

# **Clinical Investigator Career Development Award (2017-2020)**

## ***Guidelines and General Instructions for Application***

### **KEY DATES**

Application Release Date:	June 8, 2016
Application Deadline:	August 31, 2016 at 5:00 PM EST
Peer Review Process:	September and October 2016
Applicant Notification Date:	December 2016
Earliest Project Start Date:	March 1, 2017

### **Introduction**

#### **LYMPHOMA RESEARCH FOUNDATION OVERVIEW:**

The Lymphoma Research Foundation (LRF) remains dedicated to finding a cure for lymphoma through an aggressively-funded research program and by supporting the next generation of lymphoma researchers. LRF provides education for people with lymphoma, their loved ones and caregivers, including comprehensive disease guides and facts sheets, in-person conferences and online resources. The Foundation also provides continuing medical education programs designed to increase the knowledge, skills and performance of healthcare professionals. The Foundation's patient services, including the LRF Helpline, Clinical Trials Information Service, financial assistance programs and Lymphoma Support Network, provide direct support to people with lymphoma.

#### **CAREER DEVELOPMENT AWARD OVERVIEW:**

The Lymphoma Research Foundation (LRF) maintains a strong commitment to supporting young investigators and ensuring they can build a successful career in the field of lymphoma research. The LRF Clinical Investigator Career Development Award (CDA) Program is designed to support physician investigators at the level of advanced fellow or junior faculty member who will contribute to the development of new lymphoma therapies and diagnostic tools. Eligible investigators must have no greater than five years of experience beyond completion of their fellowship or post-doctoral training (the five year limit may be non-sequential in cases of pregnancy or illness).

The goal of the program is to prepare physician investigators to design and administer clinical research studies in lymphoma and assume primary responsibilities for clinical research, protocol writing, Institutional Review Board (IRB) submission and publication. As such, a Career Development Plan is required as part of the Grant Application. The proposed research plan should also develop the necessary knowledge and clinical research skills relevant to the investigator's career goals. The Grant is designed to provide physician investigators with support to spend 35-50 percent of their time implementing clinical research studies in lymphoma.

The LRF Clinical Investigator Career Development Award provides a total of \$225,000 to grantees over three years. The Grant provides salary support in the amount of \$70,000 per year. Incidental funds of \$5,000 per year which may be budgeted for research supplies or professional development expenses such as tuition, registration fees, and travel for courses and meetings that are integral to the Career Development Plan. This Grant does not provide institutional overhead.

## RESEARCH OBJECTIVES AND EVALUATIVE FACTORS:

All projects must be focused on hypothesis-driven clinical research in lymphoma. The project should be developed by the Applicant and should include at least the framework of a research protocol. Applications will be reviewed by members of the LRF Scientific Advisory Board (SAB).

Review of Applications will be based on, but not be limited to, the following factors. Each factor will be judged in reference to its relevance to clinical research in lymphoma.

- Applicant qualifications, relevant clinical research experience, and commitment to pursuing a career in lymphoma clinical research.
- Mentor(s)'s qualifications and record of success in training independent Clinical Investigators.
- Career Development Plan, which clearly leads to research independence.
- Innovation of proposed research strategy and objectives.
- Relevance and research impact to the future of lymphoma treatment.
- Research Implementation Plan.
- Availability of resources, such as facilities and patient study group, to support the project.

