



RESEARCH PROGRAM GUIDELINES

Program Oversight

CLL Society's Research Program is managed by the Director of Scientific Affairs & Research. Administrative oversight pertaining is provided by the Research Program Administrator who is responsible for tracking any issues pertaining to the Project(s) and administration of the Grant between the CLL Society, Grantee, and the Sponsoring Institution(s).

Definitions

The following definitions shall apply in this document:

- "Budget" shall outline the details of how the Grantee and Sponsoring Institution will spend the Grant Funds.
- "Deliverables" include the progress reports, financial reports, and other materials to be produced or submitted on behalf of the Project that CLL Society and the Grantee have agreed upon for the Project.
- "Funder" is any third-party organization that may have provided support to CLL Society to sponsor this research.
- "Grant Funds" are the amount of funds that CLL Society is awarding to the Institution as further described in Section II.
- "Grant Term" shall mean the period of performance for this Agreement, which begins on the Effective Date and ends on the Termination Date.
- "Grantee" is identified as the key individual with the primary responsibility for the Project for the entire Grant Term at the level of involvement specified in the Proposal.
- "Medical Records" are any medical records of Project subjects reflecting treatment provided in connection with the Project, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs, and other diagnostic images.
- "Proposal" is the final version, approved by CLL Society, of the proposal for the Project, which is the final version as of the Effective Date.
- "Study Data" are records and reports, other than Medical Records, collected or created pursuant to or prepared in connection with the Project including, without limitation, reports (e.g., case report forms, any data summaries, any interim, any annual, or final report) and all information regarding inventories and disposition of any and all drugs and devices used in or resulting from the Project to the extent housed or maintained at the Institution.

Award of Grant

CLL Society shall provide the Grantee's Institution with Grant Funds in the total amount as outlined in their Agreement. Grant Funds will be paid to the Sponsoring Institution. Because of the importance of the Grantee to the Project, CLL Society reserves the right to provide information about the Grantee (e.g., name, degrees, institution, project title) to any Funders and or media outlets.



Term

The Grant Term of each Grant Award will be as outlined in the Request for Proposal and can vary for each different grant offered. CLL Society will evaluate the progress reports annually for each grant and renew contracts one year at a time for a maximum of the full Grant term. If the performance of a Grant Awardee is ever in question, issues and concerns will be taken to the Research Review Committee for evaluation and discussion and the Awardee will be notified of any suggested opportunities for improvement.

Payments

All payment amounts together for the Grant term should equal the total award amount of the Grant. The Grant Funds shall be divided into equal installments over the grant term and paid annually after approval of submitted annual progress and budget reports. If the annual financial report indicates that an amount less than the annual payment is due to the Grantee's Sponsoring Institution, only the amount indicated will be provided by CLL Society. The final Grant payment will only be made after CLL Society is in receipt of the annual progress reports as set forth within the finalized Grant Agreement.

Use of Grant Funds

The Sponsoring Institution will permit the Grantee to use the Grant Funds for direct research expenses in accordance with the Proposal and Budget following the Grant's Effective Date. The Institution shall be responsible for administering the Grant in accordance with the Proposal. All disbursements shall be in strict accordance with the Grant Agreement.

Grant Funds will be used for research expenses attributable to the Project, which may include:

- Salary and benefit expenses of the Grantee.
- Indirect costs/overhead are limited to 10% of the total annual award amount.

Indirect costs must be kept to a minimum and shall not exceed 10% of the total direct costs of the Grant.

In addition, no Grant Funds may be directed towards salary or benefits of any other supporting individuals. No Grant Funds provided may be used for any political campaign, or to support attempts to influence legislation by any governmental body, other than making available the results of nonpartisan analysis, study, and research. Grant Funds may not become part of the Institution's or any organization's endowment fund, capital campaign, construction, or renovation costs.

