UNITED MITOCHONDRIAL DISEASE FOUNDATION®

UMDF Research Grant Agreement

This Agreement is effective this	day of	, 20XX ("Effective Date"),
between	("Institution	n") and The United Mitochondrial
Disease Foundation ("UMDF").		

WHEREAS, UMDF is a charitable institution organized for the purposes of promoting research for diagnosis, treatments and cures of mitochondrial disorders and providing information and support to affected families (the "Purposes"); and,

WHEREAS, UMDF has established a fund to be used to provide grants for medical and scientific research in furtherance of the Purposes (the "Grant"); and,

WHEREAS, _____, an employee of Institution (the "Principal Investigator") has submitted proposal number _____ (the "Proposal") and attached hereto as *Exhibit A* for a research project entitled ______ dated ______, 20XX (the "Research Project") to be conducted at Institution; and,

WHEREAS, UMDF's Grant Review Committee and/or its Scientific and Medical Advisory Board have evaluated the Proposal and found it to merit the Grant and is therefore willing to provide funding to Institution for the Research Project in accordance with the period and payment schedule shown in *Exhibit B* to this Agreement and under the following general terms and conditions; and,

WHEREAS, the authorizing agent for UMDF for the Grant shall be the UMDF Executive Director and the authorizing agent for Institution for matters related to the Grant shall be ______.

NOW THEREFORE, intending to be legally bound hereby, UMDF and Institution, hereby agree as follows:

1. RESEARCH PROJECT PERIOD.

The Research Project Period shall be as identified in *Exhibit B* to this agreement. The Principal Investigator shall be responsible for monitoring the progress of the Research Project and periodically report on the progress of the Research Project to UMDF. The Principal Investigator must request in writing a no-cost extension from UMDF for any change to the Research Project Period.

Institution shall ensure that the Principal Investigator, and other employees at Institution as directed by the Principal Investigator, shall diligently undertake and carry out the Research Project.

2. CHANGES TO THE RESEARCH PROJECT.

Institution agrees to promptly notify UMDF of any change in the employment status of the Principal Investigator. If the Principal Investigator is unable or unwilling to continue diligent efforts in completing the Research Project. UMDF reserves the right to immediately terminate the Agreement and have returned any unused Grant funds.

The Grant is being provided to Institution by UMDF in reliance on the Proposal and Agreement by Institution and the Principal Investigator to the Progress Period and payment schedules shown in *Exhibit B*. If the Principal Investigator or Institution propose to change the scope of the Research Project, progress schedule, budget or any other term and condition of the Research Project or the Grant, they shall promptly submit for approval to UMDF the details of any such proposed change prior to implementation. UMDF reserves the right to discontinue funding if changes to the Research Project are implemented without prior written consent from UMDF. UMDF shall exercise reasonable discretion with regard to approving proposed changes and shall promptly notify Institution and the Principal Investigator of its decision.

3. CONSIDERATION.

In consideration for the Grant and diligent efforts in performance of the Research Project: (a) UMDF will pay to Institution up to the total amount identified in *Exhibit B*, which is full compensation under this Agreement; and (b) Institution will pay to UMDF the amount specified in Section 4D of this Agreement if Research Project Proceeds are received. To ensure timely payment, all invoices from Institution should be accompanied by UMDF Research Grant Payment Request Form shown in Exhibit C. All funds paid to Institution shall be utilized in accordance with the activities described in the Research Project. During the Research Project Period, Institution shall create and maintain accurate records of expenditures of UMDF funds and retain those records for a minimum of two (2) years after the completion of the Research Project. Institution shall make true and correct copies of the records available to UMDF upon reasonable advance request and at mutually agreeable times during normal business hours. Any Grant funds not spent or committed exclusively for the purposes of the Research Project or not used by the end of the Research Project period shall be promptly returned to UMDF. UMDF also reserves the right to deduct from any future installment of the Grant any surplus that may exist from the previous installment. UMDF shall be entitled to inspect and audit the Institution's records for the Research Project during the Research Project and two (2) years after completion of the Research Project. UMDF will provide a thirty (30) day prior written notice of the audit.

