Mantle Cell Lymphoma Therapeutic Studies Grant

Guidelines and General Instructions for Application

TIMELINE:

Application Release Date:	May 24, 2017
Application Deadline:	September 6, 2017 at 5:00 PM EST
Peer Review Process:	September and October 2017
Applicant Notification:	December 2017
Earliest Project Start Date:	March 1, 2018

AWARD OVERVIEW AND SUPPORT:

The Lymphoma Research Foundation (LRF) seeks proposals for clinical/translational studies, including correlative studies, in mantle cell lymphoma (MCL). **Applications to this initiative should relate to work in the clinical setting and/or involve primary MCL patient samples. Proposals which are adjunct to an existing research project in MCL are strongly encouraged.**

Innovative research by definition may uncover new questions and areas requiring further investigation. The intention of the current request for proposals is to fund an adjunct study to complement and build upon existing MCL research. Applications may be for a time frame of up to three years in duration for a budget of no more than $250,000. A minimum of two projects will be funded in this grant cycle.

RESEARCH OBJECTIVES:

Correlative project applications are welcome. Applicants are encouraged to design proposals that will complement existing LRF-funded clinical projects or ongoing clinical trials/recently completed within the NCI Cancer Cooperative Groups or investigator-initiated clinical trials. Possible projects include correlative studies to ongoing trials, utilization of patient samples for specialized analyses, and Phase I or II clinical trials of novel therapeutic approaches. The proposed project should be:

- Focused on the diagnosis, treatment, outcomes, and/or any of the below priority areas as they affect MCL patients.
- Intended to test a new hypothesis based on initial findings in the major study.
- Capable of furthering the understanding of MCL and/or its diagnosis and treatment.
- Have direct clinical relevance/involvement or include primary MCL patient samples or data.

Priority areas identified for funding include:

- **Minimal residual disease.** Projects which seek to examine MRD in MCL and/or develop methods for detecting MRD in MCL patients.
- **Immunotherapies for MCL.** Projects assessing immunotherapy in MCL, for example, biological or epidemiological correlatives of a clinical trial of immunotherapy for MCL.
- **Genomic/genetic analysis of MCL.** Projects identifying critical pathways involved in MCL lymphomagenesis and the molecular predictors of tumor behavior.
- **Prognostic or predictive biomarkers**. Projects identifying prognostic biomarkers of MCL and/or biomarkers predictive of outcomes.

- **Drug Resistance.** Projects identifying and/or defining the role of molecular, biologic, immunologic and micro-environmental factors determining MCL patients' resistance to rituximab and other key anti-lymphoma agents.
- **Host-Tumor Interactions in MCL.** Projects exploring the role of the immune system in modulating MCL and/or the role of the tumor microenvironment in the resistance of MCL to therapies.
- **Heterogeneity of MCL Behavior.** Projects exploring or identifying molecular, biologic, immunologic and micro-environmental factors determining the variability in clinical behavior of MCL.
- **Enhancement of Accrual of MCL patients to clinical trials.** Despite a plethora of attractive agents for clinical trials, progress is slow due to the low accrual rate of patients to clinical trials in the USA. Convincing strategies with measurable endpoints documenting improvement in MCL trial accrual will be considered for funding.
- **Novel therapies.** Projects focused on new therapeutics should explore and elucidate the mechanisms of action.

REVIEW EVALUATIVE FACTORS:

The goal of this LRF research project is to advance and improve treatment and long term outcomes for people with MCL. Applications will be reviewed by the LRF Scientific Advisory Board Executive Committee with this goal in mind. The committee will make a recommendation on applications to the LRF Board of Directors. The LRF Board of Directors will make final funding decisions based on research program priorities.

Reviewers will be asked to evaluate the applications in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of the project's goal. The committee will then consider each of these criteria in assigning the application's final ranking:

- Applicant qualifications and research experience;
- Innovation of proposed research project strategy and objectives;
- Potential clinical application to advancing treatment of MCL patients;
- Reviewers' estimation of likely success and impact of the project;
- Responsiveness of application to the priority research objectives listed in this request.

Additional review considerations:

- Feasibility of the project and other methodological considerations.
- Relationship of the study to a larger project, and the degree to which it will contribute to the outcome of the larger project.
- The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.
- Adequacy of proposed statistical analysis.