Diversity, Equity, and Inclusion

CLL Society is committed to embracing diversity and building spaces of equitable representation to meet the unmet needs of all individuals living with chronic lymphocytic leukemia and small lymphocytic lymphoma (CLL/SLL) in every aspect of our programs and support services. CLL Society believes that in order to meet the needs of all CLL/SLL patients, there must be intention about ensuring diverse representation in research projects supported by the organization. CLL Society embodies this belief by identifying and minimizing health disparities across racial and ethnic groups as a key objective of the Research Program.

CLL Society looks forward to funding Investigators who are inclusive of diversity in their research proposals and who are continually looking to establish a better understanding of the unmet needs of CLL/SLL across all demographic groups. CLL Society believes minority applicants are valued members of the research community and are vital to its success. Women and underrepresented minorities are particularly encouraged to apply for funded opportunities.



Responsibilities of the Sponsoring Institution

The Sponsoring Institution will be accountable for the appropriate use of the Grant Funds and for the performance of the Project. The Institution shall be liable for reimbursement to CLL Society of any Grant Funds associated with any inappropriate or unauthorized expenditures of Grant Funds or fraudulent or improper conduct involving the use of Grant Funds.

The Institution shall ensure that:

- All Project staff use Grant Funds solely and expressly for the approved Research Project.
- The Grantee must exercise proper stewardship over the Grant Funds and ensure that costs charged to the Project are allowable, allocable, reasonable, necessary, and consistently applied.
- CLL Society may disallow any cost if it determines through audit or otherwise, that the cost does not meet the tests of allowability, allocability, reasonableness, necessity, and consistency.

Partial funding of the Project from other sources is acceptable and encouraged to leverage the impact of CLL Society's Research Grant(s). However, it is the responsibility of the Sponsoring Institution to ensure that:

- The total amount charged for any given research expense across all funding sources does not exceed 100% of the actual cost of that research expense.
- Acceptance of this Grant would not jeopardize support it or the Grantee may receive from other sources.
- The Grantee documents any additional funding supporting this Project, or other research that may significantly affect the Project, in the annual progress reports as described in the Agreement.

The Sponsoring Institution and Grantee are required to respond to requests from CLL Society within thirty days when additional information is requested about other funding, such as budgets and project aims, for an evaluation of potential overlap.

If there are any unexpected changes during the agreement term, the Sponsoring Institution will:

- Return to CLL Society any unexpended Grant Funds upon the expiration or earlier termination of the Grant Agreement.
- Notify CLL Society of any change in Project or Use of Funds.
- Notify CLL Society of any changes from the Proposal that may substantially alter the goal, methodology, or specific aims of the Project. These changes must then be reviewed by CLL Society's Research Review Committee. Proposed changes must be approved by the Research Review Committee prior to expenditure of Grant Funds on any such matters not described within the Proposal.
- CLL Society reserves the right to terminate the Grant if the Grantee's position, Project, Institution, or funding support changes substantially from what was described in the original Proposal.
- Notify CLL Society's Research Program Administrator of any absence from professional duties by the Grantee during the Grant Term that extends 30 or more days and the reason for such absence.
- Notify CLL Society in writing within 15 days if the Grantee is appointed to a new position at the Institution during the Grant Term so that CLL Society may determine if the continuation of the Grant is appropriate.
- Notify CLL Society in writing within 30 days if the Grantee notifies the Institution of an intent to transfer to a new institution during the Grant Term. The Grant will be terminated unless a written request is made to CLL Society by the Grantee to transfer the Grant, and such request is approved by CLL Society.
 - In order to request such consent, the Grantee will fill out a transfer application form and submit to CLL Society in writing: (i) a request to transfer the Grant, (ii) an interim progress report, (iii) an updated milestones report, (iv) a financial report of expenditures to date and the amount remaining to be transferred, (v) a written confirmation from the current Institution that it is aware of the transfer, (vi) a written confirmation from the new institution of its willingness to accept responsibility for the Grant, (vii) an updated budget and budget justification outlining how remaining funds will be spent at the new institution, and (viii) a description of any Project



modifications that may be required. CLL Society may request additional information from the Grantee, Sponsoring Institution, or the new Institution as needed. CLL Society will determine, within a reasonable period following receipt of the aforementioned information, if the transfer of the Grant to the new Institution is acceptable. If approved, CLL Society will execute a new Grant Agreement with the new Sponsoring Institution.

