

Kathryn Barton Hobbs

Medical Research Grant Application Guidelines

We would like to thank you for your interest in Liam's Land Organization medical research grants. These guidelines highlight the goals and policies for Liam's Land and list the specific information required when submitting a proposal.

I. Statement of Research Grant Policy and Procedures

Liam's Land Organization awards grants to applicants who seek to conduct research to find the cause, treatment, or cure for lymphatic malformation (also known in the past as cystic hygroma or lymphangioma).

II. Application Guidelines

The following general guidelines apply to our research grants:

- a. Principal investigators (PI) must hold post-doctoral position or beyond.
- b. Proposed projects must have specific relevance to lymphatic malformations and show promise for contributing to the scientific advancements, disease treatments, or cures in the field of study.
- c. Awards will be granted only to applicants affiliated with institutions with 501(c)(3) statuses or equivalent for foreign institutions.

III. Funding Guidelines and Limitations

The following are general guidelines and limitations for our research grants:

- a. Projects will ordinarily be funded for a two year period. Under exceptional circumstances, funding will be continued for a third and fourth year of the project.
- b. Grant awards will be provided in amounts up to \$25,000 annually.
- c. Payments will be made on a quarterly basis at the beginning of each quarter, with exception of the final quarter of each year of the grant, which will be paid thirty days after receipt and approval of the year-end report as specified in Section VI below.
- d. LLO reserves the right to withhold payment at any time pending resolution of any discrepancies in the use of funds, and/or if the specific aims are not met, all as set forth in the grant proposal and any revisions required.
- e. Awards may not be contributed to a unified or pooled fund that will be used to award grants or support other projects.
- f. Grants are awarded on the basis of the content of the proposal, as well as the specified Principal Investigator (PI) and sponsoring institution. If the PI terminates his/her affiliation with the institution identified in the grant award, and wishes to continue the project at another institution, the PI must notify LLO in writing and obtain approval. LLO reserves the right to require resubmission of the grant with the appropriate changes in staff and/or venue, and LLO reserves the right to such a change.
- g. If the PI wishes to discontinue the project prior to completion, he/she must notify LLO in writing within sixty days of the termination of work on the project. The original institution identified in the grant award shall have the opportunity to identify another PI within sixty days of

notification. LLO reserves the right to require resubmission of the grant with the appropriate changes in staff and LLO reserves the right to reject a change. If the original institution does not wish to continue the project, the remaining funds must be returned to LLO.

- h. The following will not be funded:
 - i. Overhead or indirect cost
 - ii. Collaborator salaries
 - iii. General institutional expenses
 - iv. Journal subscriptions, advertisements, tuition fees, professional society dues, meals, receptions, seminars, or parking fees.
 - v. Any research that does not fall within LLO areas of interest

IV. Processing of Grant Applications

Grant applications will be accepted and considered once per year. The LLO Medical Advisory Board will review each proposal and deliberate their findings. Recommendations from the LLO Medical Advisory Board will be made by the LLO Medical Advisory Board Chairman to the LLO Board of Directors. The LLO Board of Directors will have final decision on the awards. The deadline for applications to be considered at a specific meeting is six weeks prior to the meeting date. Please email janetsteffen@liamsland.org or visit our web site at www.liamsland.org for the most up to date schedule.

Notifications of accepted and denied proposals will be made within three weeks of the LLO Board of Director's meeting. For approved awards, the grant period will begin within three months thereafter, at the discretion of the PI.

V. Application Instructions

Submission of an incomplete application will result in a delay in review or non-consideration. Only proposals written in English language will be considered.

