PI:

Institution:

Re:

**Deborah W. Brooks**

*Co-Founder &*

*Chief Executive Officer*

**Michael J. Fox**

*Founder*

**Todd Sherer, PhD**

*Executive Vice President,*

*Research Strategy*

***Board of Directors***

**Skip Irving**

*Chairman*

**Jeff Keefer**

*Vice Chairman*

Holly S. Andersen, MD

Bonnie M. Bandeen

Glenn Batchelder

Susan Bilotta

Mark Booth

Jon Brooks

Barry J. Cohen

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John S. Daly

Donny Deutsch

David Einhorn

Karen Finerman

Lee Fixel

Nelle Fortenberry

Akbar Gbajabiamila

Willie Geist

David Glickman

Mark L. Hart III

Anne M. Holloway

Melanie Bolch Isbill

Edward Kalikow

Alex Krys

Amar Kuchinad

Marc S. Lipschultz

Barry Malkin

Colin R. Masson

Ofer Nemirovsky

Andrew J. O’Brien

Douglas I. Ostrover

Lisa A. Piazza, MD

Tracy Pollan

Jack F. Quinn

Ryan Reynolds

Hartley T. Richardson

Frederick E. Rowe

Lily Safra

Carolyn Schenker

Curtis Schenker

Richard J. Schnall

Woody Shackleton

Anne-Cecilie Engell Speyer

George Stephanopoulos

Bonnie Strauss

Rick Tigner

Fred G. Weiss

Sonny Whelen

Peter Zaffino

***Founders’ Council***

Lonnie and Muhammad Ali

Steven A. Cohen

Albert B. Glickman

John Griffin

Andrew S. Grove

David Golub

Katie Hood

Jeffrey Katzenberg

Morton M. Kondracke

Edwin A. Levy

Nora McAniff

Donna Shalala, PhD

Project Title:

Grant ID:

Dear ***[PI Name]***,

On behalf of the Board of Directors of The Michael J. Fox Foundation for Parkinson’s Research (MJFF), it is a pleasure to make this award in the amount of ***[$ amount]*** to conduct the research described in your proposal, [***project title]***

This **XX**-month award is offered based on your representation that you have no other grants or funding for the same work funded by this award. Please contact MJFF immediately if at any time during this period additional third-party funding is sought or received for the project, or if circumstances arise prohibiting completion of your project on schedule. The terms and conditions governing this award are detailed in the attached agreement. Please read it carefully and contact us with any questions.

To accept this award, please sign the enclosed agreement (including appropriate institutional sign-off). We ask that you return a signed agreement through the MJFF Grant Portal no later than ***[date]*** If you do not wish to accept funding, please notify MJFF as soon as possible.

The Michael J. Fox Foundation for Parkinson’s Research is enthusiastic about supporting your research and wishes you utmost success with this project and all your pursuits. Congratulations!

Sincerely,

Sohini Chowdhury

Deputy CEO

**The Michael J. Fox Foundation for Parkinson’s Research**

***Award Terms and Conditions***

**Principal Investigator(s):**

The Michael J. Fox Foundation for Parkinson’s Research (“MJFF”) is pleased to make you this award (the “Award”) to support the work described in your application, ***[project title]*** (the “Project”). In accepting this Award, you and your institution (collectively, “You” or “you” or “Grantee(s)”) agree to the following terms and conditions in this Agreement.

1. *Sources of Funds*

The Award is made with the understanding that the Project currently has no additional sources of funding for the work set forth in the milestones (see Appendix B). You agree that you will neither solicit nor accept additional funding for this Project without prior written notice to MJFF. If there is overlap between the Award and another grant made to you by a third party for the same work funded by this Award, MJFF will renegotiate the budget of the Award with you (a copy of the final budget is provided with this Agreement as Appendix A) and reserves the right to provide less funding than identified in the Award or obtain a refund from you, so that funding from the Award does not overlap with another grant. If you receive additional funding for the Project without MJFF’s advance written consent, MJFF reserves the right to withhold funding and require repayment of the Award if MJFF is not satisfied, in its reasonable discretion, that the additional funding is for incremental research activity which does not overlap with the Award or conflict with your ability to perform the Project.

