

## I. CLL Global Research Foundation

The CLL Global Research Foundation (CLLGRF) is a non-profit organization committed to accelerating progress towards the control and cure of chronic lymphocytic leukemia (CLL) and related leukemias and lymphomas. The organization facilitates the development of effective diagnostic, monitoring and therapeutic tools for the management of CLL and related disorders. CLLGRF intends to fast-track the funding process and speed the development of new therapies while focusing on ideas that can reach the clinic within two to three years.

Patients and families provide funding and participate as organization decision-makers. CLLGRF is classified as a public charity and is exempt from federal income taxes under Section 501(c)(3) of the Internal Revenue Code.

## II. Program Aims

The research program's aim is to provide funding for clinical, laboratory, or translational scientists who intend to research innovative ideas for improving the treatment, monitoring or diagnosis of chronic lymphocytic leukemia (CLL). A research priority for the organization is to improve the understanding of CLL cell biology, biochemistry, physiology, morphology and response to therapy.

The program funds patient-oriented research and intends to accelerate the development of new tools for application to CLL patients. *Applications are sought which will have the potential to reach the clinical setting within the next two to three years.* The funds are intended for use as accelerant support for previously initiated projects rather than seed funding.

A further goal of CLLGRF's research program is to strengthen collaborations within the CLL research community, which encourage innovation. As such the CLLGRF will also consider funding projects that promote interaction among the CLL research community.

## III. Proposed Funding

CLLGRF grant funds are not intended to serve as a recurring source of support; rather the funds will serve as accelerant support and hopefully to lead to other grants. The grants are to be used to support the specific project proposed in the application rather than general research functions. Awards will be made for an initial one-year period. Grant recipients can submit a renewal application for an additional year of funding. To be eligible for a second year of funding, applicants must re-compete based on progress made toward pre-established milestones. *Awards will be limited to an annual amount of \$100,000 of which 5% may be used for institutional overhead.* Complete budget justification of the project is required with the full application.

## IV. Eligibility

Individuals with an M.D., Ph.D. or equivalent degree are eligible to submit an application. Applicants must be affiliated with an accredited academic center or research institute (domestic or foreign). Individuals must have demonstrated experience in CLL research as well as an adequate research environment. An application may have collaborators from multiple institutions. However, CLLGRF will contract only with the principal investigator and his or her host institution named in the application. In any given funding cycle, an individual may be the principal investigator on only one application. For prior CLLGRF grant recipients, applications must be unrelated to the previously funded project.

## V. Research Priorities

CLLGRF requests that applications fall under one of the following research priorities:

- ❑ Proteomics and other post-genomic technologies applied to the investigation of CLL
- ❑ Drug development; Molecular definition and characterization of prognostic factors, relevant to the natural history of CLL
- ❑ Molecular targets in CLL; Identification of and interruption of CLL survival pathways
- ❑ New vaccine, gene therapy and immunotherapy approaches
- ❑ New monoclonal antibodies that target CLL cells or restore immune functions
- ❑ Etiology of CLL: a) molecular genetics b) extrinsic factors
- ❑ Methods for quantifying residual disease in CLL
- ❑ Cell/Stroma interaction

CLLGRF intends to promote innovative thinking. Therefore, we will also accept applications that do not directly fall under one of the aforementioned priorities. We will ask all applicants to demonstrate the impact of their proposed project and how it will address the mission of the organization.