Rebudgeting

Prior approval from the CLL Society is required to significantly rebudget. Significant rebudgeting is defined as when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorical commitment level established by the approved budget by more than 20% of the annual Grant amount. To obtain prior approval, the Grantee must submit a formal request in writing, along with a revised budget and budget justification, sent electronically to CLL Society's Grant Specialist. All other budget revisions may be made at the Grantee's discretion, as long as they do not exceed the threshold established by CLL Society and are for eligible expenses as outlined within the executed Grant Agreement.

Reporting Requirements

Initial funding and continued funding of the Project are contingent upon compliance by the Grantee and Sponsoring Institution with the reporting requirements set forth in the Agreement and is based on approval of the annual reports submitted to CLL Society as described.

Progress reports as outlined in the Agreement are due according to the exact dates outlined in the Grantee's Agreement. Annual reports must be submitted using the templates provided by CLL Society no later than 30 days after the report's due date or ongoing funding of the Project will be in jeopardy. Continuation of the Grant funding is dependent upon the Grantee's productivity and evidence of scholarship, and not on obtaining a particular result. CLL Society will withhold release of any future Grant Funds until the scheduled annual reports corresponding to the status of the Project have been submitted and approved. If any scheduled annual report is more than 30 days past due, CLL Society reserves the right to terminate the Grant. CLL Society will inform the Grantee and Institution of approval or deficiencies in annual reports.

Required Annual Reports

The Sponsoring Institution is responsible for the Grantee's compliance with the following reporting requirements:

Annual Reports: The Grantee shall submit a detailed annual progress report to CLL Society corresponding to the first year of the Grant Term summarizing research progress, including a lay summary and a summary of research completed for each specific aim. The Grantee shall also include within the report an update on the progress towards the milestones for that reporting period and a financial report showing the amount of Grant Funds expended, how the Grant Funds were used, and how expenditures compared to the Budget for that reporting period. The annual reports will be due within 30 days from the end of the reporting period as outlined in the Agreement. The annual progress report should be substantive and include relevant and sufficient details.

Final Report: A final progress report, a final updated version of the milestones report, and a final financial report shall be submitted to CLL Society no later than 60 days after the ending date of the Grant Term. Specific due dates are outlined in the Agreement. Unexpended funds should be returned via check made payable to "CLL Society." Grantees may not apply for other CLL Society Grants until the final reports are received and considered acceptable by CLL Society's Medical Advisory Board Research Review Committee. The final progress report should be substantive and comprehensive.

Final Performance Evaluations

All CLL Society grant-supported research projects are subject to final performance evaluations. Annual performance evaluations may also be conducted at CLL Society's discretion. The performance evaluation will be conducted using the



Grantee's Proposal, all progress reports, and an overall performance evaluation rating will be performed by CLL Society's Research Review Committee. If CLL Society, after review of the progress reports and performance evaluation results, believes that the accomplishments did *not* meet the goals and specific aims established for the Project, detailed information on specific areas of deficiency will also be provided to the Grantee and Sponsoring Institution. Grantees will be asked to respond to any deficiencies in the progress identified by any performance evaluation. A Grantee that receives an unfavorable final performance evaluation may become ineligible for CLL Society funding in the future, and the remainder of their contract may be terminated at CLL Society's discretion.