1. *Use of Funds*
   1. Funds awarded by MJFF are to be used solely for the Project. Satisfaction of the administrative requirements set forth in this Agreement, including without limitation timely delivery of expense and progress reports, your participation in MJFF sponsored meetings at which your progress will be assessed and the other administrative requirements set forth in Sections 7 et seq., is required. MJFF assessments are based on review of your progress at regular intervals, determination of the quality of the scientific research performed, and its continued high relevance to Parkinson’s disease (“MJFF Assessment Criteria”).
   2. MJFF agrees to pay all direct costs for this Project set forth in the budget at Appendix A, for a total of ***[$ amount]***. This total also includes an allocation for indirect costs with a limit of up to 15% applied to the sum of all direct costs as set forth in Appendix A. Any unused funds at the end of the Award period, as detailed in a final expense report, must be returned to MJFF within one month from the submission of the expense report. You shall maintain complete and accurate books, records and accounts that, in reasonable detail, fairly reflect the use of the Award. MJFF shall have the right to review and audit such books, records and accounts at a mutually convenient time upon prior written notice to you.
   3. The Award is to be used as budgeted and reflected in the milestones. Any alterations, amendments, or changes in the specific goals or budget of the Project will require the review and pre-approval of MJFF. Examples of such alterations, amendments or changes include (but are not limited to): transfer of a Principal Investigator (“PI”) from one institution to another, adding or deleting a specific Project goal, material budget reallocation, or modification of the timeline, workload allocations or milestones. As used in this Agreement, “material budget reallocation” means reallocation of Award funds equal to 5% or more of the Award amount. Please note that MJFF funds shall not be used for travel or equipment costs not approved in the budget as awarded (see Appendix A).
   4. If you request an alteration, amendment or change, you must submit a written request for approval detailing the request and associated rationale in advance to the staff member assigned to monitor your Project. Failure to obtain prior approval for any changes in work timeline, milestones or budget may result in revocation of funding in whole or in part. You agree that funds expended by you either not in accordance with the approved Project or prior to pre-approval of any material change are both (i) recoverable by, and subject to restitution by you to, MJFF and (ii) may be cause for immediate termination of funding by MJFF.
   5. The Award is made with the understanding and assumption by MJFF that there is not currently nor will there be any use of any part of this Award, or credible allegation that any part of the Award is or will be utilized, for a research project, involving: (a) making up data or results and recording or reporting them; or (b) manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record (the foregoing, “Research Misconduct”). You hereby agree that you: (i) will promptly report in writing to MJFF any Research Misconduct; and (ii) reasonably cooperate to appropriately address or correct any Research Misconduct. MJFF will treat any notices to it of actual or alleged Research Misconduct as Confidential Information of Institution pursuant to Section 5 of this Agreement. Any failure on your part to abide by any term or condition of this Section 2.5 may cause MJFF to demand return of the Award amount, in which case you hereby agree that you will promptly do so. This Section 2.5 survives expiration or termination of this Award.
2. *Grant Timeline*
   1. MJFF expects that your Project will be completed according to the agreed timeline attached at Appendix B.
   2. Complete items detailed in the Planning Phase Checklist (“Checklist”), which is attached at Appendix C. Payment for costs other than administrative support, as set forth in Appendix A, will not be issued without MJFF approval signatures indicating acknowledgment that all Checklist items have been satisfied. You will be required to complete all items on the Checklist, including, but not limited to, posting trials and updating clinical site status on the Fox Trial Finder Website and providing written proof of IRB approval.
   3. At the first month following the start of subject recruitment , you shall notify MJFF (i) of the rate of recruitment and whether subjects have been recruited according to the goal(s) set forth in Appendix B; and, (ii) whether all personnel involved in the Project (including technicians and postdoctoral fellows) are hired and actively engaged in Project activities. Failure to meet these requirements will result in withholding of further payment.
   4. MJFF will require monthly recruitment updates. If you do not have a monthly recruitment template, MJFF will provide you with a standard template upon request. These updates will be assessed according to milestones set forth in Appendix B. Monthly recruitment updates must be submitted within 10 days after the 1st day of each calendar month. Recruitment updates should be emailed to submitted via the MJFF Grant Portal.
   5. Participate in regularly scheduled assessment meetings and/or teleconferences. Failure to participate in these assessments and to demonstrate satisfactory progress may result in withholding of future payments.
3. The first assessment will be held at the three-month mark of your Award by teleconference to review initial progress.
4. Following the initial teleconference, progress assessments will be scheduled at mutually agreeable time-points throughout the course of the Project.
5. An in-person assessment meeting will be held at the completion of the Award term. The individual grantee is required to attend the assessment meeting in person, unless otherwise informed by MJFF.
   1. Complete progress and expense reports detailing your progress against milestones and your associated expenditures. These reports will be due at the completion of the Project. When appropriate, additional reports may be requested before other assessment meetings and teleconferences. Templates will be provided to you to facilitate this reporting. These reports will be reviewed by MJFF against the MJFF Assessment Criteria; MJFF may thereafter provide you with suggestions, critique, and feedback.
   2. Participate openly in discussions regarding the Project with MJFF’s scientific and research staff, and advisors.
   3. MJFF shall have the right to participate as a non-voting member in any advisory, steering or other major committee discussions related to Project. You shall include MJFF on communications as calls and meetings are scheduled.
   4. MJFF recognizes that the failure to meet milestones (set forth at Appendix B), furnish scheduled deliverables, or satisfactorily meet measurable MJFF Assessment Criteria shall not serve as bases for termination of funding by MJFF. However, your failure to satisfy the administrative requirements set forth in this Agreement, including without limitation your failure to cooperate with MJFF in its administration of this Award as set forth in this Agreement; your failure to use reasonable efforts to perform; or, a reasonable determination by MJFF that the Project scientifically fails because no meaningful research result can thereafter be achieved, may serve as bases for termination of funding by MJFF.

