



LEUKEMIA &
LYMPHOMA SOCIETY®
fighting blood cancers

CAREER DEVELOPMENT PROGRAM GUIDELINES & INSTRUCTIONS

Revised July 1, 2012

What's New:

- Eligibility criteria for Fellows and Special Fellows have been redefined. Please read all appropriate sections carefully.
- Applicants with an MD coming off of a clinical fellowship with limited research experience, but who propose a basic research study, are encouraged to apply in the “Fellow” category. These applicants should clearly describe their training experience in the Eligibility Justification section.
- Applicants pursuing the Special Fellow award may apply for either two (2) or three (3) years of funding. Because LLS will not support postdoctoral research training beyond six (6) years, applicants should request only the amount of support that will keep their cumulative postdoctoral training under six years at the end of the LLS award. If the award would extend cumulative postdoctoral training beyond six (6) years you must provide explicit and compelling justification in the “Applicant Eligibility Justification” section. Please note that compelling justification will be restricted to major life events, military service, and medical emergencies and is expected to apply to very few applicants.
- LLS considers the date of the oral thesis defense to be the start of postdoctoral research training. In assessing your eligibility, please use this date. Continuation in a thesis advisor’s laboratory after the oral thesis defense is counted towards the six-year limit in postdoctoral training. If there is any gap between the date of the thesis defense and the beginning of postdoctoral research training, or in the middle of your postdoctoral training, you must provide clear and compelling justification for why this time should not be included in the six-year training limit in the “Applicant Eligibility Justification” section of the proposal.
- Applicants pursuing the Special Fellow or Fellow award will be judged in part on the Sponsor’s record of training individuals who go on to become independent biomedical researchers and on a training plan specific to the Applicant. The Sponsor’s training record will be provided in a Table (*see Sponsor Training Record*) and the individual training plan will be detailed in the Sponsor’s letter (*see Instructions/Full Application/Sponsor’s Letter of Support*).
- Each application will receive two scores: The **Priority Score** with a range from 1-9 is based on the quality of the applicant, training environment, scientific quality of the proposal and relevance to the diagnosis, treatment or prevention of blood cancer. This score may also take into consideration the likelihood of the applicant becoming a dedicated blood cancer researcher. Reviewers will also assign a **Mission Score** based on the following categories:
 - Mission Score of 1** - Addresses mechanisms relevant to the pathogenesis, diagnosis, or treatment of leukemia, lymphoma, and myeloma using patients, patient materials and/or appropriate animal model systems.
 - Mission Score of 2** - Addresses basic biological processes relevant to leukemia lymphoma, or myeloma. Has the potential to identify new pathways and clinically relevant targets.

Mission Score of 3 - Addresses basic mechanisms related to blood cell development, hematopoietic stem cell function, or immune responses.

Mission Score of 4 - Indicates that a proposal does not address mechanisms or basic biological processes relevant to blood cancers or blood cell development and function. If the reviewers assigned to the proposal are in agreement with regard to assigning the application a Mission score of 4, the application can be triaged.

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1. GUIDELINES

a. ABOUT THE LEUKEMIA & LYMPHOMA SOCIETY

The Leukemia & Lymphoma Society (LLS) is a national voluntary health agency dedicated to the conquest of leukemia, lymphoma and myeloma through research. To this end, LLS also supports patient aid, community service programs, advocacy, and public and professional education.

The research projects funded by LLS’s Career Development Program (CDP) must be of the highest quality and clearly related to this mission. Some examples of potentially relevant research areas include but are not limited to: experimental therapeutics, cell growth regulation, cell cycle regulation, DNA damage and repair, experimental carcinogenesis, basic or applied immunology, innovations in prevention, diagnosis or management, and study of infectious diseases of high frequency in immunodeficient patients. Funded projects frequently involve molecular genetics, transgenetics, genomics, proteomics, and/or other cutting edge molecular and cellular technologies.

Details on LLS’s grant portfolio may be found on our website by following this url:
<http://www.lls.org/#/researchershealthcareprofessionals/academicgrants/grantsfinder/>

b. DESCRIPTION OF AWARDS

LLS recognizes the need to support blood cancer researchers in the early phase of their careers. These individuals will continue to provide a foundation for the understanding, diagnosis, and development of treatment and prevention options that will ultimately lead to cures for blood cancer patients. CDP funding is limited to salary support only for the Applicant but may be supplemented by funds from other appropriate sources as determined by the Grantee’s Sponsoring Institution. Support for research-associated costs must be certified as provided by another appropriate source.

CDP is divided into five distinct program categories. The duration and value of a CDP award, as requested in the applicant’s budget, may not exceed what is outlined in Table 1, depending on the specific program category. The maximum award per year includes Applicant salary and fringe benefits, and indirect costs which cannot exceed five percent (5%) of the total direct costs. The final value of the award may be limited by the Applicant’s Sponsoring Institution’s allowable salary range. Fringe benefits, including medical and dental insurance, life insurance, and retirement benefits, may be paid from a Grantee’s award as mutually determined by the Sponsoring Institution and Grantee. Benefit charges applied against the Grantee’s award requires that he or she is eligible to be a participant in such programs. Expenditures for laboratory costs/equipment, travel funds, etc. are explicitly excluded as fringe benefits. The awarded value will be limited to the amount requested in the applicant’s submitted proposal. Any deviations from the applicant’s budget must be requested in writing and will require written approval by LLS.

Table 1: Maximum CDP Award Duration & Value

Category	Years	Maximum Award Per Year	Total Award
Scholar	5	\$110,000	\$550,000
Scholar in Clinical Research	5	\$110,000	\$550,000
Special Fellow	2 or 3	\$65,000	\$130,000 or \$195,000
Special Fellow in Clinical Research	2 or 3	\$65,000	\$130,000 or

			\$195,000
Fellow	3	\$55,000	\$165,000

c. WHO CAN APPLY

Eligibility criteria for CDP awards are described in this section. Please note that this section provides both criteria for all Applicants regardless of the program category (*General Eligibility Criteria*) and additional criteria specific for each program category. Please read this section carefully to determine eligibilities.

i. General Eligibility Criteria

Citizenship

Applicants need not be United States (U.S.) citizens nor associated with U.S.-based Sponsoring Institutions. LLS welcomes applications from qualified investigators outside the U.S.

Degree and Experience

Applicants should hold a PhD, MD, D.V.M. or equivalent degree at the time of review (January 1, 2013). Please refer to Table 2 for additional experience requirements.

Institution Affiliation

Applicants must be affiliated with a non-profit Sponsoring Institution at the time funding is to commence and for the duration of the award. A non-profit Sponsoring Institution includes but is not limited to the following: academic institution, university, medical center, research hospital, medical research institute, research institution or laboratory. All awards will be payable to and administered by the Grantee’s Sponsoring Institution.

Sponsor Requirement

Each Applicant must secure a Sponsor for the proposed research project. The Sponsor must be the person with the most direct supervisory relationship to the Applicant. In the case of Fellow, Special Fellow and Special Fellow in Clinical Research Applicants, the Sponsor (research mentor) provides research supervision, facilities and research financial support. In the case of Scholar and Scholar in Clinical Research Applicants, an appropriate Sponsor is for example a department head, chief of service, or program chairman who can describe the departmental and Sponsoring Institution’s commitment to the Applicant. Applicants may not serve as their own Sponsor. For additional details regarding Sponsor and required Sponsor’s letters in Full Application and Annual Reports, see the Policies & Procedures document (see [Grants Information](#) page) and the following sections of this document including *Guidelines/Terms and Conditions of Awards/Annual Renewal of Funding* and *Instructions/Full Application/ Sponsor’s Letter of Support*.

Application Limitations

Applicants may submit only one (1) application. In addition, no more than one application in each program category will be accepted from any one Sponsor (lab head) in any one calendar year. We do not limit the number of applications submitted from a specific institution; the limitation is specific to a particular laboratory within an institution. Multiple submissions by individuals within the same category of award and with the same Sponsor will result in disqualification of all Applicants with that Sponsor.

Other Career Development Support

No other award expressly intended for career development may be held prior to or concurrent with a comparable-level Society Award. Examples of such awards include but are not limited to: Fellowships or Senior Fellowships from NIH (i.e. NRSA), NSF or any private agency, Career Development or Clinical Investigator Awards, Established Investigatorships and Professorships from voluntary health agencies or the NIH. An award will not be made to an individual with full institutional salary support or with another award at the same level or a higher level than the requested Society award.

ii. Category Specific Eligibility Criteria

The following table should assist Applicants in determining the most appropriate program category in which to submit an application. The additional eligibility requirements listed below this table are specific for each program category.