Public Dissemination of Project Information

By accepting this Grant, the Grantee and the Sponsoring Institution give CLL Society and any Funders permission to include Grant information (e.g., name, degrees, institution, project title, grant amount, abstract) in publicly accessible databases. CLL Society may at their discretion provide copies of annual and final progress reports to Funders or their designees, including copies submitted by the Grantee of any publications and/or press releases and/or other publicity materials generated by the Sponsoring Institution. CLL Society and/or the Funder, or its designees, may use publicly non-confidential and/or previously published information from the reports for public dissemination, such as within their newsletters, on websites, or in other similar public resources. *Provided, however, that CLL Society shall not make any disclosure of research results that may affect the validity of the study or influence its results.*

To facilitate such public dissemination, the Grantee and Sponsoring Institution shall fully cooperate with CLL Society in responding to CLL Society's reasonable requests for information with respect to the Project. CLL Society recognizes that information contained within annual and final reports clearly marked as confidential should be treated as such and will inform Funders as necessary that prior approval from CLL Society would be necessary before disclosing confidential information publicly. CLL Society will take into consideration the comments of the Grantee prior to publicly disseminating such reports.

After the Grant Term Has Expired

The Grantee will continue to respond to CLL Society's reasonable requests for information on their career progress and may be requested to provide their current Curriculum Vitae, update their contact information, or provide other relevant information. The Grantee understands that this obligation survives the Grant Term and that they have an ongoing reasonable obligation to provide this information to CLL Society upon request.

Publications and Acknowledgment of Support

The Sponsoring Institution and the Grantee are encouraged to publish and present the results of the Grantee's research conducted under this Agreement. Any publications resulting from research funded in whole or in part by CLL Society Grants must be cited as follows: "Supported by CLL Society's Research Program Grant." If the Grant has a specific name, any reference to the CLL Society Grant should include the Grant name in its entirety.

Electronic copies of all such publications must be forwarded to CLL Society's Director of Scientific Affairs & Research after acceptance, but before publication. In addition, whether during the term of the Grant or afterwards, the Grantee and the Sponsoring Institution shall include the above acknowledgment on any publicity or communications (external or internal) resulting from the Grant, including but not limited to press releases, media reports, interviews, conference talks, and poster presentations of study data. Copies of all such publications must be forwarded to CLL Society's Director of Scientific Affairs & Research.

The Grantee, Sponsoring Institution, and CLL Society may state factually on any of their websites and other materials their involvement with this Project and may reference on such websites any materials published without seeking prior approval from CLL Society.



No external announcement, press release, or other public statement shall be made by the Grantee, Sponsoring Institution, or any of its affiliated members, agents, or subcontractors to publicize their involvement with this Project, regardless of the medium used, without prior written approval of CLL Society, unless required by law or regulation, or to respond to an urgent situation in which it is unreasonable to secure prior approval. CLL Society will use its best efforts to review the language as promptly as possible and its approval will not be unreasonably withheld or delayed. CLL Society will provide the Grantee and Sponsoring Institution with reasonable advance notice and an opportunity to comment prior to issuing any public statement regarding the Project.

CLL Society requires that the Institution list the annual support provided to the Institution by this Grant whenever Institution lists any grantor-supported research during the term of the Agreement.

Use of CLL Society Logo

Prior approval must be obtained from CLL Society for any use of logos, trademarks, or service marks.

Intellectual Property

The Grantee shall own all right, title, and interest in and to all inventions (whether patentable or not), compositions of matter, discoveries, materials, methods, improvements, formulas, processes, products, data, software and other copyrightable works created, made, developed, conceived or reduced to practice by or on behalf of Grantee in the performance of the Project, including without limitation all associated patents, copyrights, trade secrets and know-how (collectively the "Project IP"), subject to the rights granted in the Agreement and as provided herein.

Patent Prosecution and Maintenance

The Grantee shall have the right, at its sole cost, to file for and obtain any patents or other legal protection for any Project IP and CLL Society shall not have any obligations with respect thereto. The Grantee should provide CLL Society with a written disclosure of any Project IP that is or may be patentable or otherwise protectable, and shall notify the Foundation of the filing of any patent application or other legal protection claiming or covering any Project IP, the granting of any patent claiming Project IP, and the licensing or other transfer of rights to any third party to practice any Project IP (whether on an exclusive or non-exclusive basis, and whether for commercial or non-commercial purposes).

