Owen Locke Foundation Fund for Research in Macular Degeneration

Application Guide

2023

This document is not an application. It provides guidance for the preparation of your OLF funding proposal.

It is mandatory to apply via the OLF email, only complete applications received through FormStack. To apply please submit your proposal before the deadline on August 14th 2023 (2400 PST).

For questions concerning the application process, please contact:
OwenLockeProposals@gmail.com

*** Indicates required field**.

Contents

Confidentiality Statement

Your application and information/data which you submit for support may be shared with members of OLF Board and Advisory Committee members involved in the selection process, members of the technology transfer office of your institution, members of the IRB of your institution as well as external reviewers.

All application material and data will be held in strict confidence. All persons reviewing this information will have signed non-disclosure agreements with the OLF.

Timeline for Application Process

- Applications Due: August 14th, 2023 (2400 PST)
- Invitations for Pitches Sent to Applications moving forward: September 2023
- Pitches Presented: Mid to late September 2023 (Official dates TBA)
- Winners Announced: Late September early October 2023

Eligibility Criteria

Principal investigators from accredited academic medical centers, research institutions or universities in the U.S. are eligible to apply for funding.

Please confirm that you **and** your institution meet and agree to the OLF eligibility criteria including the requirements of the home institution described below. Please print and sign the signature page provided on the OLF website and submit it as PDF scan during the application process.

Additional Eligibility Requirements

- The investigator's home institution must ensure the necessary facilities and infrastructure are in place to execute the planned research project
- The home institution must accept the award conditions, including the approved use of funds and provide governance over fund expenditure
- All proposed research must comply with Institutional Review Board standards and Institutional Animal Care and Use Committee protocols as specified by the U.S. Department of Health and Human Services Office for Human Research Protections, HHS OHRP
- The home institution is responsible for ensuring the rights and welfare of individuals who participate as subjects in research activities as well as animal welfare being preserved
- Home institutions must adhere to current guidelines regarding financial conflict of interest, recombinant DNA and research misconduct

Applicant Information

If this information changes during the selection process, please notify the OLF immediately. Double funding is generally excluded.

Primary Investigator details *

- Title of PI
- Academic Title of PI
- Last Name of PI
- First Name of PI
- Position of PI
- Employer of PI
- Email Address of PI

Co-Applicant details (if applicable)

- Title of co-applicant
- Academic Title of co-applicant
- Last Name of co-applicant
- First Name of co-applicant
- Position of co-applicant
- Employer of co-applicant
- Email Address of co-applicant

Description of the team (max. 1500 characters including spaces) *

- Provide a brief description of the team that will realize your project. Include each team member's background and experience to demonstrate your credentials. Make sure to include relevant career stages, industry experience etc. List any collaborator(s) who complement your expertise, any service providers you consider contracting and any experts you have consulted concerning your project. If applicable, describe any unique infrastructural/facility advantages at your disposal.

Other Funding (max. 1000 characters including spaces) *

- Please indicate here if you are currently receiving other funding and whether these funds support aspects of the project. Please indicate the start and end dates of the funding, the amount and source of funding and whether the funding is for personnel, consumable or investment costs.

Project Description

Project Details

Non-Confidential Project Title (max. 120 characters including spaces) *

- Please pick a non-confidential title that catches the essence of your project and that may be used publicly.

Project Acronym *

- Please pick a 1-word abbreviation for your project.

Project Category *

- Select from the following options: Pharma, Medical Devices, Gene Modifying, Regenerative Therapies

Indication/Area of Research *

- Please name the indication/area that your solution is addressing (multiple indications/areas are possible).

Current IRB Status (if applicable) *

Project aim/intended use statement (max. 300 characters including spaces) *

- Please provide a very short description of what you are planning to accomplish during the initial 18-month (Phase One) funding period. Also describe how with an additional investment (Phase Two) would help bring your solution into the clinic. For example: Screen for inhibitor of X, generate data in second mouse model to validate initial results in disease X. For medical devices projects, please add the intended use statement.

Description of the "problem"/unmet medical need (max. 1500 characters including spaces)*

- Please describe the macular degeneration (MD) related problem and unmet medical need that your solution addresses.

Description of your new solution/invention (max 3,000 characters including spaces)*

- Please describe your MD solution and how it addresses a problem and/or an unmet medical need that you intend to address. Please describe the goal(s) you are trying to reach in Phase One as well as the goal(s) you plan to work on following the initial 18-month funding phase if chosen for follow-on funding. Ensure that you are aiming for a clear developmental goal at the end of the initial funding period (e.g., prototype developed, optimized lead compound) which will

be part of the selection criteria for follow-on funding. Be sure to also clearly identify and include project goals anticipated for continuing solution development if funded for Phase Two.

Uniqueness of new solution (max. 1200 characters including spaces) *

- Please describe what makes your solution unique. How does it differ from the current standard of care? Please also differentiate your proposed solution from other solutions that are already approved or in development (e.g., greater efficacy, improved safety, increased patient convenience etc.). What are the competitive advantages of your solution?