Table 2: Program Category Specific Eligibility Criteria

	Scholar	Scholar in Clinical Research	Special Fellow in Clinical Research	Special Fellow	Fellow
Must have one of the following conferred degrees (at the effective date of the award for Fellow)	MD, PhD, DVM, or equivalent	MD, PhD, DVM, or equivalent	MD, PhD, DVM, or equivalent	MD**, PhD***, DVM, or equivalent	MD**, PhD***, DVM, or equivalent
Postdoctoral <u>research</u> experience at time of review* (January 1, 2013)	not applicable	not applicable	≥ 24 months and ≤ 3.5 years	≥ 24 months and ≤ 3.5 years	< 24 months
Holds an independent, faculty-level position - may be tenured at time of review (January 1, 2013)	Yes	Yes	No	No	No
Duration of independent position is ≤ 8 years at time of review* (January 1, 2013)	Yes	Yes	not applicable	not applicable	not applicable
Can be employed by any federal or national government-sponsored laboratory (i.e. National Institutes of Health)	No	No	Yes	Yes	Yes

* Applicants **must** provide details in the application Eligibility Justification section as to the date of their oral thesis defense, date at which graduate/medical degree was conferred by their university, period of post-doctoral research training (including additional time spent in the graduate advisor’s laboratory after the oral thesis defense), and/or period of independence (*see Instructions/Full Application/Proposal Attachments*). Applicants who submit in the wrong program category may be administratively disqualified without review (*see Guidelines/Application Process and Deadlines*).

** Applicants with an MD coming off clinical fellowship with limited research experience, but who propose a basic research study, are encouraged to apply in the “Fellow” category. These applicants should clearly describe their training experience in the Eligibility Justification section.

*** Date of PhD is defined as date of oral thesis defense.

Scholar - Additional Eligibility Criteria

- Must have shown a capacity for independent, sustained, original investigation in a field directly relevant to leukemia, lymphoma and/or myeloma, documented in significant first author/last author publications in first tier, peer-review journals.
- Must be principal investigator on peer-reviewed research grant from a national agency (e.g., NIH, NSF, ACS) or other independent source that supports research costs of proposed work.
- Award is intended to further develop the independent research careers of highly qualified investigators, not to support well-established or senior investigators.
- Must have time and effort to commit to proposed research (versus teaching, administrative, clinical responsibilities) as documented in the Sponsor's letter of support (*see Instructions/Full Application /Sponsor's Letter of Support*).
- Other research support information from the Sponsor is not required.

Special Fellow - Additional Eligibility Criteria (Please read carefully)

- Must have shown a capacity for independent, original investigation in a field directly relevant to leukemia, lymphoma and/or myeloma, documented in significant first author/last author publications in first tier, peer-reviewed journals. **Applicants with an MD coming off of a clinical fellowship with limited research experience, but who propose a basic research study, are encouraged to apply in the "Fellow" category. These applicants should clearly describe their training experience in the Eligibility Justification section otherwise the application will be administratively disqualified**
- Must have a Sponsor (research mentor) who can provide supervision, facilities, and necessary supplies/support for the proposed research project, beyond any provided by a research grant to the Applicant, as evidenced by an active research grant from NIH, ACS, or a similar competitive, peer-review agency that funds the work described in the Special Fellow's application, or funds related work. This information should be explicitly addressed in the Sponsor's letter (*see Instructions/Full Application /Sponsor's Letter of Support*).
- Must be on a trajectory to an independent career that contemplates a position by the end of the award.
- The application will be judged in part on the Sponsor's record of training individuals who go on to become independent biomedical researchers and on a training plan specific to the Applicant. The Sponsor's training record will be provided in a Table (*see Sponsor Training Record*) in the application and the individual's training plan should be detailed in the Sponsor's letter (*see Instructions/Full Application/Sponsor's Letter of Support*).
- **Acceptance of a Special Fellow award requires that the recipient spend at least one year in his/her Sponsor's laboratory as a research fellow (July 1, 2013 – June 30, 2014) before he/she moves to another position.** If the Special Fellow leaves the Sponsor's laboratory before one year, or is appointed to a faculty level tenure track position before one year, the grant must be relinquished and funding returned to LLS.
- Need not, but may obtain, a research grant at the time of or during the period of the award.
- **May not request support from LLS that would extend post-doctoral research training beyond six (6) years, counted from the date of the oral defense for the graduate degree through the end of requested support from the LLS. All time spent in the thesis advisor's laboratory following the thesis defense counts as time spent in postdoctoral training. Applicants can apply for either two or three years of funding.** If the applicant applies for two years of funding, funding will begin July 1,

2013 and end on June 30, 2015. If for three years, funding will begin on July 1, 2013 and end on June 30, 2016. The applicant cannot exceed six years of post-doctoral training at the end of the training period (June 30, 2015 for two year awards or June 30, 2016 for three year awards).

- **The applicant must explain why he/she needs to continue his or her training for two or three more years, and how the Special Fellow award will allow the applicant to achieve his or her career goals.** The sponsor should provide a similar explanation in his or her letter.

Fellow - Additional Eligibility Criteria

- Must have a Sponsor (research mentor) who can provide supervision, facilities, and supplies/support for the proposed research project, as evidenced by an active research grant from NIH, ACS, or a similar competitive, peer review agency that funds the work described in the Fellow's application, or funds related work. This information should be explicitly addressed in the Sponsor's letter (*see Instructions/Full Application/Sponsor's Letter of Support*).
- The application will be judged in part on the Sponsor's record of training individuals who go on to become independent biomedical researchers and on a training plan specific to the Applicant. The Sponsor's training record will be provided in a Table (*see Sponsor Training Record*) and the individual training plan will be detailed in the Sponsor's letter (*see Instructions/Full Application/Sponsor's Letter of Support*).
- Fellows cannot have completed more than 24 months of postdoctoral training as of January 1, 2013. This includes time spent in the thesis advisor's laboratory following the thesis defense. (*See Instructions/Full Application/Download Templates and Instructions/Full Application/Proposal Attachments.*)
- **Applicants with an MD coming off of a clinical fellowship with limited research experience, but who propose a basic research study, are encouraged to apply in the "Fellow" category. These applicants must clearly describe their training experience in the Eligibility Justification section or the proposal will be administratively disqualified.**

Scholar in Clinical Research - Additional Eligibility Criteria

- Must have shown a capacity for independent, sustained, original clinical investigation in a field directly relevant to leukemia, lymphoma and/or myeloma, documented in so far as significant first author/last author publications in first tier, peer-reviewed journals.
- Must have support for research costs of proposed work from a peer-review national agency (e.g., NIH, NSF, ACS), industry, their institution, or another independent source, awarded to the Applicant.
- Award is intended to further develop the independent research careers of highly qualified investigators, not to support well-established or senior investigators.
- Must have time and effort to commit to proposed research (versus teaching, administrative, clinical responsibilities) as documented in the Sponsor's letter of support (*see Instructions/Full Application /Sponsor's Letter of Support*).
- The proposed studies should translate new concepts in the biomedical, epidemiological, or preventive sciences into clinical practice.
- Preference will be given to Applicants whose research involves an early phase clinical trial of new or innovative therapies.

- Any proposed clinical research should be independently developed and implemented by the Applicant. Ongoing collaborations and sponsorships of clinical research by an industry source (i.e. pharmaceutical or biotechnology company) are acceptable.
- Other research support information from the Sponsor is not required.