4. INTELLECTUAL PROPERTY AND PROCEEDS

A. <u>Research Project IP</u>. Any inventions, discoveries, patents, patent applications, copyrights (registered or unregistered), copyrightable works, including without limitation software, and/or any other intellectual property recognized by applicable law created, generated, reduced to practice and/or further developed in the course of the Research Project shall be the property of Institution (collectively "Research Project IP").

B. <u>Prosecution and License of Research Project IP</u>. Institution agrees to promptly notify UMDF in writing of any Research Project IP. Institution may, at its discretion and expense, file an application for, and take steps to obtain and maintain the validity of patents for Research Project IP in the United States and any other country and take any other action to protect the Research Project IP, such as copyright or trademark registration. UMDF, in return, shall have a fully paid up, royalty free, non-exclusive, sub-licensable license in and to any Research Project IP for non-commercial scientific research purposes, including, without limitation, use by researchers employed by or affiliated with for-profit entities, provided that no Research Project IP may be sold or incorporated into any product for sale.

C. <u>Abandonment of Research Project IP</u>. If Institution chooses not to apply for and/or not to maintain patent and/or other intellectual property protection for any Research Project IP, Institution shall notify UMDF and give UMDF a first right of refusal to the Research Project IP, upon request by UMDF, hereby agrees to assign any rights it may have in that particular Research Project IP to UMDF, and such protection shall be at UMDF's expense.

D. <u>UMDF's Portion of Proceeds</u>. In the event Institution receives any payment from a third party for Research Project IP ("Project Proceeds"), Institution shall pay to UMDF within sixty (60) days of receiving Project Proceeds a portion of Net Research Project Proceeds ("UMDF's Portion of Proceeds"). Net Project Proceeds shall be determined by subtracting from the Total Project Proceeds: (i) all patent and copyright costs incurred by Institution with respect to Research Project IP; and (ii) any amount under Institution's published policies owed by Institution to the inventor[s] of the Research Project IP. The UMDF's Portion of Proceeds shall be determined by multiplying Net Project Proceeds by a fraction, the numerator of which shall be the UMDF Grant plus twenty percent (20%), which shall be the UMDF overhead amount, and the denominator of which shall be the direct costs incurred by Institution to create and develop the Project IP prior to receipt of Research Project Proceeds plus the Institution overhead amount, which shall be calculated at the rate in effect as of the effective date of this Agreement for Institution with the National Institutes of Health or, if no such rate is in effect, fifty percent (50%).

5. RESEARCH PROJECT BIOSPECIMENS AND DATA.

In the event that human biospecimens and associated data are collected pursuant to the Research Project (collectively, "Resources"), Institution shall notify UMDF. Upon conclusion of the Research Project, UMDF shall have a fully paid up, royalty free, sublicensable license in and to any Resources not required by Institution or the Principal Investigator for further research ("Disused Resources") and, if it so elects to exercise such license, UMDF shall pay for any direct costs associated with transfer of such Disused Resources to UMDF or its designee. Institution shall notify UMDF in advance prior to destruction of any Disused Resources and shall give UMDF the opportunity to, at UMDF's sole discretion and expense, assume control of such Disused Resources. Institution shall ensure that any patient informed consent documents used for the Project permit the foregoing.

6. PUBLICATIONS AND PUBLICITY.

A. <u>Publications</u>. Institution and its employees shall have the right to publish the data and results of the Research Project, provided such publication does not disclose any proprietary or confidential information of UMDF or compromise any potential patent rights arising from Research Project IP. Publications resulting from the Research Project shall prominently acknowledge that UMDF funds contributed to the Research Project. Every publication resulting from the Research Project must state: "Support for this research was generously provided to ______ under grant number______ from the United Mitochondrial Disease Foundation."

