



Impactful Medicine Providing Access to Clinical Trials (IMPACT) Program

Guidelines & Instructions Letter of Intent & Full Application

Effective dates:

June 1, 2019 – May 30, 2020

Table of Contents

<u>About The Leukemia & Lymphoma Society, Inc.</u>	2
<u>Description of Influential Medicine Providing Access to Clinical Trials (IMPACT) Program</u>	2
<u>Post-Award Management</u>	3
<u>Who Can Apply</u>	4
<u>Application Process</u>	4
<u>Key Dates</u>	5
<u>General Application Instructions</u>	6
<u>Letter of Intent Phase Instructions</u>	7
<u>Full Application Phase Instructions</u>	8

About The Leukemia & Lymphoma Society, Inc.

The Leukemia & Lymphoma Society, Inc. (LLS) is a national voluntary health agency dedicated to the conquest of hematologic malignancies and relevant premalignant conditions. LLS supports research, patient aid, community service programs, advocacy, and public and professional education.

Description of Influential Medicine Providing Access to Clinical Trials (IMPACT) Program

LLS's Influential Medicine Providing Access to Clinical Trials (IMPACT) program is intended to expand access to high-quality clinical trials to patients served by community health settings, particularly patients who are rural, minority, and/or economically disadvantaged blood cancer patients. The overall goal of this award is to establish partnerships between community-based oncologists and major cancer research and treatment centers to facilitate the recruitment of blood cancer patients for participation in impactful clinical trials. This will also accelerate development, initiation, and completion of these clinical trials. As many more clinical trials now use precision medicine, based in part on mutational profiles of patients, this is an outstanding opportunity to educate community-based hematologists/oncologists about careful and appropriate use of this new information.

Each IMPACT award will be comprised of a “trials hub” that will establish a network of partnerships with community-based oncologists. The hub will be based at a major cancer research and treatment center (the host institution) which will sponsor the clinical trials. It will coordinate recruitment of patients into the clinical trials. The hub must present plans to increase the number of patients currently served by the hub that are from community centers as well as the number of rural participants, minorities, and economically disadvantaged patients. The focus should be on increasing the current clinical trials numbers from community centers as well as disadvantaged patients (rural, minority, economic status), but a minimum goal should be 20%.

The host institution/trial leaders will participate in educational outreach to community physicians and patients. They will serve as anchors for educating other physicians in the community about precision medicine and genomic initiatives using this community platform.

The maximal award value is \$250,000.00 for each year of the five year grant, which may include overhead costs of up to 5%. All trial costs must be supported by other sources.

Post-Award Management

Milestones

Annual milestones will be required after award notification. These will be associated with patient accrual numbers from community sites, increasing participation of patients from rural areas, minorities, and those who are economically disadvantaged, as well as timely commencement of clinical trials. Updates on these milestones will be provided to LLS on a semi-annual basis.

Both LLS and the host institution will need to agree to the final wording of the milestones. These are due by the contract due date.

Lay Abstract

Lay abstracts will be required of those selected for funding following award notification. ***The lay abstract is essential for LLS to continue successful fundraising to support our current and future grantees.*** Thus, a well-written lay abstract suitable for the general public is required post-award notification. After the funding decision has been made, LLS will contact the IMPACT Director regarding lay abstract submission. Wording modifications may be asked for in cases where LLS determines that improvements are warranted. ***Final lay abstracts acceptable to both awardees and LLS staff are due prior to the start of funding.***

Annual Assessment

After the final quarterly report of the year (due each July 31st), LLS staff will assess the quality of the IMPACT award and the progress made, particularly progress increasing community involvement. From this evaluation, a recommendation will be made as to the level of continued funding. In the case of productive awards, the funding will remain the same. In the unlikely event that progress is not sufficient, a warning will be provided, which may result in future funding being reduced if progress does not improve. After this assessment, LLS Research staff will work with the IMPACT Director to establish milestones for the coming year. The outcome from the Annual Assessment will be sent to the host institution within 60 days of the annual meeting.

Annual Reports

Financial, Intellectual Property, and Progress Reports are due annually while publication Reports are due quarterly. The Progress Report will contain progress in meeting the milestones, number of patients from community sites, and percentage of rural/minority/economically disadvantaged patients in the trials and is essential for staff evaluation of progress and for donor development activities. Release of the next payment is contingent on submitting satisfactory reports.

