational New Drug (IND) application, upload any associated correspondence or meeting minutes from the regulatory authorities to the **Attachments** tab.

*Collaborating Institution Requirements*

* Bank Letter: This is required for each collaborating institution that will receive funds directly from MJFF. Obtain a letter from your bank, **on bank letterhead**, clearly stating your institution name and account details, which may include (but are not limited to) account name, account number, and ABA routing number or Swift code. Bank letters must be in English. If a bank letter in English is not available, provide a notarized cover sheet to the non-English bank letter in which you translate the bank details. Upload to the **Attachments** tab (multiple documents should be uploaded if appropriate).
* W8 or W9: This is required for each collaborating institution that will receive funds directly through MJFF. According to the Internal Revenue Service (IRS) regulations, we are required to issue 1099 forms. To accurately prepare these forms, we require a W9 for each U.S.-based institution and a W8 for each non-U.S.-based institution. Upload these to the **Attachments** tab (multiple documents should be uploaded if appropriate).
* Financial Documents: For any for-profit collaborating institution, upload as separate documents to the **Attachments** tab:
  + Most recent audited statement such as income statement and balance sheet.
  + Business plan summary: Include an abstract of your company’s overall business plan and how it relates to the proposed research plan.
  + Management and ownership summary: List your company’s officers and company shareholders with ownership greater than 10%. Include a short biography (1-page maximum) for each listed individual.
  + Patent and license information for all technologies relevant to the proposed research plan: Explain any limitations or payment requirements that could impact the use of the research going forward.
  + Company contribution to proposed project: Include an abstract of your company’s contributions to the research project including financial and non-financial resources.

*Personnel Requirements*

When Co-Principal Investigators, Paid Collaborators, and Unpaid Collaborators are invited to collaborate on the proposal, they will be required to complete two activities, located under the Activities to Complete shortcut on their Grant Portal homepage.



Collaboration and Institutional Approval: First is a Collaboration and Institutional Approval activity. 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. Only one team member per institution will need to upload the institutional approval. The Principal Investigator’s institutional approval should be uploaded on the **Attachments** tab of the application and this document is required for the Principal Investigator, so if any invited team members also belong to the Principal Investigator’s institution they need not upload a separate institutional approval to their activity. 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.

* + **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: The second activity is a Biosketch activity. A biosketch is required for *every* research team member listed under Research Team Members. Team members with the roles Co-Principal Investigator, Paid Collaborator, or Unpaid Collaborator can upload their biosketch upon logging into the Grant Portal by clicking on Activities to Complete and opening the biosketch activity. The Principal Investigator can upload their biosketch directly on the Research Team Members section of the **Team Information** tab. Since it is not a requirement to invite Consultants to collaborate on the application, the Principal Investigator or other invited team members can upload the biosketches of any Consultants on their behalf on the **Team Information** tab or within the Biosketch activity. NIH format is preferred for biosketches, but alternative formats are acceptable for team members with non-research backgrounds. A non-researcher biosketch should include name, affiliation, and relevant experience. Biosketches should be limited to 5 pages regardless of format.

*Please Note*

* 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, **click the Submit button 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, contact MJFF at** [grants@michaeljfox.org](mailto:grants@michaeljfox.org) **to check on the status of your proposal.**

APPLICATION INFORMATION

PRINCIPAL INVESTIGATORClick here to enter text.

INSTITUTIONClick here to enter text.

PROJECT TITLEClick here to enter text.

APPLICATION TRACK

Please select one or more focus areas that your application addresses:

**Track 1:**

Development of a scaled-up, reliable and rapidalpha-synuclein (a-syn)seed amplification assay (SAA)as a Research Use Only (RUO) In Vitro Diagnostic (IVD) with validation package and an eventual goal of a Point of Care IVD integrable into clinical IVD integrable into clinical trials and potentially for commercial use. To achieve this (in CSF or other tissues/fluids), the Michael J Fox Foundation (MJFF) aims to identify partner organizations with technical capabilities, resources and strategic alignment to provide a scaled-up a-syn SAA for clinical studies. Successful applicants should plan to work closely with investigator(s) who originated the assay(s) and test and validate assay performance.