Before submitting for publication a manuscript describing the data and/or results of the Research Project, Institution shall forward to UMDF a copy of the manuscript to be submitted and allow UMDF thirty (30) days within which to review references to UMDF and to determine whether any type of intellectual property protection should be sought prior to publication. If UMDF does not respond within thirty (30) days, Institution shall be free to submit the manuscript and publish results in any manner.

Institution agrees to grant UMDF a royalty-free license to reprint publications resulting from the Research Project related to UMDF's mission to promote awareness of progress toward the diagnoses, treatments and cure for mitochondrial disease in a manner consistent with U.S. copyright laws and the rights of the author and publisher.

B. <u>Use of Name.</u> Unless otherwise stated herein, Institution and UMDF agree that their respective names, symbols or marks or the name of their respective trustees, officers, agents and employees will not be published or otherwise used without the express written permission of the other party, which permission shall not be unreasonably withheld or delayed. Notwithstanding the foregoing, UMDF reserves the right to list the name of Institution, the Principal Investigator, a short summary of the Research Project, and summaries of reports submitted under Section 8 of this Agreement in newsletter articles, and other publicity publications in connection with its grant programs. The foregoing shall not include any confidential information or information that would compromise Institution's intellectual property rights with respect to Research Project IP.

7. CONFIDENTIALITY.

A. <u>Proprietary Information</u>. Proprietary Information shall include information that is generally not known to the public and information that is (a) identified as confidential

at the time of disclosure; (b) identified as confidential in writing and provided to the Recipient; or (c) given the circumstances surrounding the disclosure, should be regarded as confidential.

B. A Recipient agrees (a) not to disclose Proprietary Information to any third party including a governmental patent office or other governmental agency; (b) hold the Proprietary Information in confidence using the same care and caution it affords its own Proprietary Information, but no less than a reasonable degree of care; (c) use the Proprietary Information only for the purpose of the Research Project recited herein; (d) reproduce the Proprietary Information only to the extent necessary to perform the Research Project; and (e) restrict disclosure to the Proprietary Information to employees whose duties justify the need to know the Proprietary Information in furtherance of the Research Project and who are advised as to the confidential and proprietary nature of the Proprietary Information and who are required to comply with the confidentiality provisions herein.

C. <u>Exclusions</u>. Any confidentiality obligation shall not apply to information if the information (a) was, now is or subsequently becomes publicly known and/or published through no fault of the receiving party ("Recipient"); (b) can be shown to have been independently developed by employees of the Recipient who have not referenced the Propriety Information; (c) is or was brought to the Recipient's attention by a third party who, to the best of the Recipient's knowledge, has a legal right to do so; (d) was properly known to the Recipient at the time of disclosure to the Recipient as evidenced by prior or contemporaneous written records; or (e) is disclosed by the Recipient with the Disclosing Party's prior written consent.

D. <u>Term of Confidentiality Obligation</u>. The obligations of confidentiality and non-disclosure outlined herein shall survive during the term of the Research Project and for a period of five (5) years after the earlier of termination or completion of the Research Project Period stated in *Exhibit B*.

8. REPORTS.

A. <u>Reports During the Period</u>. During the Research Project Period of this Agreement as stated in *Exhibit B*, the Principal Investigator and/or Institution shall furnish to UMDF, in a form and manner designated by UMDF, on at least an annual basis, a report of the findings and progress of the Research Project. No later than six (6) months after completion of the Research Project Period, the Principal Investigator and/or Institution shall furnish UMDF with a final report of the results of the Research Project.

Upon reasonable request by UMDF, the Principal Investigator and/or Institution shall furnish more frequent reports and updates of the progress of the Research Project and expenditures of the Grant. The Principal Investigator and/or Institution shall otherwise keep UMDF apprised of the progress of the Research Project and provide such other information and data in the form, frequency and manner as reasonably requested by UMDF. During the Research Project Period, and upon at least three (3) days advance notice and at mutually agreeable times during normal business hours, Institution shall permit UMDF or its designated representatives to visit Institution facilities where the Research Project is being conducted.