- a. Format
 - i. Maximum length is 12 one-sided 8 x 11.5 pages, singled-spaced, using a standard 12-point font (information page, documentation, budget, project personnel, funding history, references, diagrams, charts, drawings are not included in the 12-page limit)
 - ii. Number each page consecutively
 - iii. Include PI's name on each page as a header
 - iv. Abbreviate only after complete wording is provided
 - v. Use standard black type that can be photocopied
- b. Content:

The proposal should describe the rationale and potential importance of the project, and should include the specific aims and research design and methodology. Summarize previous relevant work with progress to date. Include sufficient detail in a concise manner to facilitate evaluation of the proposed work. Reviewers will consider brevity and clarity of the proposal to be indicative of a focused approach to a research objective and the ability to achieve the specific aims of the project.

The application should include the following items:

- I. Principal Investigator Information Page
 - i. Name of organization: The name of the affiliated non-profit organization or foreign institution equivalent.
 - ii. Title of the project : Choose a title that is descriptive and specific, not general
 - iii. Contact information : Mailing address (no P.O. Boxes), telephone(s), fax numbers, email addresses
 - iv. Specific amount request: Indicate the total dollar amount requested from the LLO for year one, and if applicable year two of the project.

- II. Project Description
 - i. Abstract : Provide a project summary that addresses the following:
 1. What problem does the project address?
 2. Why is this project important to patients with lymphatic malformations?
 3. How will this project be accomplished?
 4. Signify up to ten key words in bold lettering

 - ii. Specific aims: List the project's objective and describe concisely the specific goals of the research, including any hypotheses to be tested. One page is recommended.
 - iii. Background and significance: Briefly outline the background of the proposed project. Include a critical evaluation of previous research and existing knowledge, and specifically identify the gaps that the project is intended to fill. State explicitly the importance of the proposed research by relating the project's specific aims to the medical issues of lymphatic malformation patients. Two to three pages are recommended.
 - iv. Preliminary studies: For new applications, a report of the PI preliminary studies is recommended.
 - v. Research design and method: Describe the research design and methodology that will be used to accomplish the project's specific aims. Include the means by which data will be collected, analyzed, and interpreted. Describe facilities, laboratory space, and major equipment that are pertinent to the project. Describe any new methodology and its advantages over existing techniques. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the project's aims. Provide a tentative sequence or timetable for the project. Describe any procedures, materials, or situations that may be hazardous to personnel and the planned precautions to be exercised.
 - vi. Human subjects: Regulations require that all affiliated institutions establish and maintain appropriate policies and procedures for the protection of human subjects. If applicable, give a brief description of the population of subjects involved in the project, the process for informed consent, and the means by which protection will be ensured. Provide proof of current or pending project approval by an Institutional Review Board or similar oversight committee.
 - vii. Animal studies: All proposals must conform to regulations for the safe and humane treatment of animals. If applicable, give a brief description of the animals to be

studied, and measures to minimize pain and discomfort. Provide proof of current or pending project approval by the institution's Animal Use and Protection Committee or similar oversight group.

- viii. Budget: See attached budget form. Submit a detailed budget for year one and if applicable, year two of the project.
- ix. Project personnel: Provide the name, title, and role of any individual who will be involved in the project, including the PI. Indicate the percent effort that each person is expected to devote to the project. Provide the curriculum vitae (CV) of all project personnel and any collaborator(s). The CV's are not included in the twelve-page limit for the proposal, and the CV of the collaborator(s) may be abbreviated to include any relevant work and/or publications.
- x. IRS 501(c)(3) determination letter or its equivalent for international institutions.
- xi. Funding history: If applicable, indicate the amount and granting organization for any other source of funding for the proposed project. For the PI, provide a list of current funding support as well as awards received in the past seven years.
- xii. Letters of reference: For the PI, who is at the assistant professor level or below, provide three sealed, confidential letters of reference.
- xiii. Institutional support: Provide a letter of institutional endorsement of the project, signed by an appropriate official and the institution's business manager or fiscal officer. Provide contact information for each.

d. Submission

Submit the original of the completed application. Provide 9 copies and a PDF of the proposal on a CD (preferably in PC, not in MAC, format). Please include all documents, including institutional letters, publications, etc. in PDF format if possible (sealed letters are excluded).