Special Fellow in Clinical Research - Additional Eligibility Criteria (Please read carefully)

- Must have a Sponsor (research mentor) who can provide supervision, facilities, and necessary supplies/support for the proposed research project, beyond any provided by a research grant to the Applicant, as evidenced by an active research grant from NIH, ACS, or a similar competitive, peer-review agency that funds the work described in the Fellow's application, or funds related work. This information should be explicitly addressed in the Sponsor's letter (*see Instructions/Full Application/Sponsor's Letter of Support*).
- Must be on a trajectory to an independent career that contemplates a position by the end of the award.
- The application will be judged in part on the Sponsor's record of training individuals who go on to become independent biomedical researchers and on a training plan specific to the Applicant. Both should be addressed in the Sponsor's letter (*see Instructions/Full Application/Sponsor's Letter of Support*).
- **Acceptance of a Special Fellow in Clinical Research award requires that the recipient spend at least one year in his/her Sponsor's lab as a research fellow (July 1, 2013 – June 30, 2014) before he/she moves to another position.** If the Special Fellow in Clinical Research leaves the Sponsor's lab before one year, or is appointed to a faculty level tenure track position before one year, the grant must be relinquished and funding returned to LLS.
- Preference will be given to Applicants whose research involves an early phase clinical trial of new or innovative therapies.
- Ongoing collaborations and sponsorships of clinical research by an industrial source (i.e. pharmaceutical or biotechnology company) are acceptable.
- If an MD, must have at least twenty four (24) months of adult or pediatric hematology, oncology, hematology/oncology, or hematopathology training at the time of review (January 1, 2013). Training in other disciplines, for example nuclear medicine or radiation therapy, may also be acceptable, if the focus is on preparation for a career devoted to clinical research relevant to the prevention, diagnosis, or therapy of leukemia, lymphoma, or myeloma.
- If a PhD or equivalent, must have completed at least twenty four (24) months of postdoctoral research training in a clinical discipline at the time of review (e.g., cytogenetics, molecular pathology) and provide evidence that the career focus will be on the prevention, diagnosis, or treatment of leukemia, lymphoma, or myeloma.
- Need not, but may obtain, a research grant at the time of or during the award.
- Must not request LLS support that would extend post-doctoral research training (excluding clinical training) beyond six (6) years. **Applicants can apply for either two or three years of funding to comply with the requirement that** applicants cannot exceed six years of post-doctoral training at the end of the funding period without providing explicit and compelling justification in the "Applicant

Eligibility Justification” section of the proposal. Compelling justification will generally be restricted to major life events, military service, and medical emergencies.

d. APPLICATION PROCESS AND DEADLINES

All Applicants must submit a Letter of Intent (LOI) on the proposalCENTRAL website (*see Instructions/General/Using proposalCENTRAL*). It is the Applicant’s responsibility to apply in the correct category.

Once the LOI is processed by LLS, the Applicant will have access to the Full Application. LOIs and Full Applications will only be accepted via proposalCENTRAL. Applicants and Sponsoring Institutions must register independently with the proposalCENTRAL site in order for Applicants to apply (*see Instructions/General/Using proposalCENTRAL*).

The submission deadlines will be strictly enforced. Please note that all times are Eastern Standard Time (EST). If any date falls on a weekend or a U.S. holiday, the deadline then becomes the following business day.

Table 3: CDP Grant Application Deadlines – Note: 3pm EST

Application Phase	Date	Time
Letter of Intent – open	July 15	3:00pm EST
Letter of Intent – close	September 15	3:00pm EST
Full Application – close	October 1	3:00pm EST

e. REVIEW PROCESS AND APPLICANT NOTIFICATION

The oversight of the LLS research grant program is the responsibility of the Medical & Scientific Affairs Committee, a standing committee of the Board of Directors. Review of applications is delegated to the Career Development Program Grant Review Subcommittees (Regular and Clinical). Members of these Subcommittees, comprised of experts in the relevant fields of science and medicine, serve on a voluntary basis.

The Career Development Program Grant Review Subcommittees review applications in January following October submission (therefore ‘time of review’ implies January 1st in the year following October submission). Applications will be judged only in the program category in which they are submitted and may be administratively disqualified if they are judged to be in the wrong category.

The Grant Review Subcommittee recommends applicants most qualified for funding to the Medical & Scientific Affairs Committee. The Medical & Scientific Affairs Committee creates a funding recommendation based on the overall scientific quality of applications (Overall Priority Score), relevance to the LLS mission (Mission Score), programmatic review and funds available (LLS Board of Directors determines the budget available for research grants each year). The recommendation is presented to the Mission Oversight Committee (MOC) for final approval.

Each application receives two scores: The **Priority Score** with a range from 1-9 is based on the quality of the applicant, training environment, scientific quality of the proposal and relevance to the diagnosis, treatment or prevention of blood cancer. This score may also take into consideration the likelihood of the applicant becoming a dedicated blood cancer researcher. Reviewers will also assign a **Mission Score** based on the following categories:

Mission Score of 1 - Addresses mechanisms relevant to the pathogenesis, diagnosis, or treatment of leukemia, lymphoma, and myeloma using patients, patient materials and/or appropriate animal model systems.

Mission Score of 2 - Addresses basic biological processes relevant to leukemia lymphoma, or myeloma. Has the potential to identify new pathways and clinically relevant targets.

Mission Score of 3 - Addresses basic mechanisms related to blood cell development, hematopoietic stem cell function, or immune responses.

Mission Score of 4 - Indicates that a proposal does not address mechanisms or basic biological processes relevant to blood cancers or blood cell development and function. If the reviewers assigned to the proposal are in agreement with regard to assigning the application a Mission score of 4, the application can be triaged.

CDP applications will be rank ordered based on their Overall Priority Score (10-90; which reflects the average of all the reviewers' priority scores, multiplied by ten). Applications with a Mission Score in category 1 may receive funding priority despite the fact that their Overall Priority Score is lower than those of other applications in Mission Score categories 2, 3 and 4. Only applications with scores in the exceptional to excellent range (Overall Priority Score = 10 – 39.9) are eligible for funding regardless of mission category rankings.

Applicants selected for funding will be notified as soon as possible, usually within forty-five (45) days of the review (mid-February). Funding status is relayed by mail or email only and is not available by telephone. All priority scores are considered confidential and are available only to LLS Medical & Scientific Affairs Committee, the Career Development Program Grant Review Subcommittee, the LLS Mission Oversight Committee and administrative personnel. Anonymized summary feedback of reviewer critiques will be provided to Applicants only when available.

f. GENERAL SUMMARY OF AWARD TERMS AND CONDITIONS

Applicants, Sponsors and Sponsoring Institution officials should reference LLS Policies & Procedures document for a full description of award terms and conditions and to assist in the completion of the LOI and Full Application. The Policies & Procedures document can be downloaded from the proposalCENTRAL website (*see Instructions/Full Application/Download Templates & Instructions*) and is also available on LLS website on the [Grants Information](#) page. The following is meant to provide a brief summary of selected sections from that document.

Grant Payments

If an Applicant is selected for funding, a contract will be forwarded for signing by the Grantee, Sponsor and Sponsoring Institutional representatives (including the Technology Transfer Officer). The funds awarded shall be used solely for the purposes specified and in strict compliance with the budget submitted in the application to LLS and executed by the Applicant, Sponsor, Sponsoring Institution and Officers. All grant payments will be made pro rata at the end of each quarter. It is the Sponsoring Institution's responsibility to disburse funds to the Grantee during the term of the award. The final grant payment shall be made only after the receipt by LLS of a satisfactory and complete final Annual Report (see the following paragraph for an overview and the Policies & Procedures document for information on reporting requirements).

Annual Renewal of Funding

Although contracts are issued for the full term of the award, continuation of funding is **contingent upon timely submission of satisfactory and complete Annual Reports** (see LLS Policies & Procedures for specific details and submission deadlines) and LLS's ability to continually raise funds. **In general, every Annual Report includes 1) a research progress report (including scientific and lay audience summaries, update on clinical trials and relevant new publications), 2) a Sponsor's evaluation (of research progress and updates to information provided in the initial letter of support), 3) an intellectual property & invention disclosure form, and 4) a financial accounting report.** These reports shall be completed on Society provided template/forms, submitted online (see [Grant Reporting & Requests](#) page or www.lls.org) as well as in hardcopy, and shall be reviewed by LLS to evaluate the research progress of each Grantee. LLS reserves the right to terminate any grant if, in its sole discretion, it determines that there has been inadequate research progress or a failure to adhere to the original proposal submitted with the application. **Annual Reports that are more than thirty (30) days late or are incomplete or unsatisfactory will result in suspension of funds until the delinquency is resolved. If delinquency persists beyond ninety (90) days LLS reserves the right to terminate the award with prior written notice provided to the grantee and their research administrator.**

Withholding of Funds

The failure of the Grantee, the Sponsor and/or the Sponsoring Institution to adhere to any of the terms and conditions in the contract shall constitute sufficient grounds for LLS, in its sole discretion, to withhold any or all funds due until the deficiency is corrected to LLS satisfaction. Either LLS or the Sponsoring Institution may then terminate the contract upon giving ninety (90) days written notice, if the deficiency cannot be corrected. In such case, any unexpended balance of funds must be returned to LLS.