UMDF will review the reports and, if UMDF wishes, provide comments to the Principal Investigator regarding the adequacy of the report. Upon receipt of UMDF comments, the Principal Investigator has a period not to exceed thirty (30) days to resolve comments and revise the report. UMDF's review and comments on reports are not for the purpose of influencing results of the Research Project or any opinions about the results held by Institution or the Principal Investigator.

All reports required by this Section 8A shall be prepared in the form and manner designated by UMDF. The reports shall account for all expenditures of the Grant during the progress and at the completion of the Research Project. UMDF may withhold installment payments of the Grant for failure to timely submit required reports. UMDF may also condition the grant of any future awards to Institution and/or Principal Investigator upon timely receipt of the reports.

B. <u>Post-Research Project Auditing Regarding Project IP</u>. After the Research Project Period, UMDF reserves the right to audit Institution records related to the Research Project. Such audits shall include a search for: (i) whether Project IP has been further developed during the period since the previous audit or Report; (ii) whether Project IP has been licensed or otherwise transferred to any third party; and (iii) whether Institution has received any revenue in return for licensing or other transfer of the Project IP.

<u>9. TERMINATION</u>. Either party may terminate this Agreement upon thirty (30) days written notice to the other party. In the event this Agreement is terminated, Institution will return to UMDF all unused funds less any non-cancelable costs incurred through the date of termination. Within thirty (30) days of cancellation, the Principal Investigator shall submit a report detailing the outcome or status of the Research Project and expenditures of the Grant on the Research Project up to and including the effective date of termination in the manner described in Section 8A of this Agreement.

<u>10. NO CLINICAL STUDIES</u>. Institution represents and warrants that the Research Project will not include a clinical study. Institution shall promptly notify UMDF if a clinical study subsequently becomes contemplated as part of the Research Project. In that event, the parties agree that they shall negotiate in good faith to develop a separate written agreement or an amendment to this agreement regarding any clinical study. No clinical studies shall be undertaken until a separate written agreement or amendment to this Agreement is signed by the parties. If the parties cannot in good faith reach such an agreement, either party may terminate this Agreement upon thirty (30) days' written notice to the other party.

[OR]

10. CLINICAL STUDIES.

A. <u>Adherence to All Applicable Laws</u>. As between UMDF and Institution, the Institution shall be solely responsible for adhering to all applicable laws and guidelines for performance of the Research Project.

B. <u>Use of Research Project Drugs are Limited to the Protocol</u>. The Institution agrees that in utilizing any part of the Grant it will limit its use and evaluation of any Research Project drug to the activities directly related to the Protocol identified herein, unless prior written consent has been provided by the UMDF.

C. <u>Institutional Review Board</u>. All relevant policies and procedures of the Institution's Institutional Review Board shall be observed.

D. <u>Protocol</u>. The proposed Protocol shall be described in detail within the Proposal. The final Protocol, and any amendments thereto, shall be strictly adhered to during performance of the Research Project.

11. INDEMNIFICATION. Institution acknowledges that UMDF's participation in the Research Project is solely as a grantor and UMDF is otherwise a passive party in the design and conduct of the Research Project. Institution shall be responsible for the Research Project and to the fullest extent allowable by law defend, indemnify and hold UMDF, and its directors, officers, employees, agents and contractors, harmless from and against, or if the foregoing is not permissible by applicable law (e.g. because of sovereign immunity), assume the risk of, any and all claims arising out of or directly connected with the Research Project; provided that the foregoing shall not apply to any claim based on the negligent or willful acts of misconduct by UMDF or its directors, officers, employees, agents or contractors. UMDF hereby agrees to provide prompt notice to Institution of any claim, demand or cost within the scope of this section; provided that failure to provide prompt notice shall only relieve Institution of its obligations under this section to the extent that Institution is materially prejudiced by any delay in notification. UMDF shall allow Institution full control, at Institution's expense, of the defense and settlement of any such claim, demand or cost and shall reasonably cooperate at Institution's expense in such defense.