## APPLICANT ELIGIBILITY:

1. Applicants must be licensed physicians at a clinical research institution in the United States or Canada for the duration of the LRF Clinical Investigator Career Development Grant, and intending to pursue a career in lymphoma clinical research.
2. Applicants for this award should be clinical physicians in one of the ACGME accredited specialties (e.g., hematology/oncology, pathology, dermatology, radiation oncology).
3. The applicant must be an advanced fellow or junior faculty member with at least 2 years (24 months) of fellowship or postdoctoral training and no greater than 5 years of experience beyond completion of his/her fellowship or post doctoral training (the five year limit may be non-sequential) at the start of the award period (March 1, 2017). Persons with non-traditional career tracks are encouraged to apply. They should have participated in developing new therapeutics and/or diagnostic tools for lymphoma.
4. Applicants must demonstrate that they already possess a broad knowledge of lymphoma biology and treatment and their desire to apply this knowledge to developing and evaluating new treatments.
5. The Clinical Investigator must spend 35 to 50 percent of his/her time in research. This time should be free of major patient care, teaching or administrative responsibilities.
6. The Clinical Investigator will have primary responsibility for the design, protocol writing, IRB submission, conduct, analysis and publication of one or more clinical trials during the award period.
7. The CDA recipient may not simultaneously receive another competitive career development award (such as NIH K-series awards, American Cancer Society Mentored Research Scholar Grants) and/or any grant that supports primarily PI salary during the period of the LRF Grant. Supply and material costs for the clinical research project should be supported by another grant or from institutional funds. The percent of research time for the PI on all active grants should not add up to more than 100%. LRF must be informed as to the sources and the amounts of all extramural/non-institutional funding received by the CDA recipient during the term of the LRF Grant, and reserves the right to determine that the LRF Grant may not be held concurrent with other funding.
8. All LRF applications are self-initiated. LRF does not invite applications from selected individuals, institutions, or laboratories.

### **CAREER DEVELOPMENT PLAN:**

A Career Development Plan (the “Plan”) that describes the course of action the Applicant will take over the three-year grant period to develop the skills and experience necessary to progress to the next level in his or her career to obtain the necessary training to serve as a Clinical Investigator must be included in the body of the application.

Include Budget for tuition, registration fees, and travel for courses and meetings that are integral to the Plan. The Plan must also include a commitment and strategy for writing and publishing a substantial scholarly work demonstrating a mastery of lymphoma research and lymphoma treatment. Page limits and formatting instructions may be found in “Application Process” item 11.

### **MENTORS:**

A Primary Mentor at the Applicant’s institution must be identified in the application and this individual’s role in the training and research activities of the applicant must be described, including a plan for periodic evaluation of the applicant’s progress. In addition to the Primary Mentor, the applicant is encouraged to enlist Associate Mentors to provide specialized training and support in areas such as statistics and the performance and evaluation of procedures, tests, or assays used in the research. The support of an Associate Mentor with expertise in biostatistics is particularly important. It is expected that the experienced Primary Mentor of the Clinical Investigator and, when applicable, Associate Mentors, will provide counsel to the applicant in planning and implementing the clinical protocol, monitoring the research, and in reporting the results, but these documents must be the work of the applicant. The Mentor(s) will also advise the applicant in developing and implementing the Career Development Plan required under the grant. The application must describe how the Primary and, if applicable, Associate Mentors will interact with the Applicant during the period of the award. Each Mentor must submit a biosketch and provide a letter of support committing to their role and interactions as described in the application. Mentors may only support one LRF CDA applicant per grant cycle.

### **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 starting on May 1, 2012.

### **PHYSICIAN PAYMENTS SUNSHINE ACT:**

Please be advised that a portion of LRF’s funding for certain Career Development Awards is underwritten by manufacturers of pharmaceutical drugs and devices and/or other entities who are required to report payments or transfers of value made to U.S. physicians and teaching hospitals under the Physician Payments Sunshine Act. LRF’s understanding is that payments made to the recipient of a Career Development Award that has been supported by one of these entities are reportable as research grants under the Sunshine Act if the applicant is a licensed physician (MD or equivalent) in the United States. Applicants will be notified at the time of the award letter if their grant payments are considered reportable.

## 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 August 31, 2016**. Only the signed LRF Waiver and Signature Page (items 1 and 2 on the list below) should be mailed to LRF, postmarked by the deadline. Applicants are encouraged to contact LRF at [researchgrants@lymphoma.org](mailto:researchgrants@lymphoma.org) for questions or concerns relating to issues of eligibility for or responsiveness to this RFP.

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.

Applications that do not meet eligibility requirements, or that exceed page limitations, will not be reviewed.