**Track 2:**

Modification of a-syn SAAs from the current binary (positive/negative) readouts to an analytically validated quantitative assay format that measures a-syn seed concentrations.

**Track 3:**

Identification of the most sensitive, specific, reproducible, stage-appropriate biomatrix through comparative assessment of an a-Syn SAA on a variety of biomatrices (e.g., CSF, skin, nasal mucosa, submandibular gland, etc.).

☐ Check this box if you are requesting biospecimens from MJFF collections via this application. **If requesting biospecimens, you must complete the Biosample Request Form** (instructions on applicability are listed under the General Application Requirements section above) and upload it in the Other Attachments field on the portal application.

General FORMATTING GUIDELINES

* Use letter-size pages (8.5 x 11 inches)
* Minimum of one-inch margins on the top, bottom, and both sides of every page
* 11-point font
* You may delete the instructional text to save space and enter your content directly underneath the blue narrative headings, unless specified otherwise.

Scientific narrative

**REQUIRED CONTENT** – See instructional text under each narrative heading and enter your text directly on this template. You may delete instructional text, but all narrative headings must be completed for review.

5-page limit total, to include:

* Project Goal
* Study Plan
* Project Timeline and Milestones

If recruiting participants for your study, please include the following sections, limit 4 additional pages

* Clinical Narrative
* Recruitment Plan

**PROJECT GOAL**

Provide a concise (250 words or less) statement describing the objectives of your proposed project and how they will address current unmet needs/challenges in the seed aggregation assay (SAA) field.

### **STUDY PLAN**

* Summary: Provide a clear and detailed summary of the proposed work including goal(s) and specific hypotheses.
* Background & Preliminary data: Please provide relevant background and preliminary data (including assay validation data and performance characterization) of your SAA assay. Do not include background on Parkinson’s disease.
* Methods & Study Design: Describe the study design and specific plan for the project. Include sufficient detail of study methods and resources (e.g., assay, technology, a-syn seed reagents, patient samples, statistical analysis, software etc.) to ensure that scientific reviewers can evaluate your strategy without referring to extensive external sources of information. Indicate study resources that will be needed to complete the study and whether these resources are available to you. Discuss potential outcomes and challenges. Include information on the path for wide-scale use/commercialization, including any relevant intellectual property considerations (relevant for Goal #1 only).
* Sample Resource Overview: Provide an overview of the samples needed to complete this work (what matrix, what diagnostic group, etc. and associated rationale). Please note that MJFF biosamples may be requested, but strong applications will include clear justification for why a particular cohort is proposed and inclusion of collaborators with biosample access into your team.
* Sample Size Calculation: Please include power calculations to justify proposed sample size for the study as needed.
* Rationale & Impact: Indicate how the proposed project will facilitate integration of a-syn SAA into clinical trials to facilitate therapeutic development. Explain how the outcomes of this project will address one of the key goals of this initiative.

### **PROJECT TIMELINE AND MILESTONES**

### Funds awarded by MJFF are to be used solely for the project outlined in your proposal and are conditioned on your meeting certain milestones and deliverables. A table and/or Gantt chart is recommended.

### Provide:

1. Proposed timeline of key deliverables, which should include completed durable resources or project outcomes such as completion of biosamples collection (if applicable), assay optimization work, validation efforts, data analysis, manuscript delivery, etc.
2. Summary of concise, actionable milestones toward these key deliverables and their estimated completion timeline demarcated in separate 3-6 month milestone periods. Timeline for key deliverables should also be indicated in this framework. These milestones could include steps toward sample collection, completion of individual aims, assay or algorithm development, analysis, etc.