In the event of early termination of the Project, you shall terminate the trial in an orderly and prompt manner in accordance with applicable law to the extent medically permissible, including, but not limited to, providing any required follow-up treatment with respect to previously enrolled subjects. Upon termination, you shall be compensated for all completed study procedures per the completed case report forms, and MJFF shall have access to your books, records and accounts to determine whether such compensation shall be due to you.

* 1. If at any time circumstances arise that prohibit completion of the Project on schedule, you are required to notify MJFF immediately. MJFF will consider granting ONE no-cost extension per project on a case by case basis. To apply for a no-cost extension, submit a request through the MJFF Grant Portal.

1. *Payment Schedule*
   1. MJFF intends to pay the Award according to the following installment schedule:

|  |  |  |  |
| --- | --- | --- | --- |
|  | **MONTH YEAR** | **MONTH YEAR** | **TOTAL** |
| ***[Institution Name]*** |  |  |  |

* 1. MJFF reserves the right to change this schedule if necessary and will notify you and/or your administrator in writing in that event.
  2. Payments for the Project are subject to Grantee’s satisfaction of the administrative requirements of this Agreement, including without limitation continued provision of required progress reports, participation in scheduled teleconferences and assessment meetings with MJFF and the other administrative requirements set forth in Sections 7 *et seq.*, and Grantee’s reasonable efforts in meeting milestones, furnishing scheduled deliverables and satisfying measurable MJFF Assessment Criteria.

