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Leukemia & Lymphoma Society
Mantle Cell Lymphoma Research Initiative
Guidelines & Instructions

Letter of Intent
and
Full Application

March 2017

General Information

About the Leukemia & Lymphoma Society, Inc. and Sarah Cannon Fund at the HCA Foundation

The Leukemia & Lymphoma Society, Inc. (LLS) is a national voluntary health agency dedicated to the conquest of hematologic malignancies and relevant premalignant conditions. LLS supports research, patient aid, community service programs, advocacy, and public and professional education. The Sarah Cannon Fund at the HCA Foundations is a component fund of the not for profit HCA Foundation which seeks to promote cancer education, awareness, advocacy and research. The Sarah Cannon Fund has made a grant to LLS for the express purpose of funding research in Mantle Cell Lymphoma. LLS will be administering the grant in accordance with LLS guidelines with the input of experts identified by the Sarah Cannon Fund.

Description of Awards

The Leukemia & Lymphoma Society Mantle Cell Lymphoma Research Initiative (MCL-RI) grant program is intended to bring together established investigators from one or several institutions to develop a focused research program, foster new interactions and cooperation, and enhance interdisciplinary research among the participants. The overall goal of this mechanism is to enhance the development of innovative strategies for the treatment, diagnosis or prevention of mantle cell lymphoma. Strategies that move discoveries from the bench to the clinic are of high importance as are integrated translational projects.

A MCL-RI team will be judged as a unit and funding will not be available for otherwise meritorious but non-synergistic parts of an application. The quality and significance of the Projects and Cores (as described below), and the enhanced productivity that is likely to be achieved by linking the investigators, are the primary determinants of funding decisions.

Each MCL-RI is comprised of a minimum of three scientific Projects and a minimum of two scientific Cores that will cooperate under the leadership of an MCL-RI Director (described in more detail below). There must be objective evidence of interdisciplinary research among the Projects and Cores.

The maximal annual total cost for work funded directly by MCL-RI is \$500,000 for each year of the five year grant. Very importantly, in the spirit of collaboration and commitment, the research grants must be supported by a matching contribution from another source. While ideally the matching contribution will be equal to the award (\$2.5 million from LLS and \$2.5 million or its equivalent from another source), a matching contribution with a minimum value of \$ 1.25 M will be considered. The qualified matching contribution may include, but is not limited to, cash, equipment purchases, salary support for personnel, waiving of institutional indirect costs (up to 20% of the funds supplied by this grant), Pharma funding for novel clinical trial costs (e.g. drug,

patient), or other resources (e.g. patient samples or use of core facilities). The application of institutional resources towards the matching contribution must be either new efforts or extend work already underway and cannot overlap with current grants. MCL-RI will supply a maximum annual direct cost is \$416,666, while the maximum annual indirect cost is \$83,333 (20% of the direct cost). The MCL-RI Director has the authority to budget these funds among the various Projects and Cores.

Post-Award Management

Milestones and Deliverables

Projected milestones and deliverables to be achieved on a quarterly basis are required of awarded MCL-RI. As soon as the funding decision is made, LLS will contact the MCL-RI Director to initiate a discussion on milestones and deliverables. These milestones and deliverables will serve as the foundation for the annual assessment and should be brief statements related to the specific aims in your proposal. Both parties will need to agree to the final wording of the milestones and deliverables. These are due by the contract due date.

Site Visit

Annual Site Visits will occur around the anniversary of the grant start date. The MCL-RI Progress Review Committee, consisting of LLS Research staff and external reviewers, will visit the MCL-RI Director and members of the team. The MCL-RI Director, Project Leaders and Core Leaders must be present. The MCL-RI team will present an overview of the progress made within the last year in relation to the aims of the MCL-RI and the milestones/deliverables agreed upon the year before. Any problems encountered should be discussed and any changes from the original aims should be justified.

Semi-Annual Review

The semi-annual review will be held 6-months off cycle with the site visit after the grant started via WebEx to ensure that MCL-RI is meeting its milestones and on track for meeting its goals. The attendance at this meeting by the MCL-RI Director or Project Leaders and Core Leaders is required.