Development and Commercialization of Project IP

The Grantee acknowledges in the Agreement, that in accordance with CLL Society's non-profit charitable purpose, Project IP supported with CLL Society funding should be made universally available to patients in a reasonable time frame, at a reasonable price and on a non-discriminatory basis. The Grantee should inform CLL Society of any commercialization efforts with respect to any Project IP and will offer CLL Society the first opportunity to fund or otherwise invest in such commercialization efforts, before offering any third party the right to fund or otherwise invest in such efforts.

Research Ethics Requirements

Should any of the research involve human subjects, the Sponsoring Institution shall certify, and require the Grantee to certify, that the proposed research project has been reviewed and approved in writing by an accredited university or medical school Institutional Review Board ("IRB") constituted in accordance with current regulations disseminated by the United States Department of Health and Human Services ("HHS") and approved by HHS, or by the Association for the Accreditation of Human Research Protection Programs ("AAHRP"). More specifically:

1. Certification by the IRB must be documented by submitting a copy of the institutional letter of approval, which identifies the Principal Investigator (PI) of the Project, the Grantee as an individual authorized to work on the Project, the Project title, the date of approval, and is signed by the IRB Chair or equivalent responsible institutional official. Prior IRB certification for another project cannot be substituted but can be officially amended to include the Project. If the IRB has



deemed the Project to be “Exempt,” a copy of the institutional letter signed by the IRB Chair or equivalent responsible institutional official confirming exempt status must be submitted.

2. The Sponsoring Institution bears ultimate responsibility for protecting human subjects under the Grant, including human subjects at all participating and consortium sites, and for ensuring that an assurance approved by the Office for Human Research Protections (“OHRP”) and certification of IRB approval have been obtained before human subjects research can be conducted at each collaborating site.

3. Grantee shall secure a legally acceptable informed consent from any human subjects taking part in any research supervised by such Grantee funded in whole or in part by Grant Funds in accordance with and to the extent required by current regulations promulgated by HHS.

4. Grantees at non-U.S. institutions must adhere to ethical standards for the protection of human subjects that are at least equivalent to U.S. standards, and to the legal requirements of the country where the research will be conducted. Certification of ethical standards approval must be documented by submitting a letter, which cites all relevant approval and license numbers and dates required by the country where the research will be conducted. In the absence of an official ethical review board (or equivalent) or legal requirements, the Grantee must agree in writing to adhere at minimum to the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects.

Any violation by the Grantee or Sponsoring Institution related to research ethics will be considered a material breach of contract will be grounds for immediate termination of the Agreement.

Research Involving Laboratory Animals

The Sponsoring Institution shall ensure compliance with applicable chapters of the Public Health Service Policy on Humane Care and Use of Laboratory Animals, the NIH Grants and Contracts Policy & Compliance guidelines, and all requirements of the institution where such research shall occur concerning animal welfare. More specifically:

1. Certification by the Institution Animal Care and Use Committee (“IACUC”) or equivalent must be documented by submitting a copy of the institutional letter of approval, which identifies the Principal Investigator (PI) of the Project, the Grantee as an individual authorized to work on the Project, the Project title, the date of approval, and is signed by the IACUC Chair or equivalent responsible institutional official. Prior IACUC certification for another project cannot be substituted but can be officially amended to include the Project.

2. Grantees at non-U.S. Institutions must adhere to ethical standards for the care and use of animals for research purposes that are at least equivalent to U.S. standards and to the legal requirements of the country where the research will be conducted. In the absence of an official ethical review board (or equivalent) or legal requirements, the Grantee must agree in writing to adhere at minimum to the Association for Assessment and Accreditation of Laboratory Animal Care International’s Guide for the Care and Use of Laboratory Animals.

CLL Society will not support the Project if the Institution and Grantee do not provide the requested certification documentation and certification is required to continue the Project. CLL Society will withhold subsequent grant payments until such documentation has been submitted and accepted by CLL Society. Failure to provide the necessary IRB and/or IACUC certification or the equivalent could constitute a material breach of this Agreement and provide a basis for CLL Society to terminate the Agreement at their discretion.