### Indicate any relevant go/no-go decision points and rationale.

**CLINICAL NARRATIVE**  
COMPLETE AS APPLICABLE & ONLY IF THE STUDY INVOLVES HUMAN SUBJECT RECRUITMENT

* Leadership of Trial: Explain the proposed leadership of the study, including individuals responsible for management of the trial and administrative oversight.
* Communication Plan: Provide detail on how the Principal Investigator will communicate with study site(s) and investigators, how often this communication will occur, and which methods will be employed. Explain how data or study findings will be shared back with study participants, and briefly outline the framework for these communications.
* Data Safety Monitoring Plan (DSMP), if applicable: Provide plan and include specific roles of relevant participants, i.e., separate advisory committee, etc.
* Trial Governance: Include an explanation of the governance structure for the trial – who will be the study sponsor and who/what process will be used for making decisions.
* Transition Plan: Briefly describe how results of the current trial will inform next steps, including potential future studies. Indicate what additional funding sources would be pursued to continue further studies (e.g., government support, industry partnerships, other foundations.)
* Return of Value: What is the return of value to participants? Return of value may include renumeration, individualized test results, additional health monitoring, newsletters, and/or other benefits the targeted community(ies) finds of value Indicate how the community partners will be involved in next steps and how participants will be notified of the research findings. For further guidance and examples, see <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05046>.

**RECRUITMENT PLAN**

COMPLETE AS APPLICABLE & ONLY IF THE STUDY INVOLVES HUMAN SUBJECT RECRUITMENT

Provide an outline of your engagement, recruitment and retention plan. Within your plan, please consider the following questions:

* Timeline: What is your expected engagement and recruitment timeline?
* Activities: What specific activities are planned for each of the engagement, recruitment and retention phases of your study?
* Marketing Communications: What materials have you developed, or do you anticipate developing, to assist in the engagement, recruitment and retention of study patients? Which languages will these materials be available in?
* Personnel and Representative Research: Who will be responsible for each of the engagement and recruitment deliverables? Within each deliverable what specific activities will be employed? How will this structure ensure you will have representative recruitment?
* Sampling Frame: Please identify a sampling frame. That is, within a given catchment area of potential research participants at given sites.
* Resources and Experience for Equitable Research Representation: What specific resources and experience do your sites have to carry out study procedures and identify a representative cohort of study participants?
* Anticipated Challenges: What challenges around engagement, recruitment, and retention might you anticipate, and what contingency plans have you developed to overcome potential hurdles?
* Anticipated Competition: How much competition do you anticipate for participants with other studies at identified study sites?

Please refer to <https://www.michaeljfox.org/study-recruitment> when developing your engagement, recruitment and retention plan. You may include a line item in your budget for engagement, recruitment and retention activities – please include justification for these in the Budget Justification section.

**LITERATURE CITATIONS**

Literature Citations (no more than 2 pages). You may use number formatting to reduce word count if necessary.

budget narrative

The budget will be uploaded as an Excel spreadsheet on the Attachments tab of the online application, where the budget template can also be downloaded. Please ensure you are downloading the template from the Attachments tab so that you are using the most up-to-date version.

**BUDGET JUSTIFICATION**

Provide a brief description of the roles and responsibilities of each Key Personnel on the project. Provide justification of key budget items, specifying their relevance to the project (for example, recruitment and retention costs, etc.).

**OTHER FUNDING SOURCES**

This is required for the Principal Investigator(s). Include both current and pending funding sources. 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. State whether there is scientific overlap with the current application, and, where there is overlap, explain. If an individual has no other funding (current or pending), a statement should be included to specify this.

Team narrative

Applicants are encouraged to form cross-organizational collaborative teams. Provide an overview of your team, including description of what each institution/organization uniquely brings to the table (unique technical knowledge, path towards commercialization, substrate production, advanced analytics, biosamples, etc.) to accomplish the stated goals. Explain how you will leverage the specific expertise and/or institutional resources to address key SAA unmet needs/challenges. Explain why the applicant(s) are best suited to conduct the proposed studies.

Supporting materials - OPTIONAL

**FIGURES AND/OR PHOTOGRAPHS**

You may insert one additional page of figures, photographs or other supporting data.

**RELEVANT ARTICLES**

You may insert highly relevant articles referenced in the scientific narrative that are published or “in press” at the time of application submission.