PRINCIPAL INVESTIGATOR ELIGIBILITY:

All principal investigators holding an academic faculty appointment at non-profit organizations or public or private institutions in the United States or Canada, such as universities, colleges, hospitals, and laboratories, may apply**.** For-profit entities are not eligible to apply for LRF funds. Questions about eligibility may be directed to researchgrants@lymphoma.org.

Please note: Applications should be filed in the name of the person who will serve as the primary PI for administrative purposes. Co-PIs may be designated in the Key Personnel section of the application. Please see the Proposal Format section on pg. 3 and the FAQ document for further details on primary and co-PI responsibilities.

PUBLIC ACCESS POLICY – PubMed CENTRAL:

LRF funded researchers are required to submit, or have submitted for them, to the National Institutes of Health's PubMed Central database an electronic version of the author's final manuscript including all modifications from the publishing and peer review process (the "postprint") upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. This requirement applies to all grants awarded after May 1, 2012, whether LRF funds the research in whole or in part.

All scientific progress reports must include the PMC ID number (PMCnnnnn) to publications in Pub Med Central supported by the Lymphoma Research Foundation effective May 1, 2012.

APPLICATION PROCESS:

SUBMISSION INFORMATION:

All interested grant applicants must submit their applications online through proposalCENTRAL (https://proposalcentral.altum.com) by **5:00 PM EST on September 6, 2017**. Applicants are encouraged to contact LRF at researchgrants@lymphoma.org for questions or concerns relating to issues of eligibility for or responsiveness to this RFP. **Applications that do not meet eligibility requirements will not be reviewed.**

NOTE: Applications will not be accepted after the deadline.

To avoid being rushed at deadline time, applicants are encouraged to register and complete a professional profile at proposalCENTRAL ***now***. Applicants should make sure their grants and contracts office has registered their institution and signing officials with proposalCENTRAL.

PROPOSAL FORMAT:

A complete application includes the following:

1. **Application Signature Page:** proposalCENTRAL will prompt you to generate a printable version of this page when you have completed your application. The applicant and an authorized institutional official should sign in ink, with a scan of the signed page uploaded as a PDF. Please note LRF no longer requires the original document to be mailed to our offices.

2. **LRF Waiver:** the original of the Waiver must be signed by the applicant, and the authorized official of the sponsoring institution. Original signatures in ink are required. A scan of the signed page should be uploaded as a PDF.

3. **Biosketch (Applicant):** Limit to 5 pages (current NIH format). Use the template supplied by PC and upload as a PDF. The applicant should be the person who will serve as PI for administrative purposes – their institution will receive and disburse grant funds and provide financial reporting while applicant serves as primary contact for scientific progress reports.

4. **Biosketch (Key Personnel):** Limit to 5 pages (current NIH format). Use the template supplied by PC and upload as a PDF. Key Personnel should include any co-PIs, primary collaborators in other departments/institutions, or other key members of the research team.

5. **Research Plan:** Use the template supplied by PC and upload as PDF. Limit Sections 1-4 of your Research Plan to 10 pages, including tables and figures, and a minimum type face of 11 pt. Sections 8 is not included in the page limit.

The Research Plan description should discuss the nature of the proposed research plan and should cover the following points:

1. SCIENTIFIC ABSTRACT
2. SPECIFIC AIMS
3. BACKGROUND (please be concise)
4. PRELIMINARY STUDIES
5. EXPERIMENTAL DESIGN AND METHODS
6. QUANTITATIVE MILESTONES
7. RELEVANCE TO THE UNDERSTANDING AND TREATMENT OF LYMPHOMA
8. REFERENCES

Provide evidence of appropriate facility resources and an adequate number of eligible MCL patients, samples, or other data for the proposed research, and define how these materials will contribute to a significant outcome for MCL specifically. Support letters from pharmaceutical partners/other collaborating entities should be included in the Appendix.

6. **Non-Technical Abstract**: This is a brief description (100 words or less) of the proposed research plan presented in terminology for the general public. It should be in language understandable to the average reader of a daily newspaper but still convey the purpose of the project.