Annual Assessment

After the annual Site Visit, the MCL-RI Progress Review Committee will assess the quality of the integration of the MCL-RI team and the progress made. The Committee will make a recommendation as to the level of continued funding. In the case of well-integrated and productive teams, the funding will remain the same. In the unlikely event that progress is not sufficient, a warning will be provided, which may result in future funding being reduced if progress does not improve. After this assessment, the Committee will work with the MCL-RI Director to establish milestones for the coming year. The outcome from the Annual Assessment will be sent to the MCL-RI Director within 60 days of the Site Visit.

Annual Reports

Financial, Intellectual Property, and Progress Reports are due annually. The Progress Report will contain a brief summary of the year's research as presented at the Site Visit.

MCL-RI Team Meetings

A key element of a MCL-RI is the integration of the various Projects and Cores. Therefore, an essential component to the success of a MCL-RI is regular interaction of the MCL-RI team. MCL-RI teams should meet via teleconference or in person at least quarterly to discuss results.

Who Can Apply

Citizenship

LLS welcomes applications from both US citizens and non-citizens, as well as applicants who are performing research outside the U.S.

General Eligibility

Applicants must hold a PhD, MD, DVM, or equivalent degree from a non-profit Sponsoring Institution or for-profit Sponsoring Institution at the time funding commences and for the duration of the award. The Director, Project Leaders, and Core Leaders must be independent researchers who are well-established. Junior faculty who are under the direction of a mentor, are not qualified to serve as Director, Project Leaders, or Core Leaders but they are encouraged to participate in Projects that may require their expertise. Applications may involve multiple institutions.

Leadership

The MCL-RI is led by an overall Principal Investigator, called an MCL-RI Director, who is responsible for writing and submitting the application. The MCL-RI Director of a funded MCL-RI is also responsible for the disbursement of funds to the various Projects/Cores, the conduct of the Projects and Cores, and adherence with LLS policy. Each Project and Core is led by a Project Leader or Core Leader, who is responsible for the management of that Project or Core.

Modifications of leadership of funded MCL-RIs (and approved LOIs) must be approved by LLS.

Leadership Limitations

MCL-RI Director

- May only submit one application as a MCL-RI Director
- May be the Project Leader on one other MCL-RI application
- Must be a Project Leader on one proposed Project
- May or may not be a Core Leader

Project Leader(s)

- One Project Leader must be the MCL-RI Director
- May not be a Project Leader on more than one Project in a MCL-RI

- May be the Project Leader on a maximum of two Projects on separate MCL-RI applications submitted
- May have a Project co-Leader

Co-Project Leader(s)

- May be a co-Project Leader and/or Project Leader on a maximum of two Projects on separate MCL-RI applications submitted

Core Leader(s)

- May be a Core Leader on no more than one Core for any one MCL-RI application submitted
- May not be a Core Leader on more than two separate MCL-RI applications submitted
- May or may not be a MCL-RI Director

The Projects and Cores may be at the same institution or at different institutions. Either the demonstrated synergy or the potential synergy of the MCL-RI components will be a critical part of the review process.

Sponsoring Institution's Acceptance of Contract Terms

Applicants who are offered an MCL-RI Award will be sent a contract after Award notification. The Sponsoring Institutional representatives from each participating institution will need to agree to the terms of this contract. The contract is found on LLS's website, www.lls.org ("Academic Grants" subsection of the "Researcher's & Providers" section).

Application Process

The MCL-RI application process consists of two parts: the LOI and full application.

Letter of Intent

In the LOI, the applicant presents a brief description of each Project and Core together with an overview of how the MCL-RI will function as a unit.

Full Application

The full application is a more complete description of the MCL-RI. In some cases, the MCL-RI Directors of several top-ranked applications may be asked to address questions from the review panel. The review panel will then consider those answers before rendering final scores. Only top-ranked applications may be asked for clarification, but this does not guarantee funding.

Review Process

LOIs are reviewed by an independent and voluntary expert panel. The panel decides which LOIs should be invited to submit a full application using the criteria listed below (see *Review Criteria*).

Full applications are reviewed by an independent and voluntary expert panel. The panel assigns a score to each full application. In some cases, the MCL-RI Directors of several top-ranked applications may be asked to address questions from the review panel. The review panel will then consider those answers before rendering a final score. Only top-ranked applications may be asked for clarification, but this does not guarantee funding. The score follows the NIH 1-9 scoring system and score using the criteria listed below (see *Review Criteria*).