Team Meetings

A key element of an IMPACT award is the interaction of the various community centers with the host institution. Therefore, an essential component to the success of an IMPACT award is regular interaction of the clinical trial leaders and community oncologists. Teams should meet via teleconference or in person on a regular basis to discuss progress and results.

Who Can Apply

Citizenship

LLS welcomes applications from both US citizens and non-citizens. The sponsoring institution must be located in the US.

General Eligibility

Applicants must hold an MD or equivalent degree and must be affiliated with a non-profit Sponsoring Institution at the time funding commences and for the duration of the award. The award must remain with the sponsoring institution identified as the Cancer Center Hub in the application. If the IMPACT Director leaves the sponsoring institution, LLS must be notified immediately. A new IMPACT Director must be identified by the sponsoring institution and approved by LLS for the grant to continue. Applications may involve multiple institutions, but one institution must remain the Cancer Center Hub throughout the life of the grant.

Leadership

The IMPACT award is led by an overall IMPACT Director, who is responsible for writing and submitting the application. The IMPACT Director of a funded IMPACT award is also responsible for ensuring appropriate disbursement of funds and adherence with LLS policy.

Modifications to leadership of funded awards (and approved LOIs) must be approved by LLS.

Application Process

The application process consists of two parts: the LOI and full application.

Letter of Intent

The LOI presents a description of the overall IMPACT hub and its plan. In addition, the LOI has NIH biosketches for each clinical trial leader.

The LOI is a competitive step. Therefore, it is critical to have a well-thought out and well-presented LOI to enhance the chances of a favorable review. Changes to submitted LOIs are not allowed.

The LOI is reviewed for responsiveness to the goals of the IMPACT hub, and include:

- **qualifications of the IMPACT Director and clinical trial leaders**
- **significance of the clinical trials to blood cancer**
- **quality of each clinical trial**
- **the likelihood of increasing the number of patients who are rural residents, minorities, or economically disadvantaged**

Full Application

The full application is a more complete description of the IMPACT program. There should be no changes between the LOI and the full application.

Full applications are reviewed by an independent and voluntary expert panel. Full applications will be reviewed using the criteria listed in the [Review Criteria](#) section.

Review Criteria

Priority Score

The Priority Score reflects the IMPACT application as a whole.

- The likelihood that the clinical trials will increase patient participation from minorities, the economically disadvantaged, and those from rural areas.
- The likelihood of the clinical trials to significantly advance treatment options for clinical trial participants.
- The qualifications of the IMPACT Director and clinical trial leaders.
- The quality of the hub and its ability to support multiple clinical trials.
- The likelihood of clinical trials opening in a reasonable time frame.
- Demonstrated funding for the IMPACT-associated clinical trials.
- The clarity of thought and presentation.

Mission Score

During the review process, each application shall receive two Mission Scores, which reflect the purpose of the program within LLS's overall Mission.

Community center participation

Mission Score 1: High likelihood of increasing participation of patients at community centers in clinical trials above 20% within the grant timeframe.

Mission Score 2: Moderate likelihood of increasing participation of patients at community centers in clinical trials above 20% within the grant timeframe.

Mission Score 3: Low likelihood of increasing participation of patients at community centers in clinical trials above 20% within the grant timeframe.

Underserved community participation

Mission Score a: High likelihood of increasing the participation of underserved communities in the community center-associated clinical trials.

Mission Score b: Moderate likelihood of increasing the participation of underserved communities in the community center-associated clinical trials.

Mission Score c: Low likelihood of increasing the participation of underserved communities in the community center-associated clinical trials.

Missions Scores of 1, 2, a, and b are fundable. Mission Scores of 3 and c are not fundable.

Key Dates

	Date	Time
Call for Proposals	July 2019	

Letter of Intent Deadline	August 31, 2019	3:00 PM ET
Notifications of Full Application Invite	September 2019	
Full Application Phase Deadline	November 30, 2019	3:00 PM ET
Notification of Awards	April/May 2020	
LLS's receipt of signed Grant Agreement, Lay Abstract, and Milestones	June 1, 2020	
Funding start date	July 1, 2020	

*LLS's non-negotiable Grant Agreement Terms & Conditions are available on www.lls.org.

The submission deadlines will be enforced. Please note that all times are Eastern Time (ET). If any date falls on a weekend or US holiday, the deadline becomes the next business day.