2. INSTRUCTIONS

a. GENERAL INFORMATION

This document contains instructions for the submission of an application to the Career Development Program. When completing a Letter of Intent (LOI) or Full Application, please keep the following in mind:

i. USING PROPOSALCENTRAL

LLS is using [proposalCENTRAL](https://ProposalCentral.altum.com) (<https://ProposalCentral.altum.com>) for electronic submission of LOIs and Full Applications. LLS will **not accept fax or hard copy submissions**.

REGISTRATION

Registration of Applicant and Sponsoring Institution in proposalCENTRAL is required in order to submit a LOI or Full Application.

Applicants-

It is the responsibility of the Applicant to register with proposalCENTRAL. Once registered, the Applicant should complete the Professional Profile section (*see Professional Profile below*). Applicants can reference tutorials provided on the proposalCENTRAL website such as: “*How to register as a proposalCENTRAL User*”, “*How to create an application using proposalCENTRAL*”.

Sponsoring Institution-

It is the responsibility of institution officials (i.e. Grants and Contracts Officials) to register the Sponsoring Institution. The information provided by the Sponsoring Institution is important for Applicant eligibility verification and will automatically populate sections of the LOI and Full Application. Sponsoring Institution officials can reference tutorials provided on the proposalCENTRAL website such as “*How to register your institution with proposalCENTRAL*”.

PROFESSIONAL PROFILE

It is imperative that the Applicant carefully complete the Professional Profile section once registered. Much of the information from this Profile will automatically populate sections of the LOI and Full Application. Please keep the following in mind when completing the Profile:

Institutional Designation-

The Profile should be created from the standpoint of where the Applicant will perform the research, not where they are at the date of submission. The Applicant must indicate the name of the Sponsoring Institution as well as the name of the signing officials for the institution. If the Applicant’s Sponsoring Institution is not provided in the drop down menu, the Applicant should contact their institute officials (i.e. Grants and Contract Officials) and request registration of the Sponsoring Institution.

DATA ENTRY

Applicants are not required to complete the online LOI or Full Application in one sitting. The LOI or Full Application may be accessed and changed multiple times as needed prior to the submission deadlines. However, **neither the LOI nor Full Application can be changed once the deadline has passed or applications have been finally submitted.** Moreover, some fields may not be modified in the Full Application following submission of the LOI (*see Instructions/Letter of Intent/Changes*).

ii. ASSISTANCE WITH APPLICATIONS

Applicants are strongly encouraged to first read the Guidelines & Instructions as well as the Policies & Procedures document before asking for assistance.

Contacting proposalCENTRAL-

Applicants should address questions regarding the guidelines, requirements, instructions and assistance to:

*Customer Service
8:30am - 5:00pm Eastern Standard Time
Available Monday through Friday
Telephone (toll-free): (800) 875-2562 x227
or Direct dial: (301) 916-4557 x227
Email: pcsupport@altum.com*

Applicants should not contact LLS, local chapters or any other department within LLS regarding these.

Contacting LLS-

General questions concerning eligibility that are not clarified in this document should be addressed to:

*Director of Research Administration
The Leukemia & Lymphoma Society
1311 Mamaroneck Avenue, Suite 310
White Plains, New York 10605
Telephone: (914) 821-8301/8859
Email: researchprograms@lls.org*

Applicants should not contact the local chapters or any other department within LLS regarding eligibility.

b. REQUIREMENTS

The following are some additional requirements that the Applicant needs to consider while completing the LOI and Full Application.

Relevance-

Proposed research projects must be justifiably related to leukemia, lymphoma and/or myeloma.

Forms and Format-

Templates/forms are provided for the Applicant on the proposalCENTRAL website. Failure to use provided templates/forms may result in the disqualification of the application. All information must be typed in English. Some information will be captured when Applicants populate fields on the proposalCENTRAL website. Fields marked with an asterisk are required. Other information will also be captured using provided templates/forms. All documents must use single-spaced text and one of the following fonts: Arial 11 pt or Times New Roman 12 pt. *Ensure that each document has the correct font size prior to filling out the details of the application.* Margins are preset in the templates

and must remain as is (1 inch all around). The Applicant's name should be typed in the upper right corner of each page. Care should be taken to ensure all documents and fields are accurately completed and follow commonly accepted grammar and punctuation. Page limitations must be observed, as described below.

Compliance-

The Applicant must carefully follow the Guidelines & Instructions as well as the Policies & Procedures or risk the proposal being disqualified.

c. LETTER OF INTENT (LOI)

The LOI was previously referred to as the Preliminary Application in LLS research grant program materials. Each Applicant must submit an LOI by **September 15th at 3:00pm EST** via the proposalCENTRAL website or the following business day if this date falls on a weekend or a U.S. holiday (*see Instructions/General/Using proposalCENTRAL*). All information required of the Applicant for the LOI will be captured electronically on the proposalCENTRAL website. The LOI consist of seven (7) sections. The following provides instructions for completing each section. The Applicant should carefully craft the information requested in the LOI as this information is automatically populated into the Full Application and is subject to the Changes clause listed below.

i. **COMPLETING THE LOI**

Title Page-

Provide a concise title for the proposed project, adhering to the eighty (80) character limitation (including spaces).

Enable Other Users to Access this Proposal-

This section is a convenience option for Applicants that have administrative assistance (at the Applicant's Sponsoring Institution) in completing sections of the LOI or Full Application. This section is not utilized in determination of the Applicant's eligibility or in administrative or programmatic review of applications.

Applicant-

The majority of this section is populated from the Applicant Professional Profile. If there are required fields that do not contain information, the Applicant should click on the Edit Professional Profile button and complete the requested information.

The Applicant Eligibility Questions section collects additional information regarding the eligibility for the specific program category in which the Applicant is applying. Responding to these questions is required of all Applicants:

Sponsor's Name & Institution-

Please provide the name of the Applicant's Sponsor, including the first and last name. Also include the name of the Sponsor's Institution. For example: Joseph Smith at The Institute for Advancing Cancer Research.

Research Cost Support & Source-

For all grants that will support costs of the proposed research, indicate the name of the investigator (Sponsor or Applicant), source, type and identifiers. For example: Joseph Smith's RO1 from NIH, CA#####

Beginning of Training / Appointment-

In the case of Scholars and Scholars in Clinical Research, provide the date (mm/yyyy) the Applicant began their first independent, faculty-level appointment. In the case of Fellows, Special Fellows and Special Fellows in Clinical Research, provide the date (mm/yyyy) the Applicant began post-doctoral training or a clinical fellowship. Please note that for applicants with a graduate degree, the **thesis defense date is defined as the beginning of postdoctoral training.** Thus, time spent in the thesis advisor's laboratory following the thesis defense counts as time in postdoctoral training.

Graduate Research Mentor & Degree Conferring Institution-

This section is only required for Fellows, Special Fellows and Special Fellows in Clinical Research. Indicate with which investigator the Applicant accomplished pre-doctoral research, including first and last names, and the name of the degree-conferring institution. For example: John Wilson at The Medical Center for Cancer Research.

Institution-

This section is automatically populated from the Sponsoring Institution's Profile. The Applicant cannot modify Sponsoring Institution Profiles. However, the Applicant should confirm that the appropriate Sponsoring Institution is listed. If a Sponsoring Institution is not listed or listed incorrectly, the Applicant should select the correct Sponsoring Institution from the list provided. If the Applicant's Sponsoring Institution is not on the provided list, the Applicant should contact the Sponsoring Institution Official (i.e. Grants and Contracts Office) to request that the institution be registered in our proposal site.

Abstracts-

The Applicant should carefully craft the following abstracts:

General Audience Abstract-

Clearly state relevance to one or more blood cancers and briefly describe your proposed research, including problem/question to be addressed, specific aims, and anticipated results, in 200 words or less using non-technical language that can be easily understood by an eighth grade reader. Scientific/Greek characters or symbols must not be used.

Scientific Abstract-

Briefly describe your proposed research, including disease relevance, problem/question to be addressed, specific aims, and anticipated results, in 200 words or less using appropriate technical language. Scientific/Greek characters or symbols must not be used.