Mail materials to:

Liam's Land Organization, Inc.
P.O. Box 5715
Savannah, Georgia 31414

Fed Ex or other delivery service address:

Liam's Land Organization, Inc.
818 East 41st Street
Savannah, Georgia 31401

No applications will be accepted via fax or email.

e. Acknowledgement of Receipt

LLO will acknowledge receipt of proposals within fourteen days of receipt. Applications will be evaluated for completeness within thirty days and then will be forwarded to the Medical Advisory

Kathryn Barton Hobbs
Medical Grant Application Form

(To be signed along with the Liam's Land Patent, Intellectual Property,
and Technology Transfer Policy after a grant is awarded)

1. In accepting a Grant from Liam's Land Organization, Inc. (LLO), the Principal Investigator (PI) and the grantee institution (Institution) assume an obligation to expend grant funds for the research purposes set forth in the application, and to affirm that there is no duplicate funding for these or substantially similar purposes. The PI and Institution will promptly notify LLO of activation or funding of any application for support to which LLO support is alternative.
2. Grant Period : The start date of the grant period is the earliest that funds may be obligated or expended. Termination date of the award will be the date indicated in the original notification letter or the date provided by an authorized extension. Termination date is the latest that funds may be expended except to liquidate authorized obligations.
3. The Institution is obligated to administer the grant in accordance with the regulations and policies governing the grant programs of LLO, or where not specified, consistent with the policies and practices of the Institution.
4. The fiscal officer of the Institution will provide an Expenditure Report co-signed by the PI within 60 days after termination of the award. The fiscal officer of the Institution will agree to make available to representatives of LLO, following due notice, accounting records of disbursements made from LLO's grant funds.
5. Every twelve months during the grant period, the PI shall submit a Progress Report of his/her technical accomplishments and a financial report, or more frequently at the discretion of LLO with thirty day notice. In the final year or at the earliest date possible thereafter, the PI shall submit a list of articles published or accepted for publication, and a summary of the research results.
6. The final quarterly payment for each grant year will be withheld pending receipt and approval of all required reports. This sum will revert to LLO in the event the reports are not received and approved within 6 months following the report due date.
7. Results of research will be made freely available to the public through appropriate scientific channels and all publication will bear the statement: "THIS WORK WAS SUPPORTED BY A GRANT FROM THE LIAM'S LAND ORGANIZATION FOR LYMPHATIC MALFORMATION RESEARCH". The PI and Institution will not permit release of any publicity regarding award or the research without advance written clearance from LLO.

8. If the research results are to be published, the PI shall provide LLO with advance written notice, no later than one week before publication, a PDF of the article and any press release related thereto. LLO shall not disclose such information to the public until the article is published and embargo released, if required. LLO has discretion to permit shorter notice if circumstances warrant.
9. Permission for a change in PI or Institution must be authorized by LLO in advance or the grant will be terminate on the date the PI leaves or ceases to work at the Institution at which the grant was awarded.
10. With regard to any and all research tools that are created in the course of a grant funded, in whole or in part, by LLO, including but not limited to construct antibodies and animal models for lymphatic malformation and LLO, such tools must be made freely available to LLO and any and all researchers who reasonably request it for the purposes of academic, non-commercial research. The creation of a mouse model, for example, shall be deposited by PI and Institution in a repository that will make the model available to the general research community.

The information regarding the availability of said tools shall be available through LLO web site and any other means LLO deems reasonable and appropriate. These tools must be made available within 6 months of publication of results, or 6 months after the grant has ended, whichever comes first. The PI and Institution shall promptly provide to LLO the name and contact information of those requesting and receiving said research tools.

If the PI and Institution fail to make such research tools freely available as provided above, PI and the Institution shall return all research grant monies provided by LLO for the project for which the grant is given.

