

Adolescent/Young Adult Correlative 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 correlative clinical/translational studies in adolescent/ young adult (AYA) lymphomas. **Applications to this initiative may focus on either biomarkers and the biology of AYA lymphomas, or clinical outcomes/survivorship and health services studies which specifically impact the AYA lymphoma population.**

Innovative research by definition may uncover new questions and new areas requiring investigation. Basic funding often does not allow for additional, correlative studies to explore these areas. Adolescent/young adult patients with lymphoma are an understudied population that would particularly benefit from adjunct studies. The intention of the current request for proposals is to fund adjunct studies to complement and synergize with ongoing lymphoma clinical trials, as well as facilitate cooperation between pediatric and adult oncologists who work with this population. **The applications should clearly focus on lymphoma research and have a high degree of relevance to research questions pertinent to adolescent and young adult lymphomas. Projects that incorporate cooperation between pediatric oncology researchers or institutions and adult oncology researchers or institutions are strongly encouraged. Projects should be based at academic or nonprofit research institutions in the United States or Canada.**

Applications may be for a time frame of up to 2 years in duration for a budget of no more than \$50,000 **per year (\$100K in total over 2 years)**. LRF allows 25 percent overhead, smaller overhead amounts are preferred. Up to three projects will be funded based on the recommendations of the grant review meeting and funding availability. The Foundation hopes to fund at least one project in both biomarkers/biology and clinical outcomes/survivorship/health services.

RESEARCH OBJECTIVES AND EVALUATIVE FACTORS:

Applicants are encouraged to design proposals that will complement existing, ongoing clinical trials/recently completed¹; including studies where data collection will be completed in the time frame of the grant. Possible projects include correlative studies to ongoing trials (including translational

¹ "...Recently completed clinical trials," for instance, a case where accrual has been completed but where outcome data are maturing.

laboratory or imaging studies), utilization of patient samples for specialized analyses, quality of life and survivorship issues, and Phase I or II clinical trials of novel therapeutic approaches.

Applications will be reviewed by the LRF Scientific Advisory Board who will make recommendations on applications to the LRF Board of Directors. The LRF Board of Directors will make final funding decisions based on available funds and program priorities. Reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of this goal:

1. Applicant qualifications and research experience;
2. Innovation of proposed research strategy and objectives;
3. Quality and impact of previous work in AYA lymphomas and lymphoma in general;
4. Potential translational/clinical application to advancing treatment and/or improving outcomes for AYA lymphoma patients;
5. Reviewers' estimation of likely success and impact of the project;
6. Responsiveness of application to the priority research areas listed above, including collaborative aspect.
7. Resources, such as facilities and patient study group, available to support the project;
8. Financial resources available from other sources and overlap with possible LRF funding.

The application does not need to be strong in all categories to be judged as likely to have major scientific impact and thus be worthy of a high ranking. Ranking will be assigned based on the overall merit of the proposal. **However, please note that applications that do not directly address AYA lymphomas will be disqualified.**

Additional review considerations:

- Focused on the diagnosis, treatment, outcomes, and/or any of the below priority areas as they affect adolescent and young adult patient populations. Projects may focus on either biomarker/biology/imaging priority areas, or clinical outcomes/survivorship/health services priority areas.
- Associated with an ongoing, clinical research project focused specifically on lymphoma and/or any of its subtypes.
- Intended to test a new hypothesis based on preliminary findings in the major study.
- Capable of furthering the understanding of lymphoma and/or its diagnosis and treatment.
- Have direct clinical relevance/involvement or include primary lymphoma patient samples or data. Research proposals should specify the number of AYA patients or samples in the study.
- Collaboration between pediatric oncology researchers or institutions and adult oncology researcher or institution is strongly encouraged.

