

# 2024 Clinical Trial Readiness Full Proposal Form

## Submission Reference Identifier

{{ submission.reference\_id }}

## A. Investigator (Applicant)

**NOTE:** Applicants at any stage of career are eligible for this grant program.

First Name (i.e., JOHN Smith) \_\_\_\_\_

Last Name ( i.e., John SMITH) \_\_\_\_\_

Academic Title(s) (MD, PhD, etc. ) \_\_\_\_\_

Academic Rank (Postdoctoral Fellow, Professor, Associate Professor, Assistant Professor, etc.) \_\_\_\_\_

## B. Sponsoring Institution

**NOTE:** Applicant must be an investigator at the sponsoring institution. List the person within your department at the sponsoring institution responsible for receipt and disposition of grant funds.

Sponsoring Institution Name \_\_\_\_\_

Department Name \_\_\_\_\_

Telephone \_\_\_\_\_

Email \_\_\_\_\_

Street Address 1 \_\_\_\_\_

Street Address 2 \_\_\_\_\_

City \_\_\_\_\_

State \_\_\_\_\_

Postal Code \_\_\_\_\_

Country \_\_\_\_\_

Department Grant Administrator Name \_\_\_\_\_

Department Grant Administrator Email \_\_\_\_\_

Department Grant Administrator Telephone \_\_\_\_\_

## C. Project Title

Please provide a Project Title that succinctly describes the nature of the research project. (Maximum 160 Characters)

\_\_\_\_\_ ({{ submission.title }})


\_\_\_\_\_ ({{ submission.title }})


\_\_\_\_\_ ({{ submission.title }})

## D. Project Abstract

Please provide a scientifically rigorous summary of the proposed research in sufficient detail to allow for a preliminary assessment of merit, RFP responsiveness and UMDf mission relevance.

**NOTE: This abstract will be used for triaging purposes (250 words maximum)**

 E. Project Costs Clinical Trial Readiness grants will be up to one year in length with a maximum budget of 100,000 USD. Smaller budgets are encouraged and will be viewed favorably. Please see Section H (Budget) for details on allowable costs. **Indirect Costs are not an allowable expense**

 F. Project Description  
G. References

Sections F and G must be completed offline and then uploaded as a separate task. **Sections F and G should be uploaded as a single combined document, no longer than six pages.** **F. Project Description** Include and clearly identify the following sections: 1. Justification/Significance of the project; 2. Specific goals; 3. Objectives, expected outcomes, and how resulting data will be utilized; 4. Activities and methods to be employed; 5. Target population; 6. Timeline for completion; 7. Details of any plans to use research gains for commercial activities and/or patents; 8. Other pertinent information, including highlighting changes if this is a resubmission of a previous proposal. 9. Any human or animal subject issues of concern: Is IRB or IACUC approval in process? Submission date? 10. Statement verifying this project is not a continuation of a past or current UMDF grant. **\*\*Note:** UMDF recognizes that the utility of research is inherently linked to rigor and reproducibility, as highlighted by NIH Guidelines on this subject. It is suggested the significance section should briefly address efforts to ensure rigor & reproducibility in the proposed research. **G. References** A specific citation format is not required.

Sections F and G must use type size no smaller than 11 point font (Times or Times New Roman) for all text and Figure legends. Allow for margins of at least ½ inch.

**SIX PAGE MAXIMUM INCLUDING ALL FIGURES, CHARTS AND REFERENCES. APPLICATION WILL NOT BE REVIEWED IF MAXIMUM EXCEEDED.**

Accepted upload formats: .pdf (preferred), .doc and .docx

 H. Project Budget


All figures in USD \*Enter 0 for any required fields that are not applicable\* Include expenses related to this request and % effort of all key personnel. Itemize personnel, supplies, and miscellaneous expenses. Budget notes: \* Include salary and fringe for all appropriate technical staff, consistent with NIH guidelines or standards within country of work\* Postdoctoral Fellow should be named, if listed\* No travel support allowed except travel costs directly related to research (e.g., patient travel for clinical trials)\* Printing & publication costs are not permitted **No institutional indirect costs may be included in the budget**