Validate-

It is highly recommended that the Applicant validate the LOI. The Validate function is a safety measure for the Applicant to ensure that all required fields of information are completed. Using the Validate function may reduce the risk of LOI disqualification due to incompleteness. If required fields are empty, the system identifies and notifies the Applicant of fields that require information.

Submit-

The Applicant can submit the LOI for consideration in this section. Signatures of the Applicant, Sponsor and Sponsoring Institution are not required for submission of the LOI.

ii. **CHANGES**

Information collected in the LOI will automatically populate fields in the Full Application. Once submitted, changes may only be made after receiving prior approval from the Director of Research Administration. The Applicant should email LLS requesting any change and identifying the elements to be changed (at researchprograms@lls.org; see *Instructions/General/Assistance with Applications*). Any changes made without the prior approval of LLS may result in the disqualification of the application.

iii. **SUBMISSION OF THE LOI**

LLS will not accept fax or hard copies of the LOI. Each Applicant must submit a LOI by **September 15th at 3:00pm EST** via the proposalCENTRAL website or the following business day if this date falls on a weekend or a U.S. holiday. The Applicant will receive an email from proposalCENTRAL stating that the LOI was successfully submitted.

iv. **REVIEW OF THE LOI**

LLS will process submitted LOIs. Do not call or e-mail LLS to determine whether the LOI has been received or when it will be processed. Once a LOI is processed, the Applicant will be notified via email and will then have access to the Full Application. If you submitted an LOI and did not receive the confirmatory e-mail from LLS please e-mail us at researchprograms@lls.org.

3. FULL APPLICATION

Each Applicant must submit a Full Application by **October 1st at 3:00 pm EST** via the proposalCENTRAL website or the following business day if this date falls on a weekend or a U.S. holiday (*see Instructions/General/Using proposalCENTRAL*). Some sections of the Full Application will be captured electronically on the proposalCENTRAL website or were captured during the LOI phase. Other vital pieces of information will be captured in documents that must be downloaded, completed and then uploaded by the Applicant. The Full Application consists of fourteen (14) sections and the following provides instructions for completing each section. The Applicant may not modify any information provided in the submitted LOI as this information is subject to the Changes clause listed above, and may result in disqualification of the application.

a. COMPLETING THE FULL APPLICATION

Title Page-

This information was provided during the LOI phase and should not be modified.

Resubmission: Please indicate if the Applicant has previously submitted a CDP grant application. This is a required field.

Date of Previous Submission-

Provide the date, if known, in the format of mm/yyyy.

Research Descriptors-

These designations provide information that assists in reviewer assignment and portfolio management. The Applicant must follow the instructions below and select only the most relevant descriptor for each category. The Applicant will be provided the opportunity to select additional relevant descriptors in the Abstract section below.

Disease Relevance-

Select from the drop-down list the one disease that is most relevant to this application or select “Basic Research” (see below). The Applicant can only select one option from the drop down menu. LLS recognizes that the work proposed in an application may be directly relevant to more than one blood cancer, and the Applicant will be able to indicate other disease relevance in the Abstract Section. The list of options is provided here in more detail to assist Applicants.

- Acute myeloid leukemias
- Chronic myeloid leukemias
- Other myeloid diseases (including myelodysplastic syndromes, myeloproliferative diseases)
- Acute lymphoid leukemias
- Chronic lymphocytic leukemias / small lymphocytic lymphomas (excluded from Indolent non-Hodgkin’s lymphoma)
- Indolent non-Hodgkin’s lymphomas (including follicular, lymphoplasmacytoid, marginal zone, MALT, cutaneous T-Cell / mycosis fungoides / Sezary syndrome)
- Aggressive non-Hodgkin’s lymphomas (including diffuse large cell, diffuse mixed cell, large cell immunoblastic, lymphoblastic, blastic NK, Burkitt’s, mantle cell, primary mediastinal B-cell, anaplastic large cell, various T-Cell except cutaneous, true histiocytic, primary effusion, central nervous system, AIDS-related)
- Hodgkin’s lymphoma (formerly Hodgkin’s disease)
- Myeloma (including multiple myeloma, plasmacytoma, MGUS and related lymphoid diseases)

- Pediatric blood cancers (including leukemias and lymphomas in children and adolescents)
- Basic research (including but not limited to fundamental biological processes / molecules broadly involved / implicated in cancer formation and/or progression with relevance to more than one blood cancer)

Research Area-

Select from the drop-down list the one research area that is most relevant to this application. The Applicant can only select one option from the drop down menu. LLS recognizes that the work proposed in this application could cross into more than research areas, and the Applicant will be able to indicate additional research areas in the Abstract Section. The list of options is provided here in more detail to assist Applicants.

- General hematopoiesis / immunology / embryology / cell biology (including but not limited to DNA / chromosome replication and repair, cell cycle, apoptosis, migration / homing, signal transduction and including model, non-hematopoietic systems for these studies)
- General blood stem cell biology (including plasticity, lineage commitment)
- Lymphoid, myeloid cell carcinogenesis (including cancer stem cell biology)
- Blood cancer biomarkers (including biomarkers for early detection, diagnosis, prognosis, risk stratification, treatment management)
- Blood cancer therapies, excluding stem cell transplantation (including small molecules, DNA/RNA-based, biologics = antibodies /growth factors / cytokines / other proteins / peptides, cell-based and other immunotherapies)
- Stem cell transplantation (including but not limited to allogeneic, autologous, non-myeloablative)
- Long-term and late effects (including detection / prevention / treatment)

Step Towards Improved Patient Outcomes (Development Step)-

Select from the drop-down list the one step in the development process that best describes the proposed research. The Applicant may only select one option. LLS recognizes that project timelines are not always linear and that more than one step may be applicable. The Applicant will be provided an opportunity to indicate other relevant development steps in the Abstract Section. The list of options is provided here in more detail to assist Applicants.

- Applied technology development (including assays and animal models)
- New biomarker / treatment/ target discovery (including oncogene, tumor suppressor and immunotherapy targets)
- Pre-clinical target validation (including chemo-, radio- and immunotherapy targets)
- Pre-clinical treatment validation (including chemo-, radio- and immunotherapy safety and/or activity in animal and other models)
- Pre-clinical biomarker validation (including biomarkers for early detection, diagnosis, prognosis, risk stratification, treatment management)
- Pre-clinical treatment development (pharmacokinetics, pharmacodynamics, and/or toxicology in animal and other models)
- Phase 1 clinical trials (safe / tolerable dose-finding, in humans)
- Phase 2 clinical trials (preliminary efficacy, in humans)
- Phase 3 clinical trials (efficacy compared to “standard”, in humans)

Download Templates & Instructions-

This section provides a single location for the Applicant to access and download all templates/forms. The Applicant should download a copy of each document and complete the information in the templates/forms provided. Please reference the *Proposal Attachments* section below for detailed guidance regarding the information to include on the

templates/forms. Additional information regarding uploading of documents is also provided in that section. The following is a list of the available documents:

Table 4: Templates & Instructions

Document Name	Document Type	Document Format
Guidelines & Instructions	Instructions	PDF
Policies & Procedures	Instructions	PDF
Applicant - Biographical Sketch	Template	Word document
Sponsor - Biographical Sketch	Template	Word document
Sponsor – Training Record	Template	Word document
Eligibility Justification	Template	Word document
Applicant - Other Research Support	Template	Word document
Sponsor - Other Research Support	Template	Word document
Budget	Template	Word document
Project Description	Template	Word document
Appendices Table of Contents	Template	Word document

*Fellows and Special Fellows only

Enable Other Users to Access this Proposal-

This section allows the Applicant to provide other users access to the proposal, as when an Applicant might have administrative assistance (at the Applicant’s Sponsoring Institution) in completing sections of the Full Application. This section is not used to determine an Applicant’s eligibility, or in review of an application.

Applicant-

The information the Applicant provided in the Professional Profile will automatically populate this section. No additional information is required. Modification of this information from that provided in the LOI can result in the disqualification of the application.

Institution and Contacts-

The first part of this section is automatically populated from the Sponsoring Institution’s Profile. The Applicant cannot modify the Sponsoring Institution’s Profile. The remainder of this section is designed to capture contact information for various individuals that LLS may need to contact if the Applicant is selected for funding. The Applicant should reference the “Instruction” button on the page for detailed directions. Below is a list of the required contacts. If the Applicant does not know who the appropriate individual is, the Applicant should contact the Sponsor or Grants and Contracts officials (or equivalent) for guidance.