### 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. Original signatures from the applicant, sponsor, and institutional official are required. The signed original should be sent along with the LRF Waiver to the address on page 8.
2. **LRF Waiver:** the original of the Waiver must be signed by the applicant, the primary Mentor, 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, and the original should be sent (along with the signature page) to the address on page 8.
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. (Note: The non-technical and technical abstracts should explain the significance of the proposed work for patient treatment in lymphoma.)
5. **Statement of Level of Effort:** Provide the approximate percentage of time that the applicant will devote to each work activity (e.g., research, clinical, teaching, administration, other). The Clinical Investigator must spend a minimum of 35 to 50 percent of his/her time in lymphoma clinical research. This time should be free of major patient care, teaching, or administrative responsibilities.
6. **Current and Pending Research Support:** List all active and pending research support for the applicant. 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.*

Research support for the mentor should be indicated using the Mentor Support template and uploaded as an attachment; list all active support with support in lymphoma/CLL highlighted, and indicate if the support will apply to the project proposed in the application.

7. **Primary Mentor's Letter of Support:** This letter should demonstrate the Mentor's support of your project and commitment to provide the necessary training and supervision. Upload in PDF format.
8. **List of three Individuals who will supply Letters of Support:** In addition to providing a letter of support and commitment from the Applicant's Mentor, list three (3) additional individuals who are familiar with your past work and/or training and who are providing letters of support. The PC application manager will notify these individuals, and their (blinded) letters of support will automatically be included with your submission. **Please be sure to list the names of your letter writers early enough so that they have adequate time to submit a letter. Letters must be submitted by the deadline of August 31, 2016 or you will not be able to submit your application.**
9. **Applicant's Biographical Sketch:** Limit to 4 pages. Use the template supplied by PC and upload as PDF.
10. **Mentor(s) Biographical Sketch(es):** Limit to 4 pages. Use the template supplied by PC and upload as PDF.
11. **Career Development Plan:** Limit to 2 pages. Use the template supplied by PC, and upload as PDF. The Career Development Plan should describe the course of action the Applicant will take over the 3-year grant period to obtain the necessary training to serve as a Clinical Investigator. The Plan should provide sufficient detail to demonstrate that, at the conclusion of this award, the Applicant will have acquired a high level of knowledge, skills and experience in lymphoma clinical research. The Plan should include how the Applicant intends to participate in advanced courses, seminars, research meetings and other educational activities at the sponsoring or an affiliated institution, or how such clinical research training will be otherwise acquired. It also should include a commitment and strategy for writing and publishing a substantial scholarly work demonstrating a mastery of lymphoma research and lymphoma treatment.
12. **Description of the Proposed Research:** Use the template supplied by PC and upload as PDF. Limit Sections 1-4 of your Research Plan to 10 pages, as per instructions on the template. Sections 5-8 are 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. SPECIFIC AIMS
  2. BACKGROUND
  3. PRELIMINARY STUDIES
  4. EXPERIMENTAL DESIGN AND METHODS
  5. MILESTONES
  6. SIGNIFICANCE
  7. RELEVANCE TO THE UNDERSTANDING AND TREATMENT OF LYMPHOMA
  8. LITERATURE CITED

Provide evidence of appropriate facility resources and an adequate number of eligible patients for the proposed research. Support letters from pharmaceutical partners/other collaborating entities should be included in the Appendix. If approval for this trial is pending, provide estimate of when approval decision is expected.

Define how the available patient study group will contribute to the outcome of the project.

Propose a clinical protocol.

The Research Plan must address all items listed above. Within page limits, additional pertinent information may be provided. References are not included in the page limitation.

13. **Budget:** Enter a budget in the proposalCENTRAL template outlining the planned expenses for the grant. For salary, fill in \$70,000 for each year (fringe may be included in this amount). In the non-personnel section, outline the planned expenses for the \$5,000 incidentals each year. The start date for Year 1 should be no earlier than March 1, 2017. **Institutional overhead or salary for non-PI personnel is not allowable.**

#### APPENDICES:

The following additional documents should be uploaded in PDF format:

1. **Other Research Support for Mentor:** See “Current and Pending Research Support” directions on pg. 4 of the RFP.
2. **Support Letters from Pharmaceutical Partners or Other Collaborators:** See “Description of the Proposed Research” on pg. 5 of the RFP.
3. **Vertebrate Animals Certification or Statement of Exemption:** See LRF Terms and Conditions, Section 12.
4. **Human Subjects Certification or Statement of Exemption:** See LRF Terms and Conditions, Section 12.
5. **Biohazards Certification or Statement of Exemption:** See LRF Terms and Conditions, Section 12.
6. **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