12. AMENDMENTS. This Agreement, the documents referred to herein, and the Exhibits hereto, constitute the entire, full, and complete Agreement, between the parties concerning the subject matter hereof, and supersedes any and all prior oral or written agreements between the parties regarding the same subject matter. No amendment, change, or variance from this Agreement shall be binding unless mutually agreed to by the parties in writing and executed by their authorized officers in writing. No purported amendment, change or variance from the printed form of this Agreement shall be binding unless initialed by the parties. The persons signing this Agreement represent the parties in authorizing any such amendment or in any other business or contractual matter arising under this Agreement. This Agreement is made under and shall be construed, interpreted and controlled by the laws of the Commonwealth of Pennsylvania, and all claims arising out of or related to the parties relationship created by this Agreement, whether in contract, tort, or otherwise, shall be decided pursuant to the laws of the Commonwealth of Pennsylvania, including Pennsylvania's statutes of limitations but not including its conflicts of law rules. The parties

agree to submit to the courts of said jurisdiction and that such venue shall be exclusive regarding disputes arising out of this Agreement.

13. DISCLAIMER OF WARRANTIES. INSTITUTION AND PRINCIPAL INVESTIGATOR EXPRESSLY DISCLAIM ALL WARRANTIES RELATED TO THE RESEARCH PROJECT AND ANY RESULTS GENERATED THEREFROM, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

[signature page to follow]

INSTITUTION

By: _____

(Name)

(Title)

(Date)

THE UNITED MITOCHONDRIAL DISEASE FOUNDATION

By:

Kristen Clifford Chief Executive Officer

Date

EXHIBIT A (Submitted Research Proposal Attached)

EXHIBIT B

Progress Period and Payment Schedules

Research Project Period:

Payments, by year (where applicable):

Project Year	Amount Requested in Proposal	Award (UMDF to complete)	Report	Invoice Periods
Year 1			Year 1 Report Due:	
Year 2			Final Report Due:	
Final Report on Research Project (due 6 months after the end of the project)	N/A			(Upon receipt & approval of Final Reports)
	Total Award	1:		·

Checks are to be made payable to:

Exact address where checks are to be mailed or bank wiring instructions:

Attn: _____

EXHIBIT C

UMDF Research Grant Payme	nt Reque	st	PROJE	ECT BL	JDGET	and Act	ual Expenses	
Project Period:	_			Invoice P	eriod:			
		nvestigator :		In		Institution:		
1) Personnel:	_							
Name and Role in Project	% Effort on Proj.	Base Institutional Salary	Fringe Benefits	Budget Amount Year 1	Budget Amount Year 2	Total Budget	Current Billing	Cumulative Billing
						\$0 \$0		
						\$0		
Include % effort of PI. Do not include salary.						\$0		
Tota	al Personnel:	\$0	\$0	\$0	\$0	\$0	\$0	Ş
2) Supplies and Equipment (itemize by major	categories):							
, , ,	5).					\$0		
						\$0		
						\$0 \$0		
						\$0 \$0		
Total Supplies and Equipment:				\$0	\$0	\$0	\$0	\$
3) Miscellaneous (list specific amount for each	item):							
<u> </u>	,					\$0		
						\$0		
						\$0		
Total Miscellaneous:				\$0	\$0	\$0	\$0	Ş
Total Direct Costs:				\$0	\$0	\$0	\$0	\$
Total Costs:				\$0	\$0	\$0	\$0	\$
			FUNDS REQUESTED THIS PERIOD:					
Payments : UMDF Use Only			Year 1	Payment Date		Payment Amount		
			Year 1	Payment Date		Payment Amount		
			Year 2	Payment		Payment		
			Year 2	Date Payment		Amount Payment		
				Date Baumant		Amount		
			Final Payment	Payment Date		Payment Amount		
					Total Payments			