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3-year (2009-12)

Clinical Investigator Career Development Grant

GUIDELINES AND GENERAL INSTRUCTIONS FOR APPLICATION

PURPOSE OF AWARD

The purpose of the Lymphoma Research Foundation's (LRF's) 3-year Clinical Investigator Career Development Grant is to fund training of clinicians who will participate in developing new therapeutics and diagnostic tools for lymphoma. Clinicians with up to 5 years of experience after their first full time faculty appointment post fellowship are eligible.

The focus of the training is to prepare clinicians to design and administer clinical studies in lymphoma and to take on the primary responsibilities for clinical trial design, protocol writing, Institutional Review Board (IRB) submission, and publication. The proposed research plan should develop the necessary knowledge and clinical research skills relevant to the investigator's career goals. The Grant is designed to provide clinicians with support to spend a minimum of 35% and up to 50% of their time implementing clinical studies in lymphoma. A Career Development Plan is required as part of the Grant Application.

In our efforts to improve our grant process, Lymphoma Research Foundation will be using an electronic grants submission process. **All interested grant applicants must submit their applications online through proposalCENTRAL (<https://proposalcentral.altum.com>).**

Our online applications for Lymphoma Research Foundation will be available for preparation and submission by June 2, 2008.

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.

ELIGIBILITY

- 1) Applicants must be licensed physicians at a clinical research institution in the U.S. or Canada for the duration of the LRF Clinical Investigator Grant.
- 2) Applicants for this award should be clinical physicians including recognized ACGME accredited specialties (e.g., hematology/oncology, pathology, dermatology, radiation oncology).

- 3) As noted above, clinicians with up to 5 years of experience after their first full time faculty appointment post fellowship are eligible. 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) There must be a Primary Mentor at the applicant's institution who will oversee the applicant's research training. The Primary Mentor may support only one applicant.
- 6) In addition to the Primary Mentor, the applicant is encouraged to enlist Associate Mentor(s) to provide specialized training and assistance. The support of an Associate Mentor with expertise in biostatistics is particularly important.
- 7) The Clinical Investigator must spend a minimum of 35 to 50 percent of his/her time in research. This time should be free of major patient care, teaching, or administrative responsibilities.
- 8) 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.
- 9) The Clinical Investigator may not hold another competitively applied for fellowship or career development award during the period of the LRF Grant.
- 10) Supply and material costs for the clinical research project should be supported by another grant or from institutional funds. Applicants must provide evidence of adequate research support.
- 11) 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 3-year grant period to develop the skills and experience necessary to move 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. See GENERAL INSTRUCTIONS FOR COMPLETING APPLICATION, Item # 10.

RESEARCH PLAN

The Applicant must include a description of the proposed research plan in the body of the proposal.

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. 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 bio-sketch and provide a letter of support committing to their role and interactions as described in the application.

EVALUATION CRITERIA

Applications will be reviewed by members of LRF's Scientific Advisory Board (SAB). 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.

EVALUATIVE FACTORS

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 and relevant clinical research experience.
- 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.

STIPEND

The LRF Clinical Investigator Career Development Grant provides support in the amount of \$75,000 per year for 3 years (\$225,000 total). The Grant provides salary and educational support only and does not provide institutional overhead. Funds may be budgeted for tuition, registration fees, and travel for courses and meetings that are integral to the Career Development Plan.

HOW TO APPLY -- PROCESS AND DEADLINES

As noted on page 1 of these Guidelines, in our efforts to improve our grant process, Lymphoma Research Foundation will be using an electronic grants submission process. All interested grant applicants must submit their applications online through proposalCENTRAL (<https://proposalcentral.altum.com>).

Our online application process is expected to be available for preparation and submission by June 2, 2008.

Registration and Profile Submission – Applicant and Applicant Institution

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.

Helpline

A proposalCENTRAL helpline is available for questions from applicants during normal business hours (8:30 a.m. – 5:00 p.m.), Monday-Friday, EST.

Phone: 1-800-875-2562 (toll free) or 703-964-5840

E-mail: pcsupport@altum.com

Benefits

Grant applicants will find many benefits to this new e-grant application process, including:

- Easy-to-complete applications that can be developed, stored, revised, and submitted on-line;
- Paper copies of the application will no longer be required;
- Immediate confirmation of application submission and status updates throughout the process
- Toll-free (1-800-875-2562) and e-mail (pcsupport@altum.com) technical and customer support;

- On-line tutorials available for preparing your proposal online;

IMPORTANT: PLEASE READ!

Portable Document Format - .pdf

Lymphoma Research Foundation will require that applicants submit portions of their proposal (e.g., research plan, biosketches) in portable document format (.pdf). Unlike MS Word or other word processors, the PDF format preserves the formatting of your document: what you see/submit is what reviewers see.

In order to save your documents as PDFs, you will need to use PDF generator software. There are a number of software products available for both PCs and Macs that will convert your documents to PDFs. There are also websites that will do the conversion for you.

Below is a sampling of some of the PDF generators on the market (list provided from the website of the National Endowment for Humanities <http://www.neh.gov/grants/grantsgov/pdf.html>).