1. *Confidential Information* 
   1. MJFF treats all Grantee pre-proposals, applications, research projects, associated research information, underlying data, results, Project Data (defined below) and Project Intellectual Property (defined below) (collectively, the “Confidential Information”) as confidential, using no less than reasonable care in protecting the Confidential Information from disclosure to third parties who do not participate in the application or Award review and assessment processes. All Confidential Information will be used by MJFF staff or third party reviewers under a duty to maintain and not use or disclose Confidential Information except as set forth in this Agreement only for the purpose of reviews and assessments, and will be shared only in accordance with its Sharing Policy (see Section 7 below). Notwithstanding the foregoing, these obligations governing the disclosure and use of Confidential Information do not apply to information that:
2. was generally known to the public at the time of disclosure through no unlawful or unauthorized act or omission or violation of this Agreement;
3. was independently developed without use of or reference to any Confidential Information of Grantee; or
4. was disclosed by a third party who has the right to make such disclosure.
   1. Provided that subsections (a)-(c) above do not become applicable, if MJFF is asked to produce any Confidential Information pursuant to a legal or governmental proceeding, MJFF shall give the Grantee or other owner of such Confidential Information (the “Discloser”) as much prior notice of such request as is reasonably practicable under the circumstances and shall use its reasonable efforts to assist the Discloser of such Confidential Information in defending Discloser’s rights (at Discloser’s cost), including objecting to such request, obtaining confidential treatment for Confidential Information, disclosing only that portion of the Confidential Information responsive to a judicial or governmental order, and providing Discloser with any copies of Confidential Information so disclosed if permitted by law to do so.
5. *Project Data and Project Intellectual Property*
   1. The Grantees shall own all rights, title and interest in: (a) the completed case report forms, any other information generated by Grantees during performance of the Project, including clinical and other information such as summaries, analyses and compilations thereof (“Project Data”); and (b) any inventions and discoveries, conceived, created, developed or reduced to practice by employees, students and/or other researchers of a Grantee in the performance of the Project, and any patent, trade secret or other intellectual property rights with respect to the foregoing (“Project Intellectual Property”).
   2. With each monthly progress report, Grantees agree to provide MJFF, in a format prescribed by MJFF, summary data regarding recruitment information and demographic information to assess progress against each milestone (“Project Milestone Data”), which may be shared by MJFF as set forth in Section 7.
   3. With the final progress report, you agree to provide MJFF, in a format prescribed by MJFF, a written report of the results of the Project (“Final Report”) and reasonable access to all Project Data, including one or all of the following: raw data and measurements, the final clinical study report, final clinical datasets and listings that have been de-identified in accordance with the Health Information Portability and Accountability Act of 1996 and its implementing regulations. Except for the Final Report, which shall be Project Milestone Data, and de-identified raw clinical data associated with the Project (“De-identified Data”), which Project Milestone Data and De-identified Data may be used and disclosed by MJFF as set forth in Section 7.2, MJFF, its grant assessors, and MJFF consultants will use such information received pursuant to this Section 6.3 only internally to make future funding decisions.
   4. MJFF shall have the right to audit and review detailed Project Data at Grantee’s facility upon reasonable request and at mutually agreeable times. Any information obtained by MJFF through any such audit shall be treated by MJFF consistent with Sections 5-7 of this Agreement.
6. *Sharing Policy*
   1. As MJFF is a public charity, research conducted with funds from MJFF (“Research”) must be conducted in the public interest. MJFF acknowledges that discoveries and related regulatory approvals made by researchers under its funding are the property of those conducting and responsible for the Research and that unless otherwise agreed to by the parties, such researchers shall have the first opportunity to exploit the Research commercially or otherwise.
   2. Notwithstanding the foregoing, you agree that MJFF:
7. may, after reasonable consultation which will not be unreasonably denied, conditioned or delayed by you, publicly release a summary of findings of the Research 90 or more days after expiration of the Award;
8. may retain the Project Milestone Data and, 90 or more days after expiration or termination of the Award, make it available to MJFF employees, consultants, grant recipients and other researchers affiliated with or gaining access through MJFF via secure medium channels to advance scientific discovery.  This subsection shall not prohibit MJFF from making the Project Milestone Data available before expiration or termination of this Agreement to persons executing MJFF’s Confidential Disclosure Agreement for the purpose of assessing your progress toward achieving the milestones.  If the Project Milestone Data ceases to be Confidential Information as described in subsections (a)-(c) of MJFF’s confidentiality policy (see Section 5), then these restrictions on dissemination shall not apply; and,
9. may, after the earlier of (i) publication of the research findings as described below in Section 10 of this Agreement, or (ii) one year after expiration or termination of the Award, disclose the Project Milestone Data and De-identified Data through a publicly available database maintained or designated by MJFF.
10. Notwithstanding the periods set forth in subsections (a) - (c) above, MJFF will consider a request by you to delay the availability of Project Data, a summary of the research, and/or a summary of the results in order for you to complete any necessary intellectual property filings.
11. *Liability and Insurance*

You acknowledge that MJFF has not participated in the design of the Project and will not participate in the conduct of the Project. MJFF neither participates in the preparation of the clinical trial protocol nor in the treatment or study of patients. You assume any and all risks and responsibilities associated with the conduct of the Project. MJFF shall in no way be accountable for any Project safety issues.

Except as provided in the paragraph following this one, to the maximum extent permitted by law you hereby agree to release and hold MJFF, including its directors, trustees, officers, employees, agents and consultants, harmless from and against any demands, claims or judgments, and all associated costs, expenses, including, without limitation, reasonable attorneys’ fees, and damages, directly or indirectly arising out of the Project, including, without limitation, any patient injury or death (collectively, “Liability”). If permitted by law, you shall have the obligation at MJFF’s election to assume its defense and pay any third-party damages.