Signing Official:

The Signing Official is the institutional representative responsible for the signing and agreeing to the accuracy of the application and the terms of the award should the application be selected for funding.

Fiscal Officer:

The Fiscal Officer is the institutional representative responsible for the financial administration of externally funded research.

Research Administrator:

The research administrator is the institutional representative who is responsible for the day-to-day administration of externally-funded research.

Communications Officer:

The Communications (or Public Relations) Officer is the institutional representative responsible for communications of newsworthy accomplishments made by investigators at the Sponsoring Institution.

Sponsor:

The Sponsor is the institutional representative responsible for assuring, on behalf of the Sponsoring Institution, that the scientific aims of the project are met and to describe the Sponsor's and the Sponsoring Institution's role in development of the Applicant's career.

Letters of Reference-

The Applicant should use this section of proposalCENTRAL to request and monitor the submission of confidential letters of reference. The Applicant should keep in mind the following:

- Three (3) letters are required.
- At least two (2) of the three (3) letters must be from individuals outside the Sponsoring Institution.
- Because faculty and staff members are often away from their home institutions during the summer months, we suggest that Applicants arrange to obtain recommendation letters well in advance of the October 1st deadline.
- These letters must remain confidential and are not to be viewed by the Applicant. For this reason, these letters must be uploaded by the individual who writes the letter.
- The Applicant must enter the email address of each individual from whom a confidential letter has been requested. Then the Applicant can send an email to each reference by clicking the appropriate button on proposalCENTRAL. The email requests a confidential letter for the candidate and provides complete instructions for its submission to proposalCENTRAL.
- The Applicant can also use this section to view the submission status of the confidential letters of reference, but cannot view the content.
- It is the responsibility of the Applicant to ensure that the letters of reference are submitted by the application deadline. For Fellows and Special Fellows, one of these letters should be from the PhD thesis advisor.
- The Applicant's Sponsor may not serve as a reference. The Sponsor letter will be submitted/uploaded from within the *Proposal Attachments* section (see below).

Abstracts-

The Applicant should not modify the Scientific or General Audience Abstracts that were created during the LOI phase as doing so may result in disqualification of the application. The remainder of this section serves to capture additional information that will assist in reviewer assignment and portfolio management. This is the section where the Applicant can indicate additional Disease Relevance, Research Areas and Development Steps relevant to the research proposed in this application.

Keywords-

The Applicant should choose from the following list keywords that are most relevant to the research in this application. This information will assist LLS in reviewer assignment. While there is no limit on keyword selection, the Applicant should choose only keywords that are relevant to the application.

<ul style="list-style-type: none"> • Antibody-based therapeutics / immunotoxins • Antisense oligodeoxynucleotides • Apoptosis / cell survival including Bcl-2, XIAP • Autophagy • C. elegans / worm models • Carcinogenesis, including leukemogenesis, lymphomagenesis, oncogenes, tumor suppressors • Cell adhesion / motility / migration / cytokinesis / cytoskeleton / scaffold • Cell cycle, including cyclins, CDKs, checkpoints • Cell division / mitotic spindle / mitotic checkpoint • Cell growth / proliferation regulation • Cellular aging / senescence 	<ul style="list-style-type: none"> • Chemotherapy, including. Drug resistance, drug discovery • Chromosome biology, including segregation, centromeres, telomeres, chromosome translocations, karyotypes • Clinical trials • D. melanogaster / fly models • DNA damage / mutations / repair, including genomic stability • DNA methylation / DNA methyltransferase • DNA recombination • DNA replication • Embryology • Embryonic stem cells
<ul style="list-style-type: none"> • Endocytosis / internalization / trafficking / clathrin-coated vesicles / intracellular transport / chaperones • Epigenetics, including chromatin, nucleosomes, histone modification, DNA methylation, lysine methylation • Extracellular matrix including integrins, cadherins, stromal cell interactions • Familial inheritance • Genomics • Hematopoiesis / immunology, including Ab and TCR Class Switch, B cell, T cell, dendritic cell, NK cell and myeloid cell biology, differentiation • Immunotherapy, including adoptive, vaccines 	<ul style="list-style-type: none"> • JAK/STAT • Metabolomics, mitochondria, electron transport, glycolysis • MicroRNAs, siRNA, RNA interference • MLL • Myc • NFκB, IKK • Notch • p53 • Pediatric cancers • Pharmacogenomics • Pharmacokinetics, pharmacodynamics • Proteasome / protein folding / ubiquitin
<ul style="list-style-type: none"> • Protein modification (not histones), including farnesylation • Proteomics • Ras • RNA folding • RNA Polymerase • S. cerevisiae / S. pombe / yeast models • signal transduction, including cytokines, growth factors, interleukins, interferons, kinases, protein phosphorylation, phosphatases, glucocorticoids, • Signal transduction, including cytokines, growth factors, interleukins, interferons, kinases, protein phosphorylation, phosphatases, glucocorticoids, ligand/receptor biology, lipid metabolism, phospholipase, GTPase 	<ul style="list-style-type: none"> • Stem cell biology, including niche, self-renewal • Structural biology • Transcription / transcription factor / pocket proteins / mRNA processing, stability • Translation • Transplants, including allogeneic, autologous, bone marrow, cord blood stem cell, and graft-versus- tumor (leukemia), graft-versus-host disease • Virology, including. Viral-associated cancers • Wnt • WT1 • X. laevis / frog models

Disease Relevance-

The disease most relevant to the proposed research was captured in the Title Page section; this section allows the Applicant to identify two (2) additionally relevant diseases. **Choosing more than two (2) may result in disqualification of the application.** The list of options is provided here in more detail to assist Applicants.

- Acute myeloid leukemias
- Chronic myeloid leukemias
- Other myeloid diseases (including myelodysplastic syndromes, myeloproliferative diseases)
- Acute lymphoid leukemias
- Chronic lymphocytic leukemias / small lymphocytic lymphomas (excluded from Indolent non-Hodgkin's lymphoma)
- Indolent non-Hodgkin's lymphomas (including follicular, lymphoplasmacytoid, marginal zone, MALT, cutaneous T-Cell / mycosis fungoides / Sezary syndrome)
- Aggressive non-Hodgkin's lymphomas (including diffuse large cell, diffuse mixed cell, large cell immunoblastic, lymphoblastic, blastic NK, Burkitt's, mantle cell, primary mediastinal B-cell, anaplastic large cell, various T-Cell except cutaneous, true histiocytic, primary effusion, central nervous system, AIDS-related)
- Hodgkin's lymphoma (formerly Hodgkin's disease)
- Myeloma (including multiple myeloma, plasmacytoma, MGUS and related lymphoid diseases)
- Pediatric blood cancers (including leukemias and lymphomas in children and adolescents)
- Basic research (including but not limited to fundamental biological processes / molecules broadly involved / implicated in cancer formation and/or progression with relevance to more than one blood cancer)

Research Area-

The most relevant research area was captured in the Title Page section; this section allows the Applicant to identify two (2) additionally relevant research areas. **Choosing more than two (2) may result in disqualification of the application.** The list of options is provided here in more detail to assist Applicants.

- General hematopoiesis / immunology / embryology / cell biology (including but not limited to DNA / chromosome replication and repair, cell cycle, apoptosis, migration / homing, signal transduction and including model, non-hematopoietic systems for these studies)
- General blood stem cell biology (including plasticity, lineage commitment)
- Lymphoid, myeloid cell carcinogenesis (including cancer stem cell biology)
- Blood cancer biomarkers (including biomarkers for early detection, diagnosis, prognosis, risk stratification, treatment management)
- Blood cancer therapies, excluding stem cell transplantation (including small molecules, DNA/RNA-based, biologics = antibodies / growth factors / cytokines / other proteins / peptides, cell-based and other immunotherapies)
- Stem cell transplantation (including but not limited to allogeneic, autologous, non-myeloablative)
- Long-term and late effects (including detection / prevention / treatment)

Step Towards Improved Patient Outcomes (Development Step)-

The most relevant development step was captured in the Title Page section; this section allows the Applicant to identify two (2) additionally relevant development steps. **Choosing more than two (2) may result in disqualification of the application.** The list of options is provided here in more detail to assist Applicants.