It is highly recommended that submissions are done prior to the deadline. Internet traffic may be slow near the deadline, which may result in difficulties in submission. In addition, LLS's response time to questions may be delayed by the high volume received near the deadline. Therefore, it is imperative that any questions be posed to LLS as far ahead as possible. The LLS Research Portal automatically shuts down new submissions after the deadline has passed.

General Application Instructions

The IMPACT application will be completed in two phases: Letter of Intent and Full Application. Below are step-by-step instructions for applying:

1. Read the Guidelines & Instructions (this document) in full.
2. Log in to the [LLS Research Portal](http://www.lls.org) and select IMPACT. Click "Apply to IMPACT!" to begin the application process (well ahead of the deadline).
 - o If you need a new account or need to reset your password for an existing account, contact researchprograms@lls.org.
3. Familiarize yourself with the LLS Research Portal.
4. Click "Edit" and follow the instructions for each web form field. Bold font indicates required information.
 - o Character limitations include spaces. Character and other length limitations are strictly enforced on the web form and the uploaded program description template. If character limits are not adhered to, the application may be triaged.
 - o You may save your work and return to it at any time by clicking "Save." Clicking "Submit" will lock your application and prevent further modification at that stage. Contact researchprograms@lls.org if you submit in error (must be before the deadline).
5. Within two business days after your LOI is submitted, you will receive an automated email from the Research Portal. Consider that emails may end up in your spam filter.
6. If your LOI is accepted, you will have access to the full application. Click on your request, found in New or Pending, to continue with your application.

7. Please carefully follow the instructions on the LLS Research Portal and this document. Full Applications require completion of both the web form and the current application template, which should be downloaded from the *Project and Supporting Documentation* section of the LLS Research Portal. **Failure to follow all application instructions may result in administrative triage of your application.**
8. Submit your Full Application to LLS prior to the Full Application deadline. **We strongly recommend submitting at least one week in advance of the deadline, as site traffic on the day of and days leading up to the deadline will be heavy.**
 - Contact researchprograms@lls.org with any questions about the application that are not addressed in the LLS Research Portal or this document.

Carefully check every page of your application prior to submission. You are ultimately responsible for this submission, even if someone else submits your final application.

At any time during the application process, including after submitting your Full Application, you can check the status of your application by logging in to the LLS Research Portal, selecting your application (under *Requests* in either “New or Pending” or “Submitted”) and referring to the Status in the yellow box at the top of the page.

If you have any technical difficulties with the [LLS Research Portal](#), please contact researchprograms@lls.org.

Letter of Intent Phase Instructions

Information for the Letter of Intent will be entered on the web form in the [LLS Research Portal](#). Since the LOI is competitive, and no changes may be made to submitted LOIs, the LOI should be well-thought out and well-presented.

IMPACT Title

100 character limit including spaces.

Brief Statement of Current Community Center Participation

2,000 character limit including spaces.

Brief Overview of the Plan to Increase Community Center Participation

2,000 character limit including spaces.

Number of Hematology/Oncology Clinical Trials at the Cancer Center

Number of Suitable Hematology/Oncology Clinical Trials for the IMPACT Program

Clinical Trials

Provide the title and Clinical Trial Leader(s) of each trial, enrolling or soon to be open, that will be part of the IMPACT. There should be at least 10 trials. Provide a 1,000 character description of each trial, including specific aims and anticipated results for each. See [Leadership](#) under the [Who Can Apply](#) section.

Biosketches

All Clinical Trial Leaders must provide a biosketch using the current NIH format, which includes Other Research Support.

Upload all biosketches to the Project and Supporting Documentation section of the LLS Research Portal as one single PDF file.

Submission and Confirmation

Carefully check your work and PDF prior to submission. After clicking the “Submit” button, you will receive an automated email stating that your information was successfully submitted. **If you do not receive the email confirmation within two business days of submission, contact researchprograms@lls.org.**

Changes

If you notice problems with your PDF or if extra documents remain after you have submitted but prior to the deadline, email researchprograms@lls.org.

Only the following changes are allowed post-submission:

- Significant updates to clinical trials:
 - IRB updates
 - opening of the trial
 - patient enrollment
 - opening of new clinical sites
 - efficacy and/or safety updates
- Manuscripts that have been accepted for publication; the following must be provided:
 - list of authors
 - title
 - journal
 - a copy of the letter from the journal
- Change of institution of key personnel, and/or changes of key personnel resulting from a new hiring

Please email these updates to researchprograms@lls.org.

Review and Notification

LLS will notify applicants via email if the LOI is accepted for full application submission. See [Key Dates](#).