For any Liability arising out of MJFF’s (a) negligent or willful misconduct in performing its obligations under this Agreement, or (b) MJFF’s use or sharing of Project Data or Project Intellectual Property, as those terms are defined herein, MJFF shall release and hold you harmless.

You shall maintain a reasonable level of professional and general liability insurance sufficient to cover the risks associated with the Project.

1. *Use of MJFF Brand*

You agree to abide by the following policy regarding use of MJFF’s name, logo, marks, trade dress, image, and likeness of Michael J. Fox, its founder (collectively, the “MJFF Brand”). MJFF prohibits any use of the MJFF Brand in any publicity efforts, notices, releases, statements or publications without its prior written approval. Any use of the MJFF Brand including, without limitation, the name/image/likeness of Michael J. Fox shall be submitted in advance to MJFF for approval. Failure by MJFF to approve any proposed use of the Brand within five (5) business days of its receipt of any request for approval of a proposed use shall be deemed by you to be non-approval of the proposed use. You acknowledge that these terms are reasonable precautions to protect the MJFF Brand and its goodwill, both of which are extremely valuable assets of MJFF. Any goodwill resulting from an approved use of the MJFF Brand by you shall inure solely and exclusively to MJFF.

1. *Publication*
   1. MJFF expects that you shall use all reasonable efforts to publish the research findings of the Project regardless of positive or negative outcome(s) in a forum that is widely available to scientific researchers within one (1) year from the date that the Project concludes (or such longer period as is agreed upon by MJFF in accordance with Section 7.2 (d)). Publication shall be consistent with high standards of scientific excellence and rigor.
   2. Consistent with MJFF philosophy for open sharing of results, you hereby agree that you will adhere to MJFF’s Open Access policy attached to this Agreement as Appendix D or as set forth in http://www.michaeljfox.org/openaccesspolicy. The MJFF Open Access Policy weblink provided here always supersedes information contained in the attached appendix.
   3. In accordance with the National Institutes of Health’s policy on section 42 CFR part 11 of the Public Services Health Act, you agree to publish the results on ClinicalTrials.gov within one (1) year from the date that the project concludes (or such longer period as is agreed upon by MJFF in accordance with Section 7.2 (d)).

1. *Recognition of Funder*

Any publications resulting from this Award shall include acknowledgement of the funding provided by The Michael J. Fox Foundation for Parkinson’s Research and shall reference the Grant ID of the Project. When publications result from work funded under the Award, you are required to update MJFF, even if such publications occur after the expiration of the Award term*.*

1. *Human Subjects and Compliance with Law*
   1. Since the Project involves the participation of human subjects, you shall provide to MJFF proof of approval by each applicable institution’s IRB or other regulatory assurance body in accordance with Section 3.1(a).
   2. You are solely responsible for complying with any and all applicable laws, regulations or guidelines governing the Project.
2. *Good Clinical Practice*
   1. You shall perform the Project in accordance with the Project’s protocol and applicable standards of good clinical practice and good medical practice, including applicable regulatory guidance and all applicable federal, state, and local laws, rules and regulations relating to the conduct of clinical investigations, including, without limitation, the Federal Food, Drug and Cosmetic Act, as amended, and other such laws, rules and regulations pertaining to clinical investigations (including without limitation, 21CFR 50, 54, 56, and 312) and the protection of subject privacy as may be applicable.
   2. You shall promptly notify MJFF of any serious adverse events that are possibly Project-related (“SAE”s). For the avoidance of doubt all communications regarding SAEs shall be treated as Confidential Information of Grantee.
3. *Miscellaneous*
   1. This Agreement, including appendices, constitutes the entire agreement of the parties related to its subject matter and supersedes all prior agreements, oral or written. This Agreement may not be modified, amended or waived except by written agreement of the parties.
   2. This Award does not establish any partnership, joint venture, employment or agency relationship between the parties to this Agreement, and Grantees remain independent contractors of MJFF.
   3. All notices to MJFF required or permitted by this Agreement shall be sent by email to Rachel Passmore, rpassmore@michaeljfox.org, unless MJFF specifies a different person to you in writing.