Study Data

The Sponsoring Institution shall ensure the prompt, complete, and accurate collection, recording, and classification of any Study Data and Medical Records under the Grantee’s supervision. The Institution shall:



- Maintain and store Study Data and Medical Records in a secure manner with physical and electronic access restrictions, and environmental controls appropriate to the applicable data type and in accordance with applicable laws, regulations, and industry standards.
- Protect the Study Data and Medical Records from unauthorized use, access, duplication, disclosure, loss, and damage.
- Maintain all Study Data and Medical Records for a period of 10 years after the end of the Project, or as long as required by applicable laws and regulations.
- Afford CLL Society or its designee reasonable access to the Grantee's facilities and shall, at CLL Society's expense, provide copies of Study Data.

Reports referenced in this section should be prepared as part of the Project and not at any additional expense to CLL Society. The Sponsoring Institution and the Grantee shall, upon request, afford regulatory authorities the reasonable access to its facilities and to Medical Records and Study Data, and the right to copy Medical Records and Study Data, subject to appropriate confidentiality and HIPAA protections.

CLL Society will comply with all applicable laws and regulations regarding subject data privacy as they relate to the use and disclosure of individually identifiable health information contained in any patient records. This section will survive termination or expiration of the Agreement between all Parties.

Termination of the Grant Agreement

Grantee may not terminate the Project prior to the end date without compelling cause and prior written approval from CLL Society. Failure to obtain such approval may constitute a breach of the Agreement. The Sponsoring Institution shall require the Grantee to comply with this provision and provide CLL Society with prompt notice of any intent to terminate the Project. If approved, the termination shall be effective on the date upon which the Grantee is notified by CLL Society of approval of Grantee's request to terminate. Any unspent funds shall be returned to CLL Society, and final progress, milestones, and financial reports must be submitted to CLL Society within 60 days of termination.

CLL Society may terminate an Agreement between the Parties at any time, and cease further funding, if CLL Society determines, in its sole discretion, that:

- The Grantee, or Sponsoring Institution has materially breached the Agreement and such breach has not been cured within 30 days after notice is provided of said breach.
- Has significantly deviated from the stated aims of the Proposal without prior approval from CLL Society.
- Is not using Grant Funds for work as set forth in the Proposal or has acted inconsistent with the stated objectives of the Proposal.
- Has committed scientific fraud including fabrication, falsification, or plagiarism in proposing, conducting, or reporting the results of the Project.
- The Sponsoring Institution ceases to be qualified as a non-profit entity that is tax-exempt under federal and state laws.
- Scheduled reports are more than 30 days past due without an explanation having been provided satisfactory to CLL Society.
- The Project is not commenced or pursued in a timely manner or in accordance with the Goals, Specific Aims, and Deliverables outlined in the Proposal.

CLL Society will allow the Grantee or Institution to take corrective measures should the possibility of termination arise from financial, ethical, administrative, or programmatic insufficiencies. In such cases, the Grant will be suspended until corrective actions are taken. CLL Society will notify the Grantee and Institution as to the nature of such insufficiencies and give the Grantee and Institution a reasonable opportunity (no more than 30 days) to resolve the insufficiencies to the satisfaction of CLL Society. If the insufficiencies are not resolved within 30 days or are not otherwise resolved to the reasonable satisfaction of CLL Society, written notice will be provided to the Sponsoring Institution for termination of the Grant.



CLL SOCIETY

Upon notification by CLL Society of termination, a final financial report of expenditures must be submitted by the Sponsoring Institution with a check for the remaining balance of the Grant Funds, as well as final progress and milestones reports outlining the work accomplished to date.

Miscellaneous

The Sponsoring Institution must continue to be during the terms of the Grant Agreement recognized by the Internal Revenue Service (IRS) as a non-profit entity that is tax-exempt under federal and state laws. The Sponsoring Institution must notify CLL Society immediately of any change in its tax-exempt status.

CLL Society has no obligation to provide additional support to the Grantee, Sponsoring Institution, or any other person.