11. Discoveries or inventions resulting from the PI's research, or to which the investigator is a party, and carried out during the tenure of the LLO Grant, will be subject to the current Patent, Intellectual Property, and Technology Transfer Policy of LLO attached. Such policy may be amended from time to time. Amendments are timely posted on LLO website.
12. LLO endorses the principles of the Association of American Medical Colleges (AAMC) report, "The Maintenance of High Ethical Standards In The Conduct of Research. "
13. With respect to human and animal experimentation, the Executive Officer of the sponsoring institution and the PI affirm: that the investigations which might involve human subjects have been endorsed by a committee on clinical investigation, or other clearly designated appropriate body, of the sponsoring institution; and that any research involving human subjects will conform ethically with the guidelines prescribed by the National Institutes of Health (NIH) including the provision of suitable explanation to human subjects or their guardians concerning the experimental design and all significant hazards, so that they may be in a position to provide appropriated informed consent prior to the investigations; and that research involving animals will conform with the current "Guide for the Care and Use of Laboratory Animals, " NIH publication, DHHS/USPHS, and with federal laws and regulations, and has been approved by the Institutional Animal Care and Use Committee; and that wherever applicable, the

research protocol will be reviewed and approved by the institution's biohazards committee, as well as confirming to NIH guidelines.

14. The nature of this arrangement is a funding agreement, and no employment or agency relationship is created.
15. LLO is not responsible for any claim, judgment, award, damages, settlement, negligence or malpractice arising from the research or investigation related to this award. The institution acknowledges responsibility for the conduct of research or investigations related to this award, and releases LLO from all claims or liability that may arise from the conduct of research or investigations related to this award resulting from any act or omission on the part of the institution, its employees, agents, or representatives.
16. LLO reserves the right to modify the terms or conditions of this contract with six months written notice to the PI and the sponsoring institution.
17. The PI/Institution agrees to indemnify and hold harmless Liam's Land Organization, Inc. against loss or threatened loss or expenses by reason of the liability or potential liability of Liam's Land Organization, Inc. for or arising out of any claims for damages.

SIGNATURES APPEAR ON THE NEXT PAGE

Signature of Principal Investigator

Print Name

Date

Address

City, State, Zip Code

Telephone and FAX Numbers

E-Mail Address

Award Period From, To Date: _____

Name of Fiscal Officer preparing Expenditure Report

Title

Address

City, State, Zip Code

Telephone and FAX Number

Email Address for Fiscal Officer

Patent, Intellectual Property, and Technology Transfer Policy

(To be signed with the Liam's Land Grant Application Form after grant is awarded)

1. The primary purpose of LLO is funding medical research through its research grantees to support its mission to find the cause, treatment, and cure for lymphatic malformation. LLO recognizes that such research may result in discoveries and inventions that have public health, scientific, business, or commercial value. LLO is interested in supporting and promoting science in the public interest and in making any such valuable discoveries and inventions available for public use as early as reasonably possible. Accordingly, this Patent, Intellectual Property, and Technology Transfer Policy, and any subsequent amendments hereto, are guidelines that shall apply to all discoveries or interventions created through the performance of research supported in the whole or in part by a LLO Grant.
2. All interventions or discoveries made in the performance of research supported in whole or in part by a LLO Grant shall be reported in writing to LLO at the earliest practical time, but in no event later than when the invention or discovery is disclosed to the grantee institution where the research was performed (Institution).
3. The Principal Investigator of the grant ("PI") shall promptly notify LLO in writing of any decision to file a patent application or seek an application for any other type of legal protection for intellectual property rights in connection with any discoveries or interventions developed under a LLO Grant. LLO shall keep information regarding such applications confidential, except to the extent that such information is otherwise made public through operation of law or by someone other than LLO, or to the extent that it is necessary for LLO to obtain legal advice regarding such an application. The PI shall notify promptly and in writing of any patent subsequently issued.
4. LLO recognizes that the PI may be subjected to certain obligations owed to the Institution or others with respect to research conducted on the Institution's premises. Notwithstanding such obligations, and, except as provided below, LLO shall abide by the PI's decision, and/or the Institution's decision, if applicable, concerning whether to seek a patent or any other legal protection in connection with discoveries or interventions developed under LLO Grant. However, to the extent that the PI (and/or the Institution, if appropriate) decides not to file a patent application or otherwise seek legal protection for intellectual property rights in connection with discoveries or interventions developed under LLO Grant, including decisions to abandon any such application, the PI shall notify LLO in writing as soon as possible of such decision, but in any event within such reasonable time frame as would be necessary to preserve all intellectual property rights in any such discoveries or inventions. LLO, at its sole option and at its sole expense, may then decide to file patent application or seek an application for any other type of legal protection for intellectual property in the U.S. or abroad. In the event that LLO makes such a determination, the PI (and/or Institution, if appropriate) shall assign to LLO all right, title, and interest in and to any such discovery or intervention and provide all reasonable cooperation and assistance necessary to assign and transfer such rights to LLO. The PI (and/or Institution, if appropriate) shall further provide all reasonable cooperation and assistance to LLO in seeking to obtain and enforcing a patent or other legal protection for intellectual property in the U.S. or abroad.