Full Application Phase Instructions

Information provided in the LOI phase will carry through to the full application and must not be changed. The following information is required on the LLS Research Portal and the project template.

Project Description Template

Download the project template (including budget and signature page). Complete the information, including required signatures, and upload to the Project and Supporting Documentation section of the LLS Research Portal.

Follow the character (which include spaces) and page lengths. Margins are preset at 0.5 inches on each side and should not be changed. The margin size does not include the headers and footers on the project template, which also should not be changed. Only single-spaced, Times New Roman 12 pt. font is acceptable.

Figure legends should be formatted with a font size equivalent of 10 pt. or above.

- 1. Table of Contents**
- 2. Application Information**
- 3. Cancer Center Hub Statement (see template for detailed instructions)**
- 4. Current Community Center Involvement (see template for detailed instructions)**
- 5. Plan to Increase Community Center Involvement (see template for detailed instructions)**
- 6. Eligible Clinical Trials (see template for detailed instructions)**
- 7. Education and LLS Resources (see template for detailed instructions)**
- 8. Overall Structure of Proposed IMPACT Program (see template for detailed instructions)**
- 9. Key Clinical Personnel (see template for detailed instructions)**
- 10. Institutional Commitment (see template for detailed instructions)**

11. Budget

The Detailed Budget and Budget Justification sections should provide itemized detail for each major category for each year of the program. Complete all totals and subtotals. Enter the information on the web form and on the budget template. Payments are made to the IMPACT Director's Institution and it is the responsibility of the IMPACT Director to divide funds among participating institutions.

Use of Funds

The funds must be used for costs related to infrastructure for the clinical trials while overhead/indirect costs strictly should be kept at a minimum as further described below.

Permissible Direct Costs include the following with the specified limitations:

- 1) Personnel expenses including salary, wage or stipend and fringe benefits
- 2) Other Direct Costs that are clearly related to the IMPACT infrastructure needs

Permissible Indirect Costs (often referred to as Institutional overhead, IDC, M&A, G&A or pooled costs) are those costs incurred for common or joint objectives that cannot be readily identified with a particular project (general maintenance, utilities, library, etc.) as defined in Office of Management and Budget Circular A-21. Indirect costs are limited to 5% of total direct costs requested.

Impermissible Costs include (but are not limited to) research, research supplies, membership dues, tuition, books, journals and publication costs.

12. References

13. Signature Page

Provide all requested signatures.

14. Appendix

This section should include, in this order:

- Table of contents
- Biosketches
- Partnership Letters with Community Centers (even if patients are not yet a part of a clinical trial)
- Clinical protocols: Include up to a 2 page summary for each trial and include a link to the full protocol. Include approval date and compliance number. Indicate if IRB approval is pending. Provide information as a figure or a narrative regarding timelines for any clinical trials (ongoing or future).
- Assurances (signed copies from appropriate institutional representatives, to be uploaded in addition to information provide in the “Assurances” section of the LLS Research Portal web form)

Human Subjects

The status (approved, pending or exempt) of IRB approval must be provided.

Documentation of any current or pending approvals must be contained in the full application template. There is also a section on the web form that must be completed.

An application may be submitted with IRB approval pending, but IRB approval must be obtained and provided to LLS prior to the Award start date.

Upload the full application components, as a single PDF, in the “Project and Supporting Documentation” section on the LLS Research Portal.

All uploaded documents must be combined into a single PDF in the order listed above. Failure to submit as a single PDF in the order above may result in disqualification of the application.

Submission and Confirmation

After clicking the “Submit” button, you will receive an automated email stating that your application was successfully submitted. **If you do not receive the email confirmation within two business days of submission, contact researchprograms@lls.org.**

If extra documents remain after submission and before the deadline, email researchprograms@lls.org and let us know which documents to remove.

Carefully check your PDF prior to submission. If you notice problems with your PDF after you have submitted, but prior to the deadline, email researchprograms@lls.org.

Only the following changes are allowed post-submission:

- Significant updates to clinical trials:
 - IRB updates
 - opening of the trial
 - patient enrollment
 - opening of new clinical sites
 - efficacy and/or safety updates
- Manuscripts that have been accepted for publication; the following must be provided:
 - list of authors
 - title
 - journal
 - a copy of the letter from the journal
- Change of institution of key personnel, and/or changes of key personnel resulting from a new hiring

Please email these updates to researchprograms@lls.org. Any other questions regarding the submission process should be emailed to this address as well.