7. **Technical Abstract**: In addition to describing the project using technical language, the Technical Abstract should explain (in 100 words or less) the significance of the research plan to the field of lymphoma. (Note: The non-technical and technical abstracts should explain the significance of the proposed work for patient treatment in lymphoma.)

8. **Keywords:** Please select any applicable keywords in each of the four Areas of Study categories. A thorough, accurate selection of keywords will enable LRF to match your application with appropriate reviewers.

9. **Current and Pending Research Support:** List all active and pending research support for the applicant and co-PIs. Include all individual and institutional support available for the proposed work during its duration. For each item, provide a source of support, identifying number, project title, name of Principal Investigator/Program Director, annual direct costs, and total period of support. Failure to provide evidence of sufficient supporting funds for the proposed research can invalidate the application. ***Note: proposalCENTRAL now records other support in your personal profile. Follow the instructions in the application system to enter or import information from your profile to this section.***

10. **Letters of Reference:** Recommendation letters are not required, but must be submitted before the deadline to be included in an application.

11. **Budget:** Applicants must complete in line with the proposed project budget of up to $250,000 for a project up to 3 years in length (yearly allotments can vary based upon timelines and need). Personnel expenses may include fringe. Institutional overhead is allowable up to 25% (smaller amounts are preferred). The start date for the project should be no earlier than March 1, 2018 and no later than July 1, 2018, with earlier start dates preferred.

APPENDICES:

The following additional documents **should be uploaded in PDF format:** additional information on certifications, review the sample LRF Policy, Terms, and Conditions, section 12.

1. **Support Letters from Pharmaceutical Partners or Other Collaborators**: See "Research Plan" above.
2. **Vertebrate Animals Certification or Statement of Exemption:** See LRF Terms and Conditions, Section 12.
3. **Human Subjects Certification or Statement of Exemption:** See LRF Terms and Conditions, Section 12.
4. **Biohazards Certification or Statement of Exemption:** See LRF Terms and Conditions, Section 12.
5. **Publication Reprints:** Each application is limited to 5 (five) publications.

PLEASE NOTE--About attachments/appendices:
When uploading documents to proposalCENTRAL in the appendices, please be sure to follow the guidelines below in order to ensure that your attachments will be viewed by the reviewers as you intended.

- Ensure that all electronic signatures in your PDF attachment have been validated.
- Review the permissions and security settings in the PDF attachment and be sure that the file is not password protected or locked for editing so that it can merge properly with the rest of the application when downloaded.
- Check all merged documents created in Adobe PDF to make sure that each page is merged properly.

It is important to view the application as a whole as well as each individual attachment before it is submitted. Some unresolved issues above can create problems with the download for reviewers and the application may be missing pages. To check that the whole application is correct and in the proper order, please select the blue hyperlink "Signature Page(s)" in the left menu tab. Then, click the red button "Print Signature Pages and Attached PDF Files." This will create a merged PDF of your application, which includes the attachments that you uploaded. If any pages are missing, please contact PC customer support for further assistance.

FOUNDATION CONTACTS:

Whitney Steen
Manager, Research Grants and Communications
Email: researchgrants@lymphoma.org
Telephone: 212-349-2910

TECHNICAL HELPLINE:

Questions concerning use of the proposalCENTRAL electronic submission system should be directed to the proposalCENTRAL helpline, which is available for questions from applicants during normal business hours (8:30 a.m. – 5:00 pm EST), Monday-Friday.
Phone: 800-875-2563 (Toll-free) or 703-964-5840
Email: pcsupport@altum.com

APPLICATION DEADLINES AND TIMETABLE:

- **Application**

  Submission Deadline: September 6, 2017 at 5:00 PM EST.
  EXTENSIONS WILL NOT BE GIVEN

- **Review**

  September-October 2017

  All applications will be reviewed by the LRF Scientific Advisory Board (SAB).

- **Notification**

  December 2017

  Applicants will receive notification of funding decision no later than December 15, 2017
  Individuals selected as LRF Grantees will receive with their notification an LRF Research Grant Agreement and Policy, Terms, and Conditions for signature by the LRF Grantee and the Sponsoring Institution.