## VI. Review Criteria

- ❑ Relevance to the organization's research priorities
- ❑ Novelty of the concept and strategy.
- ❑ Strength of the scientific rationale
- ❑ Likelihood will lead to advance in treatment, diagnosis or monitoring of CLL and related disorders in the near-term
- ❑ Presentation of how research findings will be applied in the clinic in a timely manner (2-3 years)
- ❑ Demonstrated commitment to CLL
- ❑ Strength of the investigator (background, work history, publications, patents)
- ❑ Strength of research environment (facilities, patient population, lab space, data management/analysis)
- ❑ Feasibility to accomplish within proposed budget
- ❑ Demonstration of how CLLGRF funds will accelerate existing support or enable

the activation of new projects

## **VII. Review Process**

Investigators will submit a letter of intent (LOI). The LOI will detail the working hypothesis or question to be addressed, the scientific rationale and experimental design. A subcommittee of the Scientific Advisory Board (SAB) will review the LOIs and the most promising applications will be requested to submit a full application. The SAB will conduct scientific peer review using the review criteria listed above. Two reviewers will be responsible for each application: one SAB member and a relevant external reviewer. External reviewers will be non-voting participants.

Using the reviewer's recommendations, the SAB will assign priority scores and will make recommendations as to which projects should be funded. (The amount of funds available for awards will be pre-determined by the Board of Directors. The Board of Directors reserves the right to change the number of awards or amount of total funds at any point.) The priority scores of the SAB will be considered confidential.

## **VIII. Award Terms**

### **A. Use of funds**

Awarded funds will be used specifically for the purposes outlined in the application. The investigator and institution will comply with the budget provided with the application. The grantee can reallocate funds among expense categories without approval from CLLGRF provided they comply with the limitations below. If significant budget changes are necessary, which would cause deviation to the limitations below, a request must be made and approved by CLLGRF.

Specific limitations on the funds include:

- No funds will be used for secretarial or office expenses
- No more than 5% of the award can be used for institutional overhead
- No more than \$1,000 on travel (for research purposes or the presentation of data pertaining to the grant)
- No more than 30% can be used for permanent equipment purchase (without obtaining prior approval from CLLGRF).

All grants should be activated within three months of the award notification. Delays will be considered only on an individual basis. An executed contract (signed by the grantee/sponsoring institution and CLLGRF) is necessary to consider a grant activated. CLLGRF reserves the right to nullify an award offer if a sponsored research agreement/contract cannot be executed within three months of award notification.

CLLGRF will make payments at the end of the quarter to the controller or other relevant financial officer. The institution will be accountable for disbursing funds to the investigator in accordance with the budget presented in the application.

If the investigator or sponsoring institution fails to comply with the terms and conditions in the contract, CLLGRF could, at its discretion, withhold any or all funds until such deficiency is resolved. At the time, both the sponsoring institution and CLLGRF would be able to terminate the contract by giving ninety (90) days written notice if the deficiency cannot be resolved. At that time, any unexpended funds must be returned to CLLGRF.

If the grantee transfers institutions during the funding period, the investigator must submit an impact statement to CLLGRF describing the effect on the research. CLLGRF will consider the transfer of funds on a case-by-case basis.

Awarding of grants by CLLGRF to investigators should not be considered an employer-employee relationship. Furthermore, CLLGRF does not take legal responsibility for the conduct and acts of the grantee.

#### B. Expectation of Ongoing Interaction with CLLGRF

CLLGRF expects satisfactory research progress and accounting reports during the funding period and at the completion.

##### **After nine months**

The principal investigator will submit a progress report after nine months of funding. The report will be reviewed by CLLGRF to evaluate the progress of each grant. In addition to the scientific progress update, the investigator will provide a summary for the lay public and particularly for CLLGRF's donors. Upon activation of the grant, grantees will be notified as to the deadline of the progress report. Any progress report delinquent by more than thirty (30) days could result in the suspension of funds; the final payment (equal to 25% of the total grant) will be withheld until the progress report is received. Upon review of research progress, CLLGRF reserves the right to terminate any grant if the organization finds insufficient research progress has been made. The progress report will be considered strongly in any renewal application.

In addition, the sponsoring institution's financial officer must submit an accounting report as to how the funds were expended.

##### **Upon expiration of the grant**

A final research report is required within ninety (90) days of the expiration of the grant. The report should summarize the research activities and include copies of any publications pertaining to the research. In addition, the grantee will provide a summary (less than 1 page) for the lay public and particularly for CLLGRF's donors.