Many of these products are free or very low-cost. The descriptions were accurate as of July 2004. Please consult vendor websites for additional information. Lymphoma Research Foundation and proposalCENTRAL do not endorse any particular software.

PDF Generators:

The vendor websites are listed in alphabetical order:

- Adobe: <http://www.adobe.com/products/acrobatstd/main.html>
Print driver that will work with any application. For PC or Mac.
- BLC Technologies: <http://www.gohtm.com/>
Web-based converter. Can be used by PC or Mac. Vendor e-mails PDF back to you.
- Blue Squirrel: <http://www.bluesquirrel.com/products/Click2PDF/>
Print driver that will work with any application. For PC.
- Create Adobe PDF Online: <http://createpdf.adobe.com/>
Web-based converter. Can be used by PC or Mac. Vendor e-mails PDF back to you.
- CutePDF: <http://www.cutepdf.com>
Print driver that will work with any application. For PC.
- Go2PDF: <http://www.go2pdf.com>
Print driver that will work with any application. For PC.
- PdfF995: <http://site4.pdf995.com/>
Print driver that will work with any application. For PC.
- Win2PDF: <http://www.win2pdf.com/>
Print driver that will work with any application. For PC
- Zeon Corporation: <http://www.pdfwizard.com/>
Print driver that will work with any application. For PC

APPLICATION DEADLINES AND TIMETABLE:

❖ **Application**

➔ **Submission Deadline: 5:00PM, September 10, 2008.**

- ✓ All interested grant applicants must submit their applications online through proposalCENTRAL (<https://proposalcentral.altum.com>). 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 p.m.), Monday-Friday, EST. Phone: 1-800-875-2562 (toll free) or 703-964-5840 E-mail: pcsupport@altum.com
- ✓ Questions concerning issues such as eligibility should be directed to E-mail: researchgrants@lymphoma.org

❖ **Review:**

➔ **Deadline: December 31, 2008**

- ➔ All applications will be reviewed by the LRF Scientific Advisory Board (SAB) by the end of December 2008.

❖ **Notification:**

➔ **Deadline: March 2009**

- ✓ Applicants will receive notification of funding decision no later than March 2009

- ❖ Individuals selected as LRF Grantees will receive with their notification an LRF Clinical Grant Agreement and Policy, Terms and Conditions for signature by the LRF Grantee, the Mentor(s), and the Sponsoring Institution.

❖ **Funding:**

➔ **Deadline: July 1, 2009**

- ✓ Funding will commence no later than July 1, 2009. 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 cover page and the LRF Waiver page must be printed out, and must be 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 the cover and waiver pages ***must be mailed*** to LRF at the following address:

Lymphoma Research Foundation
115 Broadway, 13th floor
New York, NY 10006
Attn: Research Department/CDA

The other important document to download or request is the "Clinical Investigator Career Development Grant Policy Statement and Terms and Conditions ("Terms and Conditions")". All Applicants and LRF Clinical Investigators must adhere to all requirements as stated in the "Terms and Conditions."

Receipt of each application will be confirmed via e-mail sent to the Applicant.

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. Written critiques of applications and priority scores are not made available to Applicants. Although LRF and PC endeavor to protect the confidentiality of proposal and evaluation materials, confidentiality cannot be guaranteed.

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

A **complete** application includes the following:

- 1) **Application Cover Sheet:** The original of the cover sheet must be signed by the applicant, the primary Mentor, and the authorized official of the sponsoring institution. Original signatures in ink are required.
- 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.
- 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.
- 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 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.
- 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.
- 9) **Applicant's Biographical Sketch:** Limit to 2 pages. Use the template supplied by PC and upload as PDF.
- 10) **Mentor(s) Biographical Sketch(es):** Limit to 2 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:** Limit to 10 pages, including tables, figures, etc. but not including bibliography. Use the template supplied by PC and upload as PDF. The Research Plan description should discuss the nature of the proposed research plan and should cover the following points:

- SPECIFIC AIMS
- BACKGROUND
- PRELIMINARY STUDIES
- EXPERIMENTAL DESIGN AND METHODS
- MILESTONES
- SIGNIFICANCE
- RELEVANCE TO THE UNDERSTANDING AND TREATMENT OF LYMPHOMA
- LITERATURE CITED

Provide evidence of appropriate facility resources and an adequate number of eligible patients for the proposed research.

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 the 10-page limit, additional pertinent information may be provided. References are not included in the page limitation.

APPENDICES:

The following additional documents are required and should be uploaded in PDF format:

- 13) **Vertebrate Animals Certification or Statement of Exemption** (*See LRF Terms and Conditions, #11 for direction*).
- 14) **Human Subjects Certification or Statement of Exemption** (*See LRF Terms and Conditions, #11 for direction*).
- 15) **Biohazards Certification or Statement of Exemption** (*See LRF Terms and Conditions, #11 for direction*).
- 16) **Publication Reprints:** Each application is limited to 5 (five) publications. .

FURTHER INFORMATION

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 p.m.), Monday-Friday, EST. Phone: 1-800-875-2562 (toll free) or 703-964-5840, E-mail: pcsupport@altum.com.

Questions concerning issues such as eligibility should be directed to E-mail: researchgrants@lymphoma.org.