- **Funding**

  Earliest – March 2018

  Funding will commence at the earliest on March 1, 2018. Payments will be made semi-annually to the comptroller or other financial officer of the Institution as indicated on cover sheet of the application form. The Institution will be responsible for disbursing funds to the LRF Grantee and any collaborating institutions.

GENERAL INSTRUCTIONS FOR COMPLETING THE APPLICATION:

Please follow the instructions on the proposalCENTRAL(PC) website. You do not need to complete the application at one time; your application will be saved on the PC server until completed. Incomplete applications cannot be submitted. A complete application must include all of the items listed in the checklist below. All applications must be submitted in English.

PC will enable the Applicant to print out all or part of the application. The signature page and the LRF Waiver page must each be printed out and signed in ink by the Applicant and the Sponsoring Institution's authorized official. Proxy or electronic signatures are not acceptable. The signed document should then be scanned and uploaded to the application before submitting. Please note: LRF no longer requires that the original document be mailed to the LRF offices.

You may also wish to review the Research Grants Policy, Terms and Conditions, which are available on the LRF website at lymphoma.org/grants**.** All **chosen awardees must adhere to** all requirements as stated in the Policy, Terms, and Conditions. Please contact researchgrants@lymphoma.org if you or your institution has concerns or questions about the requirements.

After a successful submission of an application, applicants will receive a confirmation email from proposalCENTRAL.

If selected for award, payments will be made semi-annually to the comptroller or other financial officer of the Institution as indicated on the cover page of the application form. The Institution will be responsible for disbursing funds to the Principal Investigator in accordance with the budget submitted with the application.

All LRF applications, application evaluations, and priority scores are considered confidential and are made available only to the SAB, the Board of Directors (BOD), LRF and PC administrative staff, and other LRF representatives involved in the application process. Applications discussed during the final round of review may receive some feedback from the committee with their response letter, however, full critiques of applications, scores, and rankings are not made available to applicants. Although LRF and PC endeavor to protect the confidentiality of proposal and evaluation materials, confidentiality cannot be guaranteed.

Checklist for Applicants

MCL Therapeutic Studies Grant 2018

Use this checklist as a tool to help in preparing your submission. Ensure that you allow **enough time** to complete the application process to meet the deadline of **5.00 pm (EST) September 6, 2017**, as late applications **will not be accepted**. For questions not addressed in the RFP, you may wish to first review the Application FAQs linked in the left hand side bar of the proposalCENTRAL application.

Questions about these requirements may be directed to researchgrants@lymphoma.org.

Submission Checklist

- ❑ Register and complete a professional profile at proposalCENTRAL (https://proposalcentral.altum.com).
- ❑ Ensure that your grants and contracts office has registered your institution and signing officials with proposalCENTRAL.
- ❑ Begin the application process on the proposalCENTRAL system. You do not need to complete the application all at once; your application will be saved on the server until completed. ***Remember, incomplete applications cannot be submitted.***
- ❑ While letters of support are **not** required for this application, if providing, please make sure your letters of support writers know and can comply with the deadline. ***Please note that your letter writers will not be able to upload their support letters once you officially submit your application, even if the application deadline has not yet passed.***
- ❑ Download and review the "Research Grants Program Policy, Terms and Conditions" as posted on lymphoma.org/grants. Questions about these terms may be directed to researchgrants@lymphoma.org.
- ❑ Print the signature page **and** LRF Waiver page and provide signatures (in ink) by the Applicant and the Sponsoring Institution's authorized official. Once signed, a scan of each document should be uploaded to the application before submission. *Proxy and/or electronic signatures will not be accepted.*

In addition, please note the following required application parts:

- ❑ **Applicant Biosketch**
- ❑ **Key Personnel Biosketch(es)**
- ❑ **Non-Technical Abstract**

- ❑ **Technical Abstract**
- ❑ **Areas of Study – fill out through proposalCENTRAL**
- ❑ **Research Plan – See RFP page 3 for detailed page limits.**
- ❑ **Budget – fill out through proposalCENTRAL**
- ❑ **Appendix – other items needed to support the application (limit 30 pages):**
    - **Regulatory Documentation (IRB, etc.)**
    - **Budget Justification**
    - **Support letters from collaborators/pharmaceutical partners (if essential to proposal)**