This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

Accepted and agreed to by:

Sohini Chowdhury

Deputy CEO, MJFF Date

***[PI Name]*** Date

Institutional Approval:

Name:

Title:

Ph:

Email:

Signature: Date

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Appendix A** | | |  | |  |
| Budget Summary | | |  | |  |
|  |  | |  | |  |
|  | **Year 1 Summary** | |  | |  |
|  |  | | **Institution** | | **Year 1 Total** |
|  | Personnel | | $ - | |  |
|  | Consultants | | $ - | |  |
|  | Other Direct Costs | | $ - | |  |
|  | Collaborating Institution Indirect Costs | | $ - | |  |
|  | Subawards | | $ - | |  |
|  | **Year 1 Total** | | $ - | |  |
|  |  | |  | |  |
|  |  | |  | |  |
|  | **Year 2 Summary** | |  | |  |
|  |  | | **Institution** | | **Year 2 Total** |
|  | Personnel | | $ - | |  |
|  | Consultants | | $ - | |  |
|  | Other Direct Costs | | $ - | |  |
|  | Collaborating Institution Indirect Costs | | $ - | |  |
|  | Subawards | | $ - | |  |
|  | **Year 2 Total** | | $ - | |  |
|  |  | |  | |  |
|  |  | |  | |  |
|  | **Year 3 Summary** | |  | |  |
|  |  | | **Institution** | | **Year 3 Total** |
|  | Personnel | | $ - | |  |
|  | Consultants | | $ - | |  |
|  | Other Direct Costs | | $ - | |  |
|  | Collaborating Institution Indirect Costs | | $ - | |  |
|  | Subawards | | $ - | |  |
|  | **Year 3 Total** | | $ - | |  |
|  |  | |  | |  |
|  |  |  | |
|  |  | | Institution | | **Total** |
|  | Year 1 | | $ - | |  |
|  | Year 2 | | $ - | |  |
|  | Year 3 | | $ - | |  |
|  | **Total** | | $ - | |  |
|  |  | |  | |  |
|  | **Total Collaborating Institution Indirect Costs** | |  | |  |
|  | **Grand Total** | |  | |  |

MJFF Award Agreement

Appendix B – Project Milestones

MJFF Grant ID: x-x

**The Michael J. Fox Foundation for Parkinson’s Research**

**Spring 2022 RFA: Parkinson’s Pathway Molecular Data Analysis Program**

***An Edmond J. Safra Core Program for PD Research* (INCLUDE ONLY FOR TV, RRIA, TPP)**

**Principal Investigator(s):**  x-x

**Project Title:** x-x

**Phase:**

**Number of Sites:**

**Number of Subjects:**

**Project Deliverables:**

Describe project deliverables briefly

|  |  |  |
| --- | --- | --- |
| **Milestone #** | **Estimated Timeline** | **Milestone Deliverables** |
| 1 | Months x-x | * Send fully executed project agreement to MJFF |
| 2 | Months x-x | * Complete all items listed in Appendix C: Activation Checklist * Send to MJFF a copy of the fully executed drug supply agreement (if applicable) * Work with MJFF team on the planning of the study kick-off/investigators meeting |
| 3 | Months x-x | * Begin patient screening and recruitment. Goal is X subjects recruited in Y months: X/Y = Z subjects per month * X recruited by end of milestone * Interim Progress Report as needed * Submit monthly recruitment reports to MJFF |
| 4 | Months x-x | * Continue screening and recruitment; X recruited by end of milestone * Interim Progress Report as needed * Submit monthly recruitment reports to MJFF |
| 5 | Months x-x | * Continue screening and recruitment; X recruited by end of milestone * Submit monthly recruitment reports to MJFF * Interim Progress Report as needed * Perform final data analysis |
| 6 | Months x-x | * Submit final reports to MJFF * Communicate the study results and outcomes to study subjects * Prepare manuscript for publication * Notify MJFF of any public announcement of results |

Appendix C: Planning Phase Checklist

MJFF sets deadlines for the completion of Planning Phase activities to ensure the Project begins on schedule. Using the template below, please provide an estimated date for completing each task listed in the Planning Phase of your study, but note each activity must be completed by the MJFF deadline.