Stakeholder involvement (max. 1000 characters including spaces) *

- Have you included stakeholders already? Have you received input from potential users? Describe how and in which phases of your study relevant stakeholders (e.g., study participants, patient organizations, funding agencies, researchers (including you), enterprises etc.) will be involved and will contribute to your project. Describe the support by other parties. Describe possible conflicts of interest.

Current stage of the project (max. 1000 characters including spaces) *

- Please describe what you have achieved. Provide solid, relevant data and evidence supporting the assumption that your solution will be successful, and your approach will work (proof-of-concept/technology/principle data). Please show how the data from your previous studies support your description of the new solution. Be sure to include tables/and or graphs including all data points, information on group sizes and the transparent display of the actual data distribution. Please note that supporting graphics and schemes should be uploaded separately and should not exceed the 7-page maximum.

Proposed Project During Phase One 18-month Funding Period

Description of work plan including work packages, milestones (max. 3000 characters including spaces) *

- Include structured timelines, milestones, key goals, objectives that you suggest for your first 18 months of funding. Assuming that you are successful in Phase One and are selected to receive follow-on funding of up to $1,000,000, please provide similar details on what you would do with these funds. Please note, a milestone is what you want to have accomplished at the end of a work package. A work package is what you do to reach this milestone (often experiments, clinical studies etc.). Please also include potential pitfalls of the project with sufficient risk assessment and criteria to substantiate continuation of the

program at each milestone. Work packages for Phase One **should not extend beyond 18 months**. We understand that proposed follow-on funding work packages, milestones and budget may be further refined as Phase One progress is achieved. You may include as many separate work packages as make sense for your project. Timelines on work packages may overlap.

Please describe the work plan as follows:

Work package 1 including:

- Time frame
- Accompanying description
- Statistical analysis 1
- Accompanying milestone 1
- Accompanying budget 1

Work package 2 including:

- Time frame
- Accompanying description
- Statistical analysis 2
- Accompanying milestone 2
- Accompanying budget 2

Description of Go/No-Go criteria (max. 1500 characters including spaces) *

- Please describe Go/No-Go criteria for each work package. Go/No-Go testing refers to a pass/check test principle and is an essential part of drug/product development. Please use Go/No-Go decision criteria that are precise, well-defined and as little as possible subject to interpretation.

Data Robustness & Reproducibility Strategies (max. 2500 characters including spaces) *

- For both your current data and future experiments, please describe which facts support the robustness of your data.
- Please briefly describe your strategies for **reproducibility of your study methods and results during the funding period**. Which risks of bias can you identify? What are your project specific strategies to reduce the risk of bias?
- Please describe how you will/have consider/ed sex (cells, animals, humans) and gender (humans) aspects as a biological variable. How large is your (planned) sample size and how has the sample size been calculated? Did/Do you consider effect size estimates, primary and secondary outcome measures and endpoints as well as possible confounders?
- Provide a short overview how you conduct(ed) your statistical analyses, e.g. “We use(d) a logistics regression analysis with X as dependent and Y as independent variable. We adjust(ed) for confounder Z”.
- Explain if and how you already published/shared the current data with the (scientific) community. Did you register or preregister your IRB study with HHS if

it is required? Explain when and where you plan to publish your data and (pre)register your study if required.

After the end of the initial funding period

Future development plan (max. 1200 characters including spaces) *

- If your project is chosen for Phase One funding, please describe how you intend to proceed after the first phase support by OLF. What additional steps are necessary to reach patients/market and how can they be realized? Is your intention to license IP to biotech or pharma, to apply for follow-on funding for further development, to found a start-up or partner with industry? When do you think patients will benefit from the product/solution (years from now)? Please be as specific as possible.

Description of regulatory requirements (max. 1500 characters including spaces) *

- What are the regulatory requirements that your product/solution/technology needs to meet to reach the market? How will you proceed in order to fulfill them?

Budget Overview

Total Phase One Budget (up to $150,000 for 18 months)

- Total budget, consumables and investment budget, personnel budget with justification of funding

Total Phase Two Follow-on Budget (up to $1,000,000 over 12-36 months)

- Total budget, consumables and investment budget, personnel budget

Please keep the following in mind as you prepare your budget:

- No more than $20,000 or 10% of the total funded amount (whichever is greater for each funding phase) may be used for capital expenditures or equipment
- The award may only be used for direct project expenses with no more than 10% used for institutional overhead. Any institutional overhead paid should be calculated after deducting the cost of capital equipment purchases
- The award may be used to cover salaries for post-docs, PRAs, technicians etc. equivalent to the percentage of their time/effort devoted to the project
- The award may not be used for travel, meetings, professional fees or publication fees.

Intellectual Property

Existing IP

Do one or more invention disclosure(s) and/or patent(s) exist for the technology you are validating in your project? *

- Please indicate if one or more invention disclosure(s) and/or patent(s) exist for the technology you are validating in your project (yes, no, currently being prepared, not patentable)

If no IP currently exists (max. 500 characters including spaces):

- Please describe the projected plan to generate new IP.