Review Criteria

1. The significance of the proposed research to the treatment and cure of mantle cell lymphoma.
2. The experience, background, and qualifications of the MCL-RI Director and Project/Core Leaders.
3. The synergy that is likely to derive from joining interdisciplinary Projects and Cores into an interactive group.
4. The likelihood that the research findings (those at discovery phase) will lead to eventual clinical application, ideally within the period of MCL-RI funding or soon after the funding period.
5. The quality of the resources and environment.
6. The alignment of the quality of and access to patient populations and/or patient specimens with the research plan (where applicable).
7. The clarity of thought and presentation.

Key Dates

Grant Amount	\$2.5 million
Expected Number of Grants	2
Duration	5 years
Call for Proposals	April 1, 2017
Letter of Intent Deadline	May 15, 2017 3 PM/EST
Notice of Full Application Invitation	June 15, 2017
Full Application Phase Deadline	Aug 1, 2017 3 PM/EST
Notification of Awards	Oct 1, 2017
LLS's receipt of signed contracts	November 1, 2017
LLS's receipt of Lay and Scientific Abstracts	November 20, 2017
Funding start date	January 1, 2018

The submission deadlines will be strictly enforced. Please note that all times are Eastern Time (ET). If any date falls on a weekend or US holiday, the deadline becomes the next business day.

It is highly recommended that submissions are done the day prior to the deadline. Internet traffic may be slow near the deadline, which may result in difficulties in submission. In addition, LLS's response time to questions may be delayed by the high volume received near the deadline. Therefore, it is imperative that any questions be posed to LLS as far ahead as possible. Our electronic grants management system automatically shuts down new submissions after the deadline has passed.

General Instructions for Applying

All submissions must use LLS's online grants management portal at <https://lls.fluxx.io/>. It is highly recommended that you familiarize yourself with this portal well in advance of any deadlines.

If you do not have an account with LLS, contact researchprograms@lls.org with your full name and organization contact information. A new account will be created for you and your log in credentials will be emailed to you by an LLS staff member.

Under "Information" on the left navigation bar, click "MCL-RI."

Click "Apply to MCL-RI!"

Follow the instructions for each web form field. Bold font indicates required information.

Character limitations include spaces. Character and other length limitations are strictly enforced on the web form and the uploaded project description template. If character limits are not adhered to, the application may be triaged.

You may save your work and return to it at any time by clicking "Save." Clicking "Submit" will lock your application and prevent further modification at that stage. Contact researchprograms@lls.org if you submit in error (must be before the deadline).

Once your LOI is submitted, you will receive an automated email from the system. Consider that these emails may end up in your spam filter.

If your LOI is selected by the review panel, you will have access to the full application. Click on your request to continue with your application.

Download and complete the project description template, including all required signatures, and upload to the "Project Document" section towards the bottom of the web form. Margins are preset and must not be changed. Text must be written single spaced in Times New Roman 12pt. Only one PDF file is accepted in this section, so delete any other documents uploaded during the process.

Click the "Submit" button to formally submit your application to LLS.

Specific Instructions for Applying

Letter of Intent

Institution and Department

Indicate the institution and department for the MCL-RI Director.

MCL-RI Director

Indicate the MCL-RI Director who is responsible for the application and will oversee the integration of the Projects and Cores.

Institutional Signing Official (ISO)

The ISO is the institutional representative responsible for signing and agreeing to the accuracy of the application and the terms of the award, should the application be funded.

Financial Officer

The Financial Officer is the institutional representative responsible for the financial administration of externally-funded research.

Additional Access

Access may be given to one other individual to assist in the application process. The MCL-RI Director is ultimately responsible for the successful submission of the application.

Technology Transfer Officer (TTO)

The TTO is responsible for the contractual and business-related aspects of any patentable discoveries resulting from the Grantee's research activities. Contact information for the TTO will be asked for from those applicants selected for funding.

Zip Code of MCL-RI Director's Institution

Provide the zip code of the MCL-RI Director's institution.

Amount Requested

The maximum total amount (direct and indirect costs) is \$500,000/year. The amount requested will be the amount funded, should the MCL-RI be awarded.