Max Mulcahy, MPA  
Director, Clinical and Scientific Programs

Phone: 212-349-2910  
Email: [researchgrants@lymphoma.org](mailto:researchgrants@lymphoma.org)

#### 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: 800-875-2562(Toll free) or 703-964-5840

E-mail: [pcsupport@altum.com](mailto:pcsupport@altum.com)

#### APPLICATION DEADLINES AND TIMETABLE:

- **Application**

**Submission Deadline: August 31, 2016 at 5:00PM EST.**

**EXTENSIONS WILL NOT BE GIVEN.**

- **Review**

**September-October 2016**

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

- **Notification**

**December 2016**

Applicants will receive notification of funding decision no later than December 23, 2016.

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, the Mentor(s), and the Sponsoring Institution.

- **Funding**

**Earliest – March 2017**

Funding will commence at the earliest on March 1, 2017. 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.

#### 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, the Mentor(s) and the Sponsoring Institution's authorized official. Proxy signatures are not acceptable. The signed original of both documents **must be mailed** to LRF at the following address, postmarked by the application deadline:

Lymphoma Research Foundation  
115 Broadway, Suite 1301  
New York, NY 10006  
Attn: Research Department/CDA



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

After 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 LRF Clinical 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.

## Clinical Investigator Career Development Award Eligibility Checklist

**Use this checklist to help verify your eligibility.** Persons with non-traditional career paths are encouraged to apply. If you remain uncertain about eligibility after completing this form, please email [researchgrants@lymphoma.org](mailto:researchgrants@lymphoma.org).

**Applications must meet all of the following eligibility criteria in order to be reviewed.**

ELIGIBILITY CRITERIA		
<b>1</b>	Applicant is a licensed clinical physician (MD or MD/PhD) at a research institution in the U.S. or Canada. Applicant <b>must</b> be from an ACGME accredited specialty (e.g., hematology/oncology, pathology, dermatology, radiation oncology).	<input type="checkbox"/>
<b>2</b>	Applicant is an advanced fellow (at least 24 months of fellowship training) or junior faculty member with no greater than 5 years of experience beyond completion of his/her fellowship or postdoctoral training as of March 1, 2017. (The five year limit may be non-sequential in case of pregnancy or illness.)	<input type="checkbox"/>
<b>3</b>	Applicant may not simultaneously receive another career development award (such as NIH K-series awards or equivalent).	<input type="checkbox"/>
<b>4</b>	Applicant will spend 35 to 50 percent of his or her time in research as opposed to patient care, teaching, or administrative responsibilities.	<input type="checkbox"/>
<b>5</b>	Applicant has a Primary Mentor at his or her institution, who will oversee the applicant's research training.	<input type="checkbox"/>
<b>6</b>	Applicant is primarily responsible for the design, protocol writing, IRB submission, conduct, analysis and publication of one or more clinical trials during the award period.	<input type="checkbox"/>
<b>7</b>	Applicant's proposed project involves the development of new therapeutics or diagnostic tools for lymphoma.	<input type="checkbox"/>



## Checklist for Applicants

### Clinical Investigator Career Development Award 2017

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) August 31, 2016**, as 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.
- ☐ Three (3) letters of support **in addition to** your Mentor's letter, are required. Applications cannot be submitted if three support letters have not been uploaded - make sure your letter writers know and can comply with the application deadline.
- ☐ 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](http://lymphoma.org/grants). **All** Applicants must adhere to all requirements as stated in the "Terms and Conditions."
- ☐ Print the Waiver & Signature pages and provide signatures (in ink) by the Applicant and the Sponsoring Institution's authorized official. The signed original of each document must be mailed to the address below, postmarked by the application deadline:

Lymphoma Research Foundation  
115 Broadway, Suite 1301  
New York, NY 10006  
Attn: Research Department/CDA

In addition, note the following required application components:

- ☐ Applicant Biosketch
- ☐ Applicant Career Development Plan – see RFP page 5 for detailed page limits
- ☐ Mentor Biosketch(s)
- ☐ Statement of Level of Effort

- ☐ Mentor Letter(s) of Support
- ☐ Three (blinded) general letters of Support
- ☐ 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.)
  - ☐ Mentor’s Research Support
  - ☐ Support letters from collaborators/pharmaceutical partners (if essential to proposal)