Priority areas identified for funding are:

Biomarker/Biology of AYA Lymphomas:

- **Genomic/genetic analysis of lymphoma.** What are the critical pathways involved in AYA lymphomagenesis and what are the molecular predictors of tumor behavior?
- **Identification of biomarkers or biologic features.** What biologic features and/or biomarkers of lymphoma are predictive of the outcome of AYA lymphomas?
- **Host-Tumor Interactions.** How does the immune system modulate lymphoma? Does the tumor microenvironment influence resistance to therapies?
- **Heterogeneity of lymphoma behavior.** What are the molecular, biologic, immunologic and micro-environmental factors determining the variability in clinical behavior of AYA lymphomas? In what ways do lymphomas in the AYA population differ from those occurring in pediatric or older adult groups?
- **Drug resistance.** What are the molecular, biologic, immunologic and micro-environmental factors determining resistance to key anti-lymphoma agents?
- **Novel therapies.** Projects focused on new therapeutics should explore and elucidate the mechanisms of action.
- **Imaging.** What are common imaging characteristics of AYA lymphomas? What imaging modalities offer an accurate method for staging AYA lymphomas?

Clinical Outcomes/Health Services:

- **Enhancement of accrual of 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 lymphoma trial accrual will be considered for funding.
- **Quality of Life.** What factors impact the quality of life of AYA lymphoma patients?
- **Outcomes in AYA lymphoma.** To better understand socioeconomic (race, ethnicity, insurance status, economic status) and psychosocial factors (community vs academic treatment center, pediatric vs adult providers, etc.) that impact outcomes in AYA lymphomas.
- **Late Effects and Second Cancers.** What are the late effects and second cancers associated with modern AYA lymphoma therapy? What are the risk factors (both host, treatment-related, and genetic) that impact the incidence or severity of late effects and second cancers in modern AYA lymphoma therapy?
- **Long-Term Follow Up/Survivorship Care.** To describe transition practices for AYA lymphoma patients from active treatment to long-term follow up. To understand the compliance of AYA lymphoma survivors with adhering to long-term follow up guidelines.

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 the **LRF Adolescent/Young Adult Clinical Studies Correlative Grant**. 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. 4 and the AYA 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:

All interested applicants must submit their applications online through proposalCENTRAL (<https://proposalcentral.altum.com>) **by September 6, 2017 at 5:00 PM EST.** 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. **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.

4. **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.
5. **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.
6. **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.**
7. **Applicant's Biographical Sketch:** 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.
8. **Key Personnel Biographical Sketch(es):** 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.
9. **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. Section 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
 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 AYA patients, samples, or other data for the proposed research, and define how these materials will contribute to a significant outcome for AYA lymphoma specifically. Support letters from pharmaceutical partners/other collaborating entities should be included in the Appendix.

10. **Budget:** Enter a budget in the proposalCENTRAL template outlining the planned expenses for the grant. The budget should be for \$100,000 total for a period of up to two years. Personnel expenses may include fringe. Institutional overhead is allowable up to 25% (smaller amounts are preferred). The start date for Year 1 should be no earlier than March 1, 2018. Budget

justifications may be uploaded in the appendix; if the project will include a subcontract to a collaborating entity, please provide details of the expenses covered by the subcontract in the justification.

APPENDICES:

The following additional documents **should be uploaded in PDF format:**

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 the 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:

A proposalCENTRAL helpline 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: pccsupport@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 all at once; 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 quarterly 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 and collaborating institutions 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

Adolescent/Young Adult Lymphoma Correlative Award 2018

Use this checklist as a tool to help in preparing your submission. The deadline for applications is **5:00 pm (EST) September 6, 2017**. Late applications **will not be accepted**.

Application and 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. ***Incomplete applications cannot be submitted.*** See more on required Application parts below.
- 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 Waiver & Signature pages 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, note the following required application components:

- Applicant Biosketch
- Key Personnel Biosketch(es)
- Non-Technical Abstract
- Technical Abstract
- Areas of Study – fill out through proposalCENTRAL.
- Research Plan – See RFP page 5 for detailed page limits.
- Current and Pending Research Support
- 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)**