Matching Fund

Describe the nature of the matching funds and values. While ideally the matching contribution will be equal to the award (\$2.5 million from LLS and \$2.5 million or its equivalent from another source), a matching contribution with a minimum value of \$ 1.25 M will be considered. The qualified matching contribution may include, but is not limited to, cash, equipment purchases, salary support for personnel, waiving of institutional indirect costs (up to 20% of the funds supplied by this grant), Pharma funding for novel clinical trial costs (e.g. drug, patient), or

other resources (e.g. patient samples or use of core facilities). The application of institutional resources towards the matching contribution must be either new efforts or extend work already underway and cannot overlap with current grants.

MCL-RI Title

150 character limit.

Proposed Start Date

MCL-RI start on January 1, 2018.

Proposed End Date

MCL-RI end on December 31, 2022.

Projects

Provide the title, Project Leader(s) and Institution of the Project Leader(s) of each Project. See *Leadership* under the *Who Can Apply* section.

Cores

Provide the title, Core Leader(s) and Institution of the Core Leader(s) of each Core. See *Leadership* under the *Who Can Apply* section.

MCL-RI Scientific Statement

The MCL-RI Director should provide an overview of the MCL-RI. Describe the overall proposed research and a brief overview of each Project and Core. Discuss the interactions between the components that will create synergy. Scientific/Greek characters or symbols must not be used. 6,000 character limit.

Scientific Abstract

Leave blank (we require this only for those selected for funding).

Lay Abstract

Leave blank (we require this only for those selected for funding).

Project Details

Provide a brief description, including the specific aims and anticipated results for each Project. Scientific/Greek characters or symbols must not be used. 1,500 character limit.

Core Details

Provide a brief description, including the specific aims and anticipated results for each Core. Scientific/Greek characters or symbols must not be used. 1,500 character limit.

Key Personnel or Collaborators Information

Indicate any personnel, outside of your institution, with whom you have a significant and current interaction regarding your project. Limited to 5 entries.

This information will assist in identifying potential conflicts of interest during the reviewer assignment process.

Biosketches

All Project Leaders and Core Leaders must provide a biosketch using the current NIH format, which includes Other Research Support. Upload the biosketches to the Supporting Documentation section.

Submission and Confirmation

After clicking the “Submit” button, you will receive an automated email stating that your information was successfully submitted. **If you do not receive the email confirmation within 2 business days of submission, contact LLS at researchprograms@lls.org.**

Changes

If extra documents remain after submission and before the deadline, email researchprograms@lls.org and let us know which documents to remove.

Carefully check your PDF prior to submission. If you notice problems with your PDF after you have submitted but prior to the deadline, email researchprograms@lls.org and we will help you upload the correct document if you are unable to delete the incorrect document.

Once the deadline has passed, there can be no changes to the application unless specifically authorized by LLS. The only exceptions that do not require authorization are regulatory updates.

Review and Notification

The independent review panel will review LOIs. LLS will notify applicants via email if the LOI is accepted for full application submission. See *Key Dates*.

Full Application

Full Application

Information provided in the LOI phase will carry through to the full application and must not be changed. The following information is required on the grants management portal and the project template.

Assurances (Required)

Human Subjects

Indicate if human subjects will be involved in the proposed research. The status (approved, pending or exempt) of IRB approval must be provided. Documentation of any current or pending approvals must be contained in the full application template. An application may be submitted with IRB approval pending, but IRB approval must be obtained and provided to LLS prior to the Award start date. For applications that include institutions outside the United States, equivalent documentation must be provided, together with a brief description of the approval process at that institution

Laboratory Animals

Indicate if animals will be involved in the proposed research. The status and date of the Institutional Animal Care and Use Committee (IACUC) approval must be provided. The Animal Welfare Assurance number must be included. Documentation of any current or pending approvals must be provided in the full application template. An application may be submitted with approval pending, but approval must be obtained and provided to LLS prior to the Award start date. For applications that include institutions outside the United States, equivalent documentation must be provided, together with a brief description of the approval process at that institution

Recombinant DNA

Indicate if the proposed research involves recombinant DNA. Documentation of any current or pending approvals must be contained in the full application template. For applications that include institutions outside the United States, equivalent documentation must be provided, together with a brief description of the approval process at that institution

Biohazard Statement

Indicate if the proposed research involves the use of biohazards. Documentation of any current or pending approvals must be contained in the full application template. For applications that include institutions outside the United States, equivalent documentation must be provided, together with a brief description of the approval process at that institution

Clinical Protocol (Required where applicable)

Provide a one page summary of clinical protocols essential to the proposed research. Include approval date and compliance number. Indicate if IRB (or equivalent) approval is pending.