The project’s first payment is contingent upon execution of the award agreement. Planning Phase activities begin from execution of the agreement.

|  |  |  |
| --- | --- | --- |
| PLANNING PHASE TASKS | Deadline for Completion | Estimated Date of Completion |
| FINALIZE STUDY DOCUMENTS FOR MJFF APPROVAL BEFORE IRB SUBMISSION (Suggestions) |  |  |
| Study protocol finalized and submitted to MJFF for review | 1 month from receipt of agreement |  |
| Informed consent form finalized and submitted to MJFF for review  (See MJFF informed consent language) | 1 month from receipt of agreement |  |
| Case report form finalized and submitted to MJFF for review  (See Fox Trial Finder effectiveness questions) | 1 month from receipt of agreement |  |
| Recruitment plan & materials developed and sent to MJFF for review | 1 month from receipt of agreement |  |
| OBTAIN IRB APPROVAL | | |
| IRB approval for all sites sent to MJFF | 3 months from receipt of agreement |  |
| REGISTER TRIAL | | |
| Post trial onto Clinicaltrials.gov | 3 months from receipt of agreement |  |
| Post trial onto Fox Trial Finder (FTF) website and notify MJFF Staff:  Rachel Passmore ([rpassmore@michaeljfox.org](mailto:rpassmore@michaeljfox.org) & Kayleigh Greenwood ([kgreenwood@michaeljfox.org](mailto:kgreenwood@michaeljfox.org)) | 3 months from receipt of agreement |  |
| FINALIZE LOGISTICS | | |
| Subcontracts signed (including clinical sites, drug manufacturer, etc., as applicable) | 3 months from receipt of agreement |  |
| Full study team is hired | 3 months from receipt of agreement |  |
| Study drug, supplies, and equipment onsite (as applicable) | 3 months from receipt of agreement |  |

Name, Title: Signature: Date:

**APPENDIX d**

THE MICHAEL J. FOX FOUNDATION

OPEN ACCESS publication POLICY

As The Michael J. Fox Foundation (MJFF) is a public charity, research enabled by funds from MJFF must be conducted in the public interest. We believe that the results of all MJFF-funded research should be promptly published and broadly disseminated to accelerate innovation and foster collaboration toward our shared goal of new treatments and cures for Parkinson’s disease. To that end, we have adopted an open access policy for all published research that is funded, in whole or in part, by the Foundation, including any underlying data sets.

Work with your grant’s Foundation management team to understand the implications of this policy on your individual projects and possible exceptions or exemptions.

Article Accessibility

All articles resulting from MJFF funding must be posted in an open access preprint repository with free, immediate readership rights and thereafter published:

* in a fully open access journal,
* as a fully open access article in a hybrid open access journal,
* or made freely available in the form of an author’s accepted manuscript or equivalent posted to the author’s personal website or institutional archive with free, immediate readership rights.

Data and Code Accessibility

Any data, code and software needed for independent veriﬁcation of research results must be curated and made freely and publicly available in an established, open repository no later than the publication of the ﬁrst paper based on the data or no later than the conclusion of the research project, whichever comes ﬁrst.

Reuse of Underlying Data

All publications shall be published under the Creative Commons Attribution 4.0 Generic License (CC BY 4.0) or an equivalent license. This will permit all users of the publication to copy and redistribute the material in any medium or format and to transform and build upon the material for any purpose (including commercial) without further permission or fees being required. Publication under other, more restrictive licenses (e.g. CC-BY-SA) may be considered on a case-by-case basis.

Cost coverage

MJFF shall pay reasonable fees required by a publisher to effect publication on these terms, which can include costs (e.g., article processing charges) not included in the original grant, for up to one year after grant expiration. For publications that arise directly from MJFF funding but occur more than one year after grant expiration, we may cover open access fees pending budget availability. Requests for open access funding must be made prior to grantee payment of fees to the publisher. Requests for retroactive reimbursement for open access fees may be considered by MJFF on a case-by-case basis.

Request open access coverage funds at [www.michaeljfox.org/openaccessfunds](http://www.michaeljfox.org/openaccessfunds).

COmpliance

The Foundation requires grantees to provide plans for proof-of-policy compliance as a component of interim and ﬁnal reports, with grant disbursement contingent upon conformity. Proof of compliance will also be required of previous grantees seeking to apply for new or supplementary funding. Previous awardees who are non-compliant will not be eligible for additional MJFF funding. Requests for temporary exemptions will require submission of a written justification for non-compliance and may be considered on a case-by-case basis.

Date of Implementation / Legacy Grants

The open access policy described here will take effect on March 2, 2020. All MJFF grants that enter contracting after this date will comply with this policy. We encourage awardees of active MJFF grants contracted prior to March 2, 2020 to comply with this policy as well. Legacy grants that have closed prior to March 2, 2020 should be compliant with all policies in place at the time of their contracting and closure. Legacy grantees seeking funds to cover the cost of open access publication will be considered on a case-by-case basis.