- Applied technology development (including assays and animal models)
- New biomarker / treatment/ target discovery (including oncogene, tumor suppressor and immunotherapy targets)
- Pre-clinical target validation (including chemo-, radio- and immunotherapy targets)

- Pre-clinical treatment validation (including chemo-, radio- and immunotherapy safety and/or activity in animal and other models)
- Pre-clinical biomarker validation (including biomarkers for early detection, diagnosis, prognosis, risk stratification, treatment management)
- Pre-clinical treatment development (pharmacokinetics, pharmacodynamics, and/or toxicology in animal and other models)
- Phase 1 clinical trials (safe / tolerable dose-finding, in humans)
- Phase 2 clinical trials (preliminary efficacy, in humans)
- Phase 3 clinical trials (efficacy compared to “standard”, in humans)

Budget Summary-

The Applicant should complete this section in addition to completing the Budget template (*see Download Templates & Instructions*). The details populated in these fields will be utilized by LLS for management of payments should the application be selected for funding. The Applicant must reference the Policies & Procedures document to fully understand the Terms of the Awards. The Applicant should keep the following in mind:

Personnel Costs-

The salary and fringe benefits cannot exceed limits outlined in LLS Policies & Procedures document available via proposalCENTRAL website and LLS website (*also see Guidelines/Description of Awards*). **Expenditures for laboratory costs/equipment, travel funds, etc. are explicitly excluded as fringe benefits.**

Indirect Costs-

The indirect costs are limited to five percent (5%) of the total direct costs as outlined in LLS Policies & Procedures document available via proposalCENTRAL website and LLS website (*also see Guidelines/Description of Awards*).

Organizational Assurance-

The Applicant must complete the organizational assurance section. The Applicant should carefully read the Policies & Procedures document for a more detailed explanation of organizational assurances for Society sponsored programs. The following provides an overview on completing this section.

Human Subject:

The Applicant must indicate if human materials or subjects will be involved in the proposed research. The status (approved, pending or exempt) of Institutional Review Board (IRB) approval must be provided. The Human Subject Assurance Number (OHRP) must be included. If the research project has received IRB approval, the date must be provided and documentation must be uploaded as the Human Investigation Statement (*see Proposal Attachments below*). The application may be submitted with IRB approval pending. However, an award will not be made without documented IRB approval if it was pending at the time of application submission. It is recommended that the Applicant notify LLS before review (January following October submission) regarding IRB status if approval was pending at the time of submission. If a project is exempt from IRB review, the certificate of exemption must be uploaded as the Human Investigation Statement (*see Proposal Attachments below*).

Laboratory Animals:

The Applicant must indicate if laboratory animals will be involved in the proposed research. The status and date of Institutional Animal Care and Use Committee (IACUC) approval must be provided. The Animal Welfare Assurance number must be included. Documentation of Sponsoring Institutional approval must be uploaded as the Laboratory Animal Statement (*see Proposal Attachments below*). The application may be submitted with IACUC approval pending.

However, an award will not be made without documented IACUC approval if it was pending at the time of application submission. It is recommended that the Applicant notify LLS before review (January following October submission) regarding IACUC status if approval was pending at the time of submission.

Recombinant DNA:

The Applicant must indicate if proposed research involves the use of recombinant DNA. Documentation of Sponsoring Institutional approval must be uploaded with the application. (*see Proposal Attachments below*).

Biohazard Statement:

The Applicant must indicate if proposed research involves the use of biohazards. If the Applicant indicates affirmatively, then an institutional statement of assurances regarding potential biohazards and safeguards must be uploaded as the Biohazard Statement (*see Proposal Attachments below*).

Proposal Attachments-

This section provides the Applicant with a central location in which to upload proposal attachments. Please note that all templates/forms must be converted from Word document format to PDF format as this is the only format acceptable. Format conversion can be accomplished using PDF generator software. Links to free or very low-cost options are available on the proposalCENTRAL website.

This section also provides a secondary location for the Applicant to access and download any templates/forms and instructions. Attachments are classified as optional or required. The Applicant can view three lists while in this section:

- Currently Uploaded Attachments
- Required Attachments
- Templates & Instructions available for downloading

There is not a list for optional attachments. As each document (regardless of optional or required classification) is uploaded, the document will be added to the “Currently Uploaded Attachments” list. As each required document is uploaded, the document will be automatically removed from the “Required Attachments” list. The following is a list of the attachments indicating the attachment type, the classification, and whether a template/form is provided. If a template/form is provided, the Applicant must use this template/form or risk disqualification of the application.

Table 5: Proposal Attachments

Attachment Type	Classification	Template Provided
Signed Signature Page	Required	No*
Applicant Biographical Sketch	Required	Yes
Applicant Eligibility Justification	Required	Yes
Sponsor Biographical Sketch	Required [#]	Yes
Sponsor – Training Record	Required**	Yes
Applicant - Other Research Support	Required [†]	Yes
Sponsor - Other Research Support	Required [#]	Yes
Budget	Required	Yes
Project Description	Required	Yes
Sponsor’s Letter of Support	Required	No
Appendix Table of Contents	Required	Yes
Publication #1 Appendix	Optional	No
Publication #2 Appendix	Optional	No
Publication #3 Appendix	Optional	No
Clinical Protocol Appendix	As needed	No
Human Investigation Statement	As needed	No
Laboratory Animal Statement	As needed	No
Biohazard Statement	As needed	No

* see Signature page section below for more information

**Fellows and Special Fellows only

[#] Sponsor -Biographical Sketch and Sponsor - Other Research Support required for Fellow, Special Fellow and Special Fellow in Clinical Research

[†]Applicant - Other Research required only for Scholar and Scholar in Clinical Research

The following is a list of acceptable and unacceptable optional attachments for the appendix. Inclusion of unacceptable documentation will result in the disqualification of the application.

Acceptable:

1. letters of collaboration or support
2. recombinant DNA assurances

Unacceptable:

1. Copies of previously submitted proposals to Federal or private sources
2. Appendix containing preliminary data (charts, graphs, tables, etc)

The following sections provide guidance to the Applicant for required information in each attachment.

Biographical Sketch-

A biographical sketch is required for each Applicant. A biographical sketch of the Sponsor is required for Fellow, Special Fellow and Special Fellow in Clinical Research application submission but is not a requirement for the Scholar or Scholar in Clinical Research applications. The format and content is similar to the NIH biographical sketch and should not exceed two (2) pages per person as stated at the top of the template/form. It is acceptable for the Applicant and/or Sponsor to utilize the short version of their NIH biosketch as long as it does not exceed two (2) pages, including all publications relevant to the application, and does not contain Other Research Support.

1. Education and Training:

This section should list all degrees awarded and post-doctoral training starting from conferral of the Baccalaureate degree. PhD recipients should list both the date of their oral thesis defense and the date of degree conferral by the university (mm/yyyy).

2. Professional Experience:

Concluding with the current position, list chronologically all previous research positions (mm/yyyy – mm/yyyy), other professional experience and honors. Include time spent in the thesis advisor's laboratory following the thesis defense as postdoctoral training.

3. Selected Publications:

List in reverse chronological order complete citations of Applicant-authored publications. If including all publications causes the biographical sketch to exceed two (2) pages, the Applicant should edit the publication list to include only the most relevant, notable, and recent publications.

Eligibility Justification-

Each Applicant is required to complete this template/form. Most of this information was requested in the LOI and should be duplicated without modifications into this template/form or the application may be disqualified. Do not exceed the space provided in each section of the template/form as this may result in disqualification of the application.

1. Sponsor's Name and Institution:

Provide the name of the Applicant's Sponsor; be sure to include the first and last name. Also include the name of the Sponsor's Institution. For example: Joseph Smith at The Institute for Advancing Cancer Research.

2. Research Cost Support and Source:

For all grants that will support costs of the proposed research, indicate the name of the investigator (Sponsor or Applicant), source, type and identifiers. For example: Joseph Smith's RO1 from NIH, CA####.

3. Duration of Training or Independent Experience:

Indicate the start date (mm/yyyy) of post-doctoral or fellowship training in the case of Fellow, Special Fellow and Special Fellow in Clinical Research or the start date of an independent faculty-level position in the case of Scholar and Scholar in Clinical Research. For Fellows and Special Fellows, all postdoctoral training, including time spent in the thesis advisor's laboratory post oral defense, should be included.

4. Degree Conferral Date:

Indicate the date (mm/yyyy) of doctoral and/or medical degree conferral. PhD applicants should list both the date of the oral thesis defense and the date the degree was conferred by the university.