Budget

Enter the information on the web form (and provide on the budget template).

Matching Fund

Describe the nature of the matching funds and values. While ideally the matching contribution will be equal to the award (\$2.5 million from LLS and \$2.5 million or its equivalent from another source), a matching contribution with a minimum value of \$ 1.25 M will be considered. The qualified matching contribution may include, but is not limited to, cash, equipment purchases, salary support for personnel, waiving of institutional indirect costs (up to 20% of the

funds supplied by this grant), Pharma funding for novel clinical trial costs (e.g. drug, patient), or other resources (e.g. patient samples or use of core facilities). The application of institutional resources towards the matching contribution must be either new efforts or extend work already underway and cannot overlap with current grants. Letters of intended matching resources will be required to ensure such funds are available. In the event the matching in kind resources fail to materialize during the grant period, LLS reserves the right to reduce the funding of the program or terminate the grant.

Project Description

Download the project template (including budget and signature pages). Complete the information, including required signatures, and upload on the grants management portal.

Follow the character limits (which include spaces) and page lengths. Margins are preset at 0.5 inches on each side and should not be changed. Only Times New Roman 12 pt. font is acceptable.

Figure legends should be formatted with a font size equivalent of 10 pt or above. The figure legends and the corresponding sections in the project template must clearly identify the model system(s) used (e.g. cell line name, etc.).

All uploaded documents must be combined into a single PDF in the order listed below. Failure to submit as a single PDF in the order below will result in disqualification of the application.

1. Table of Contents

2. MCL-RI Justification and Major Resources (5 page maximum)

This section should include in this order:

- Title
- Overall aims/goals
- Background with scientific and clinical significance
- Innovation
- Overall approach
- Shared Cores
- Resources (other than Cores)
- Collaborations with other MCL-RI personnel
- Citations (Blood Citation format)

There are additional requirements for applicants who are currently on a MCL-RI or who have previously submitted a MCL-RI application that was not funded.

3. Projects (5 page maximum for *each* Project)

Each Project should be listed as a separate section and include in this order:

- Project title
- Project Leader(s)
- Project description
 - Specific aims
 - Background with scientific and clinical significance
 - Previous studies/preliminary data
 - Methods for each aim including potential problems and alternative solutions
 - Interactions with other Projects and Cores
 - Statistical approaches (where applicable)
 - Description of patient populations and samples and how they will be accessed (where applicable); when applicable, robust access to patients and/or samples will form an important part of the review process
 - Resources and environment, particularly those aspects critical to the Project
 - Citations (Blood Citation format)

4. Cores (3 page maximum for *each* Core)

Each Core should be listed as a separate section and include in this order:

- Core title
- Core Leader(s)
- Core description
 - Aims/goals
 - Function/operation
 - Benefits to, and relation with other MCL-RI components
 - Citations (PubMed Citation format)

5. Appendix

This section should include in this order:

- Table of contents
- Assurances (signed copies from appropriate institutional representatives, to be uploaded with the application)
- Letters of support or collaboration (where applicable)
- Clinical protocols
- Up to 2 manuscripts that are not yet available on PubMed may be provided for each Project

6. Budget

The Detailed Budget and Budget Justification sections should provide itemized detail for each major category for each year of the program. Complete all totals and subtotals.

7. Signature Page

Provide all signatures.

Upload the full application components, as a single PDF, in the “Project Document” section on the grants management portal.

All uploaded documents must be combined into a single PDF in the order listed above. Failure to submit as a single PDF in the order above will result in disqualification of the application.

Submission and Confirmation

After clicking the “Submit” button, you will receive an automated email stating that your information was successfully submitted. **If you do not receive the email confirmation within 2 business days of submission, contact LLS at researchprograms@lls.org.**

If extra documents remain after submission and before the deadline, email researchprograms@lls.org and let us know which documents to remove.

Carefully check your PDF prior to submission. If you notice problems with your PDF after you have submitted, but prior to the deadline, email researchprograms@lls.org and we will help you upload the correct document if you are unable to delete the incorrect document.

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