5. LLO shall share in any monies received from an invention or discovery developed under LLO Grant. The PI (if appropriate) shall not enter into any agreement that will derogate LLO's right to share such monies and shall notify LLO promptly and in writing for any license, lease, sale, or other agreement concerning a discovery or invention developed under a LLO Grant that is intended to generate revenue. LLO's right to share in monies shall include the sharing of licensing fees, royalties, or any other income derived from such invention. LLO participation shall be on a pro rata basis, based on LLO's portion of funding support for the research which led to the discovery or invention. The parties shall work together to develop the details of a reasonable formula. All reasonable administrative and overhead expenses of the Institution, as determined in accordance with the Funding Guidelines and Limitations of the Grant programs of LLO, shall be factored into the calculation of indirect support.

6. In the event that the PI (and/or Institution, if appropriate) grants a license to another party to commercialize an invention developed under LLO Grant, such license shall include provisions that obligate the licensee to commercialize the intervention in a commercially reasonable diligent manner, pursuant to, for example, appropriate diligence requirements and milestones, and the licensor shall monitor performance by the licensee. Unless otherwise agreed with LLO, the PI (and/or Institution, if appropriate) agrees that if it, its designee or licensee has not taken effective steps to arrange for practical or commercial value, or such other term that is commercially reasonable under the circumstances, and the Institution or the titleholder cannot show commercially reasonable cause acceptable to LLO why it should retain rights in and title to the invention for any further period of time, then LLO shall have the right to require: (1) assignment of the patent or other intellectual property rights to LLO; (2) cancel any outstanding exclusive license agreement; (3) grant a license under such patent or intellectual property right on terms that are reasonable in the circumstances; and/or (4) any other reasonable dispositions of rights in the invention.

7. If the PI (and/or Institution, if appropriate) fails to commercialize any invention or discovery developed under a LLO Grant within commercially reasonable time, including licensing such invention or discovery to another, and LLO identifies a suitable candidate interested in commercializing such an invention or discovery, the PI (and/or Institution, if appropriate) shall consider such a candidate as a potential licensee and shall license the invention or discovery to such a candidate, provided that the terms of such license are reasonably acceptable to the PI (and/or Institution, if appropriate).

SIGNATURES APPEAR ON THE NEXT PAGE



Signature of Principal Investigator

Print Name

Date

Address

City, State, Zip Code

Telephone and FAX Numbers

E-Mail Address

Signature of Authorized Representative of Grantee Institution

Print Name

Date

Title

Address

City, State, Zip Code

Telephone and FAX Numbers

Grant Approved by Liam's Land Organization, Incorporated

Name: Janet Steffen

Title: Executive Director

Signature: _____ Date: _____