 1) Personnel:


	Name and Role in Project	% Effort on Project	Requested Salary & Fringe
Investigator	_____	_____	_____
Other Key Personnel:	_____	_____	_____
	_____	_____	_____
	_____	_____	_____
	Total Amount Requested		
Investigator	_____		
Other Key Personnel:	_____		
	_____		

 Total Personnel Costs


Total \_\_\_\_\_

 2) Supplies and Equipment:  
(Itemize by major categories)


	Description	Cost
Item 1	_____	_____
Item 2	_____	_____
Item 3	_____	_____
Item 4	_____	_____
Item 5	_____	_____

 Total Supplies and Equipment Costs

Total \_\_\_\_\_

 3) Miscellaneous:  
(itemize as necessary)

	Description	Cost
Item 1	_____	_____
Item 2	_____	_____
Item 3	_____	_____
Item 4	_____	_____
Item 5	_____	_____

 Total Miscellaneous Costs

Total \_\_\_\_\_

 Total Costs

Personnel + Supplies & Equipment + Miscellaneous **Grand Total must be no more than 50,000 USD**

GRAND TOTAL: \_\_\_\_\_

 I. Budget Justification

Detail how UMDf funds will be applied to each expense being as specific as possible. Please note that funds are to be spent only for amounts/items allocated in budget and approved by UMDf. **Any changes during the course of the project must be first approved by the UMDf.**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

 J. Other Funding Sources


Other support is defined as all Federal, non-Federal, and/or institutional funds or resources available to the principal investigator and all other key personnel named in the application in direct support of their research endeavors through research or training grants, cooperative agreements, contracts, fellowships, gifts, prizes and any other means. Include all applications pending review or award that are related to this application. Specify each amount requested and indicate each item's status as "current" or "pending". **Indicate any potential overlap with other grants and how any overlaps would be resolved. If none, please state**

that there are no current or potential overlaps.

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 K. Key Staff


List key staff and/or advisors, their institutions, and briefly describe their role in the project.

NOTE: Upload a biosketch for Applicant and one other key person named in the budget, if any (please limit biosketch uploads to a maximum of two total). Instructions can be found on proposal main summary page. Biosketches are not required for authors of Letters of Support.

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 L. Sponsoring Organization

Please provide a brief description of the sponsoring organization and its facilities, including resources and equipment required to carry out the proposed research. To assure appropriate access, Letters of Support are expected for necessary resources and equipment located outside Investigator's lab.

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 M. Statement of Relevance

Explain how this project is responsive to the current RFP and why the UMDF is the best funding source for your project at this time. **NOTE:** This section is a **very** important component of the review process. Relevance of the proposed research to the primary mitochondrial disease community must be clearly articulated.

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 N. Certification and Electronic Signatures

Before electronic signatures may be entered below, the following certification statement must be answered in the affirmative. You will not be able to complete and submit the proposal unless the certification statement is acknowledged as accurate. If you are unsure about your status as an Independent Researcher, please contact grants@umdf.org prior to submitting your proposal.

**I, the Investigator on this submission, certify that I am prepared to conduct the research described in this proposal at the listed sponsoring institution.**

- Yes  
 No

 Applicant Principal Investigator Electronic Signature

Please enter your name. This will serve as your electronic signature, attesting that all information included in this application is accurate and not misleading.

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Date

\_\_\_\_/\_\_\_\_/\_\_\_\_(YYYY/MM/DD)

 Department or Division Head Electronic Signature(if required by your institution)

Please enter your name. This will serve as your electronic signature, attesting that all information included in this application has been reviewed and approved.



Date

\_\_\_\_/\_\_\_\_/\_\_\_\_(YYYY/MM/DD)

 Institutional Officer Electronic Signature(if required by your institution)

Please enter your name. This will serve as your electronic signature, attesting that all information included in this application has been reviewed and approved.



Date

\_\_\_\_/\_\_\_\_/\_\_\_\_(YYYY/MM/DD)