If you selected not patentable (max. 500 characters including spaces):

- Please indicate how, when and by whom this was judged. For example, if it has been determined by the technology transfer office that patenting is not and will not be feasible or advisable for this technology/area (e.g., in some cases of drug repurposing etc.).

If you selected not patentable (max. 1500 characters including spaces):

- Please describe how you plan to nonetheless reach patients/market/commercialization.

If one or more invention disclosure(s) and/or patent(s) exist:

- Please list the invention disclosure reference number(s), or the patent number(s) including patent holder, inventors and any relevant details on the IP status.
    1. Invention disclosure reference number(s)
    2. Patent holder (university, public institution, private company, or person)

  Please note that in case an external entity holds the patent rights, it is mandatory that you contact the OLF advisory team before submitting this application.

Contact with the Technology Transfer Office (TTO)*

- Please indicate your contact person at the Technology Transfer Office (TTO) of your institution

+++ Only fill out the section below if you have indicated any invention disclosures or patents above. If not, please skip this section +++

INVENTION 1

Invention disclosure in preparation, Invention claimed by TTO, patent in preparation, patent submitted, patent granted to your institution exclusively or together with a second party, IP exclusively held by a private or public institution, or by a private person or company, IP held in part by a private person.

- Invention 1. Invention disclosure reference number
- Invention 1. Patent number

Patent holder (max. 500 characters including spaces).

- Who is the patent holder (university, public institution/private company, or private person)? Please list all inventors. As noted above, if an external entity holds the patent rights, it is mandatory that you contact the OLF advisory team before submitting this application.

Additional comments (500 characters including spaces)

Please provide any relevant details on the IP status of the technology you are planning to validate in this project.

INVENTION 2

Invention disclosure in preparation, Invention claimed by TTO, patent in preparation, patent submitted, patent granted to your institution exclusively or together with a second party, IP exclusively held by a private or public institution, or by a private person or company, IP held in part by a private person.

- Invention 2. Invention disclosure reference number
- Invention 2. Patent number

Patent holder (max. 500 characters including spaces).

- Who is the patent holder (university, public institution/private company, or private person)? Please list all inventors. As noted above, if an external entity holds the patent rights, it is mandatory that you contact the OLF advisory team before submitting this application.

Additional comments (500 characters including spaces)

- Please provide any relevant details on the IP status of the technology you are planning to validate in this project.

Commercialization

Does the commercialization of your product solution depend on other patents? (max. 500 characters including spaces) *

- Does the commercialization of your product/solution depend on other patents? Please describe any repurposing option for the project if applicable.

Target group (max. 1200 characters including spaces) *

- Description (quantitative and qualitative) of the targeted user and/or patient group or anticipated target/patient group. How large is the user/patient group? If several users/patient groups/indications are possible, describe the rationale for the current choice of user/patient population/indication. If you have not yet decided on a user/patient population/area of application, please outline ways forward on how to identify the most relevant one/s.

Commercial potential (max. 1200 characters including spaces) *

- Please describe the market size and market niche that your solution will address. Who are the customers of the solution you are creating (e.g., patients, clinicians, hospitals, insurance companies etc.)? Who is going to pay for your solution? What is the added benefit for them? Please estimate how many of the total number of patients/users you might be able to reach nationally and globally. Please estimate the revenue that could be created with this solution (in US/worldwide).

Indicate your potential competitors (max. 1000 characters including spaces) *

- Please describe alternative or similar solutions that are already on the market or are being developed for the problem you address. Who is or might be your competitor? Please note that it is extremely unlikely that no competition exists. Competition can include similar products or completely different solutions targeting the same problem.

Publications

Key publications (optional)

- Please list **up to 5 key** publications that you feel are important to understand the therapies/ technology that you are describing. These can relate to previous work you have done and results/data you have gathered that justify your proposed next steps, or publications providing background information to the therapy/technology. Please do not include any of your previous publications that are unrelated to the project you are describing in this proposal.

Graphics

Please upload the graphs as 1 PDF file, portrait format (max. 7 pages, max. file size 20 MB).

Supporting Graphics PDF file (PDF portrait format) *

- Please upload relevant graphics and data that help/support the understanding of your proposal and show key results. Add enough text/figure legend to explain your graphics and label them clearly. Any abbreviations used must be explained. Avoid uploading graphics from publications with lots of background data and graphics of insufficient resolution. Make sure the labeling is readable. Choose graphics that help the reviewers understand the technology and your future plans.

Confirmations and signature(s)

No alternative funding currently exists for the work applied for in this application *

- Please confirm that currently no alternative funding for the work applied for exists.

Confirmation of change notification *

- Please confirm that if this changes at any point, you will notify the OLF advisory team immediately.

Upload of signature page *

- Please upload a PDF scan of the signature page (signed legal compliance / confidentiality document). **Confirmation and signature(s) required before you can submit**. Please upload the signature page that may be downloaded here.