

I. CLL Global Research Foundation

The CLL Global Research Foundation (CLL Global) 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. **CLL Global intends to fast-track the funding process and speed the development of new therapies with an emphasis on ideas that can reach the clinic within two to three years.**

Patients and other donors provide funding and participate as organization decision-makers. CLL Global 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 primary aim is to provide funding for clinical, laboratory, or translational scientists with innovative ideas for improving the treatment, monitoring or diagnosis of CLL. Through the research program, CLL Global intends 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. Funded projects must demonstrate a visible pathway to the clinic from the original hypothesis.* The funds are intended for use as accelerant support for previously initiated projects rather than seed funding.

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

III. Proposed Funding

CLL Global grant funds should not be viewed as a recurring source of support; rather the funds will serve as accelerant support and hopefully lead to other grants. The grants are to be used to support the specific project proposed in the application as opposed to 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 demonstrate 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 an independent investigator. Independence may be demonstrated by one of the following: appointment with tenure or on the tenure track, independent own laboratory space, independent funding from home institution/other organizations, title of assistant professor or the equivalent. If there are any questions regarding this qualification, please contact Diane Lee (drlee@cclglobal.org)

An application may have collaborators from multiple institutions. However, CLL Global will contract only with the principal investigator (PI) and his or her host institution named in the application. In any given funding cycle, an individual may be the PI on only one application.

For prior CLL Global grant recipients, applications must be unrelated to a previously funded project. Individuals serving as the PI on an active CLL Global-funded project (including Alliance projects) are ineligible to apply as PI or to serve as a significant collaborator during this grant application cycle.

V. Research Priorities

CLL Global is looking for applications that fall under the following research priorities:

- ❑ Proteomics and other post-genomic technologies applied to the investigation of CLL
- ❑ Molecular definition/characterization of prognostic factors, relevant to the natural history of CLL
- ❑ Drug development; Molecular targets; Identification of and interruption of CLL survival pathway
- ❑ 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

CLL Global promotes innovative thinking. Therefore, applications that fall outside of the aforementioned priorities will also be accepted. Applicants will be asked to demonstrate the potential impact of their proposed project and how it will address the organization's mission. **All funded projects should have findings applicable to the clinic setting within 2-3 years of funding.**

VI. Review Criteria

- ❑ Presentation of how research findings will be applied in the clinic in a timely manner (2-3 years)
- ❑ Relevance to the organization's research priorities
- ❑ Novelty of the concept and strategy
- ❑ Strength of the scientific rationale

- ❑ Likelihood to lead to near-term advance in treatment, diagnosis or monitoring of CLL and related disorders
- ❑ Demonstrated investigator 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 CLL Global 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 a 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. Reviewers will sign confidentiality and conflict of interest statements.

Using the reviewers' 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 for the specific purposes outlined in the application. The investigator and institution will comply with the budget provided in the application. The grantee can reallocate funds among expense categories without approval from CLL Global 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 CLL Global.

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 CLL Global)
- ❑ All applications should utilize the NIH salary cap

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 CLL Global) is necessary to consider a grant activated. CLL Global reserves the right to nullify an award offer if a sponsored research agreement/contract cannot be executed within three months of award notification.

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

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

B. Expectation of Ongoing Interaction with CLL Global

CLL Global expects 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 to demonstrate progress. The reports will include a summary for the lay public and CLL Global's donors. Upon activation of the grant, grantees will be notified as to the deadline date 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, CLL Global 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 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 CLL Global'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 CLL Global within ninety (90) days.

Other interactions

CLL Global expects that abstracts, papers and presentations generated from CLL Global support will recognize the organization's support. The acknowledgement should state

“Support by the CLL Global Research Foundation.” Likewise any publicity (press releases, articles, etc.) generated by the 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 CLL Global to discuss the impact of the research on curing and controlling CLL and related disorders. As a condition for receiving CLL Global’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 CLL Global.

The investigator also agrees to notify CLL Global of any patent applications that result from research funded by CLL Global. If CLL Global 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 CLL Global 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 documentation of the Institutional Review Board (IRB) approval 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 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 research project to the various review and regulatory bodies.

If laboratory animals will be used in the research, the applicant must include documentation of the Institutional Animal Care and Use Committee (IACUC) approval 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. CLL Global 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 the 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 CLL Global. 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 CLL Global with a complete accounting of the funds.

Deadlines

The guidelines and call for proposals will be published via the CLL Global website. At this time we are not accepting applications.