5. Degree Received From and with Whom:

This section is only required for Fellow, Special Fellow and Special Fellow in Clinical Research applications. Indicate the supervisor for the Applicant's pre-doctoral research, including first and last names, and the name of the degree-conferring institution. For example: John Wilson at The Medical Center for Cancer Research.

***Justification for Consideration of Eligibility Outside of Specified Guidelines-**

This section is where the Applicant can provide justification for why the CDP Review Subcommittee should consider the Applicant eligible even though he or she would seem to fall outside of the time limits specified for the award. Justification for training outside of the stated limits is required or the application will be ineligible for consideration.

Acceptable personal reasons for extending the length of postdoctoral training beyond six years from the date of the thesis defense include interruptions in training due to family leave, personal illness, or

military service, and should be explained here. Examples of unacceptable justifications would be that additional time was required to complete a complex project or that training in a new technique would enhance the applicant's career prospects.

Other Research Support-

Other research support is defined as any specific funds or resources, whether Federal, private, corporate or institutional that are available to the Applicant or Sponsor in direct support of their research endeavors. This information is an important part of the review and award process and must be included. Failure to include other research support information may disqualify the application. The Applicant must list all current and pending research support, including all support available for the proposed research during the project period. Other Research Support of the Sponsor is required for Fellow, Special Fellow and Special Fellow in Clinical Research. In the case of Scholar or Scholar in Clinical Research Applicant, the Applicant Other Research Support is required. The Applicant Other Research Support may not be applicable in the case of Fellow, Special Fellow and Special Fellow in Clinical Research.

Because the Career Development Program only provides salary support, it is implied and acceptable that there is overlap between active/pending research support and CDP funding, if awarded. The overlap should be summarized with the description of each funding source (see the last row of each table on the template/form). Note that no other award expressly intended for career development may be held prior to or concurrent with a comparable-level Society Award. Applicants with pending research grants at the time of submission must advise LLS of funding prior to the date of review (January following October submission).

Budget-

The funding limitations are provided in the above Guidelines section (*see Description of Awards*) and in the Policies & Procedures document. Failure to comply with the stated limitations may result in disqualification of the application. The following information should be provided in the budget template/form:

1. The current actual salary, wage or stipend of the Applicant and fringe benefits expense.
2. The estimated salary, wage or stipend for the two (2), three (3) or five (5) year duration of the award as outlined in Table 1.
3. Cost of living increases should be included in all out years (i.e. second year, third year, etc.).
4. As mutually determined by the Sponsoring Institution and Grantee, full or partial fringe benefits can be included.

CDP Awards are limited to salary support for the Applicant, and may not be used for laboratory expenses, support for other laboratory personnel or any other use. It is acceptable for the Sponsoring Institution to supplement the Applicant's salary from sources other than the CDP grant. Expenditures for laboratory costs/equipment, travel funds, etc. are explicitly excluded as fringe benefits.

Project Description-

Detailed description of proposed project that includes the following information:

1. Scientific or Clinical Background and Disease Relevancy
2. Specific Aims
3. Own Previous Work/Preliminary Data for Project (include preliminary data, charts and figures in this section)
4. Explanation of Experimental Design and Methods (can refer to Clinical Protocol Appendix for additional details, if appropriate)
5. Anticipated Results and Potential Clinical Relevance
6. Potential Problems/Pitfalls and Planned Solutions
7. Resources and Environment

The project description may contain additional pertinent information, but must address all items listed.

The project description may not exceed eleven (11) pages (excluding cited references) for Scholars and Scholars in Clinical Research and six (6) pages for Fellows, Special Fellows, and Special Fellows in Clinical Research. Preliminary data, charts or figures may not be included in appendix material. It is recommended that the Applicant use the allotted page count to completely describe the project and not rely on any materials in the appendices.

Sponsor's Letter of Support-

A letter of support from the Sponsor must be submitted and should include the following:

1. A full explanation of the Applicant's current position.
2. In the case of Scholars and Scholars in Clinical Research, the Sponsor's letter should include a) a description of institutional support for the Applicant's research and b) future institutional plans for the Applicant's career development at the institution.
3. In the case of Fellows, Special Fellows and Special Fellows in Clinical Research, the Sponsor's letter should describe a) the plan for the candidates training and career development, b) a summary of the Sponsor's experience as a mentor (as evidenced by the Sponsor's record of training individuals who go on to become independent biomedical researchers), and c) the specific sources of funding to support the Applicant's research costs.
4. A discussion of how the Applicant's time will be divided among research and other responsibilities (such as clinical work, teaching and administration).
5. How the award will help the Applicant develop his/her career.
Should the Applicant be granted research funding by LLS, the above points must be updated and detailed in the Sponsor's evaluation (along with evaluation of research progress) which is a required aspect of Annual Reports (see LLS Policies and Procedures document for more details).

Appendices Table of Contents-

The Applicant should use this template/form to identify all appended materials. Please indicate a title for each appendix. A detailed description of each appendix should not be included.

Clinical Protocol Appendix-

Provide a one page summary of any clinical protocol essential to the proposed research. Include IRB approval date, IRB compliance number, and effective dates of approval. Projects for which IRB approval is pending must include a statement to that effect. The Applicant should notify LLS of IRB approval prior to the grant review (January following October submission) since

preference will be given to (Scholars in Clinical Research and Special Fellows in Clinical Research) Applicants whose research involves an early phase clinical trial of new or innovative applications.

Publication #1 (#2, #3) Appendix:

A set of the Applicant's or Sponsor's publications that are directly relevant to the methods or aims of the research may be included - strictly limited to three (3) publications and with any password protection feature removed. Many articles downloaded from journal sites contain password protection to prevent modifications of the document; if password protection is not removed, reviewers may have difficulty downloading the entire application. Applications with more than three (3) publications will not be accepted. Submitting numerous large files adds to application download times and can delay the submission site.

Human Investigation Statement:

If the proposed research has received IRB approval, documentation must be uploaded as the Human Investigation Statement. If the research project is exempt from IRB review, the certificate of exemption must be uploaded as the Human Investigation Statement.

Laboratory Animal Statement:

If the proposed research has received IACUC approval, documentation must be uploaded as the Laboratory Animal Statement.

Biohazard Statement:

If the proposed research has received Sponsoring Institutional approval, documentation must be uploaded as the Biohazard Statement.

Applicant Data Sheet-

Providing the information in this section is optional. However, Applicants are encouraged to complete this section as it will continue to support LLS commitment to diversity. This information will not be used in the administrative or programmatic review of the application. To add this demographic information, the Applicant can click on the Edit Professional Profile button.

Validate-

It is necessary for Applicants to validate the Full Application. The Validate function is a measure to ensure that all required fields of information are completed. If required fields are empty, the system identifies and notifies the Applicant of fields that require information.

Signature Page-

All applications must be signed by the Applicant, the Sponsor, the Signing Official and the Fiscal Officer. The signature page is provided as a printable document and completing this page is the last step before submitting the application. The Applicant should print the Signature page, and then obtain the indicated signatures. The Applicant should check with the Sponsor or Grants and Contracts officials (or equivalent) to ensure that appropriate signatures are obtained. Once all signatures are acquired, the document needs to be scanned, converted to a PDF, and then uploaded (*see Proposal Attachments section*).

Submit-

The Applicant can submit the Full Application for consideration in this section. The application is not considered submitted until successful completion of this step.

b. CHANGES

Some information collected in the LOI will automatically populate fields in the Full Application. Changes may only be made after receiving prior approval from LLS Director of Research Administration. Any changes made without the prior approval of LLS may result in the disqualification of the application. The Applicant should email LLS requesting a change and identifying the elements to be changed (at researchprograms@lls.org, and see *Instructions/General/Assistance with Applications*).

c. SUBMISSION OF THE FULL APPLICATION

LLS does not require nor will not accept fax or hard copies of the Full Application. The Applicant will receive an email from proposalCENTRAL stating that the application was successfully submitted online. Each Applicant must submit a Full Application by **October 1st at 3:00pm EST** via the [proposalCENTRAL](https://ProposalCentral.altum.com) website (<https://ProposalCentral.altum.com>). If any date falls on the weekend or a U.S. holiday, the deadline will be the following business day.

d. REVIEW OF THE FULL APPLICATION

LLS will review properly submitted applications. You can check proposalCENTRAL for the status of your application. Please do not call or e-mail LLS to determine whether the application has been received, when it will be reviewed or the results of the review. This information will be communicated via email (see *Guidelines/Review Process and Applicant Notification*).