The institution's financial officer will also submit a cumulative final accounting within ninety (90) days of the completion or termination of the grant. In the event that funds remain unexpended upon termination of the grant, the funds will be returned to CLLGRF within ninety (90) days.

### **Other interactions**

CLLGRF expects that grantees will generate quality abstracts, papers and presentations that will recognize the support of the organization. Any publications resulting from research funded by CLLGRF should state “Support by the CLL Global Research Foundation.” Likewise any publicity (press releases, articles, etc.) generated by the sponsoring institution should acknowledge “Support by the CLL Global Research Foundation.” The investigator will make available copies of any research published during the funding period and over a subsequent two-year period.

During the funding and subsequent two-year period, the investigator agrees to be available to CLLGRF to discuss the impact of the research on curing and controlling CLL and related disorders. As a condition for receiving CLLGRF’s funds, the investigator also agrees to participate in educational activities to discuss with and promote the research to the Board of Directors and donor community when requested by CLLGRF.

The investigator also agrees to notify CLLGRF of any patent applications that result from research funded by CLLGRF. If CLLGRF finds that its funding has contributed to the development of a product (for which a patent has been applied), then a reasonable royalty sharing between the investigator and/or sponsoring institution and CLLGRF will be discussed. Such provisions will be addressed in the sponsored research agreement.

#### **C. Human Subjects, Laboratory Animals and Biohazards**

If a project pertains to human research or the use of human materials or subjects, then the grantee must provide the Institutional Review Board (IRB) Approval Date and Compliance Number (or certificate of exemption). If approval is pending at time of application submission, applicants should provide a written statement to that effect. The funding will not begin until any required IRB approval is obtained. All grants should be activated within three months of award notification. Therefore, it is the responsibility of the investigator to ensure timely submission of the application to the various review and regulatory bodies.

If laboratory animals will be used in the research, the applicant must include the Institutional Animal Care and Use Committee (IACUC) approval date and the Animal Welfare Assurance number. If approval is pending, applicants should provide a written statement to that effect.

The application must also contain a statement about any potential biohazards and a discussion of the measures in place to minimize these hazards to all individuals. CLLGRF assumes no liability for biohazards and shall be held harmless from the consequences of any biohazard.

#### **D. Multiple Sites**

Grants with collaborators from multiple institutions will be awarded to the principal investigator and his or her host institution named in the application. The principal investigator’s institution will be responsible for entering into sub-contracts with the other

institutions. (Any subcontracting should be in strict compliance with the budget proposed in the application.) Any significant budget variances will need to be approved by CLLGRF. All funds will be paid directly to the principal investigator's host institution and that institution will be responsible for the transfer of funds to other institutions. The PI will be responsible for providing CLLGRF with a complete accounting of the funds.

## IX. Deadlines

The guidelines and call for proposals will be published via the CLLGRF website.

The Letter of Intent must be submitted by **Friday, August 27, 2010 by 5:00 p.m. (CST)** via email to Diane Lee ([drlee@cllglobal.org](mailto:drlee@cllglobal.org)). **In order to adhere to the proposed timetable, no exceptions will be made for late letters of intent or full applications.** Requests from CLLGRF to the investigators for full applications will be made by September 17, 2010. Full applications must be submitted electronically by **Friday, October 15, 2010 by 5:00 p.m. (CST)**. The cover page, with original signatures, must be postmarked by Friday, October 15, and should be mailed to the address below.

Electronic Announcement	7/9/2010
Letter of Intent Deadline	8/27/2010
Notification of invitation to submit proposal	9/17/2010
Full proposal due	10/15/2010
Notification of award	12/31/2010
Funding begins no later than	3/31/2011

\* Dates and other information subject to change; updated information will be made available on the website

For questions, contact:  
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