Influential Medicine Providing Access to Clinical Trials (IMPACT) Program

Guidelines & Instructions
Letter of Intent & Full Application

Effective dates:
September 2021 – June 30, 2022

Application Deadlines	
LOI due	December 15, 2021, 3:00 PM (ET)
Full Application due:	February 25, 2022, 3:00 PM (ET)
Grant Start date:	October 1, 2022

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 seeks to bring clinical trials to the patients through the Influential Medicine Providing Access to Clinical Trials (IMPACT) program. The overall goal is to expand access to high-quality clinical trials to patients by having clinical trial participation occurring at local community oncology centers. These clinical trials will be hosted by major cancer centers who will partner with community-based oncologists to facilitate recruitment and participation of patients at community oncology centers. Though all patients at these community centers are welcome in IMPACT, this program provides the opportunity to increase the participation of patients who are traditionally unrepresented in clinical trials, including those who are rural, minority, and/or economically disadvantaged.

Each IMPACT award will be comprised of a hub that will establish a network of partnerships with community-based oncology centers. The hub will be based at a major cancer research and treatment center (the host institution) which will oversee the clinical trials. Trials will be chosen based on their potential impact to all clinical trial participants, as well as the feasibility of performing most/all of the trial at the community centers (for the patients participating at these centers). The hub will coordinate with their community oncology partners to recruit patients on the trials as well as oversee the proper conduct of the trials. Since the coordination of trials with community centers will be more complicated than trials conducted solely at the major cancer center, large numbers of trials are not expected. Around 10-15 impactful clinical trials open to blood cancer patients treated at their community centers is a worthy goal, though it is not expected that this goal will necessarily be reached in the initial years of funding.

LLS will have a broad interpretation of what constitutes a community oncology center, but generally, it will be a non-academic center that see patients who are far from a major cancer center. Since a patient's zip code can be a major determinant of cancer outcomes, community centers that are farther from the cancer center are favored. Typically, a community center will be found at least 30 miles from any major cancer center. In urban areas, time to travel to the major cancer center can be considered instead of distance. In these cases, typical travel for a patient should be at least one hour to be considered appropriate for an urban community oncology center for IMPACT.

The major goal of IMPACT is to increase participation of patients in trials at their community oncology centers. Therefore, IMPACT programs will be evaluated on a yearly basis on their ability to increase the recruitment of these patients over time. Though the goal is to increase participation at these community centers over baseline, a minimum goal of 20% must be achieved during the award funding period. For programs that are already at 20%, further increases are desired.

Though there is no numerical goal for participation of those typically underrepresented in trials, it is expected that the numbers of any (and/or all) of the three mentioned underrepresented categories increases over time. Note that for the purposes of IMPACT, patients who are from rural areas, are members of racial and ethnic minority groups, or who are economically disadvantaged are considered equally important, and therefore an IMPACT program that focuses on at least one of these groups will be considered for funding. LLS also understands that any one patient may have characteristics of 1-3 of these groups.

Performance of IMPACT trials should be feasible in the community setting and must be potentially impactful for blood cancer patients. Some trials may have all trial activities for the community patients performed at the community site. However, it is also acceptable to have a hybrid model whereby some trial activities will be performed at the hub while most will be performed at the community site. This hybrid model is likely the most feasible. In addition to community patients, most (or all) IMPACT trials will also have patients treated only at the hub. The expectation is that by the end of the funding period, each IMPACT trial will have at least 20% of the trial participants having their trial activities primarily at the community site(s). The number of IMPACT trials is open-ended but should reflect a good faith effort on the part of the hub to reach the goals of the program. We anticipate a well-functioning IMPACT program having approximately 10-15 high-quality trials running by the end of the funding period.

The maximal award value is $250,000.00 for each year of the five-year grant, which can include up to 5% overhead costs. Since IMPACT is meant as an infrastructure grant, all trial costs must be supported by other sources.

Note: IMPACT is ***not*** meant as a recruitment mechanism to increase clinical trial enrollment of patients from community centers whose trial participation will occur mainly at the major cancer center.

Geographic Diversity

The IMPACT grant program is intended to help blood cancer patients access clinical trials at community centers throughout the United States. Therefore, LLS's goal is to fund multiple IMPACT programs covering a broad geographical area. LLS currently funds three IMPACT programs: Vanderbilt University Medical Center, Mayo Clinic Rochester, and Weill Cornell Medical College of Cornell University. Though we may accept applications targeting similar geographical areas, we strongly favor those programs that will add to the overall program's geographical diversity. The bar will be high for those new applications with a geographical reach that highly overlaps with the currently funded IMPACT programs.

Post-Award Management

Milestones

Annual milestones are required at the start of funding. Milestones will reflect goals for the number of trial patients participating at their community sites. Each year, these milestones will be modified to reflect changes from the prior year for each IMPACT trial as well as any changes to the trials themselves. In addition, milestones will reflect goals for the number of patients who are from rural areas, minority groups, and those who are economically disadvantaged as well as how those numbers of any of these patient categories increase year over year. In addition, updates on these milestones will be provided to LLS three times a year.

Both LLS and the host institution must agree on the milestones. These are due by the contract due date.

Annual Assessment
After the final triannual report of the year, LLS staff will assess the quality of the IMPACT award and the progress made on the milestones and the overall goals of the program. In addition, the annual assessment will evaluate the timely commencement of clinical trials. 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, the IMPACT Director will provide updated milestones for the coming year.

Annual Reports
Financial, Intellectual Property, and Progress Reports are due annually while publication Reports are due quarterly. The Progress Report is the third triannual report and will contain progress in meeting the milestones, number of open trials, number of patients from community sites (whose clinical trial participation is largely at the community sites), and percentage of rural/minority/economically disadvantaged patients in the trials. The Progress report should also report on educational and outreach activities conducted during the grant year. The Progress Report may or may not require a brief meeting with LLS staff. This report is essential for LLS scientific staff evaluation of progress and for donor development activities. ***Release of the next payment is contingent on the receipt by LLS of all satisfactory reports (and triannual updates).***

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 at least quarterly to discuss progress and results.

Who Can Apply

Citizenship
LLS welcomes applications from IMPACT Directors who are both US citizens and non-citizens.

Sponsoring Institution (Host Institution/Hub)
The sponsoring institution (hub) must be in the US. The hub is a major academic cancer center with substantial clinical research efforts in blood cancers. Most NCI-designated cancer centers will qualify, as will other major cancer centers that serve many blood cancer patients and that have robust hematological malignancy clinical trial programs.

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 to LLS policy.

Modifications to leadership of funded awards must be approved by LLS.

Application Process

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

Letter of Intent (LOI)
The LOI is a brief overview of the proposed IMPACT program as well as the hub capabilities.

Full Application
Full applications are reviewed by an independent and voluntary expert panel. Full applications will be reviewed using the criteria listed in the following section.

Review Criteria

Priority Score

- The likelihood that the IMPACT program will increase clinical trial participation of those patients whose trial participation will be mainly at community oncology settings; the minimum goal during the IMPACT period should be that 20% of the IMPACT trial participants are those treated primarily at the community sites.
- The likelihood that the clinical trials will increase patient participation of rural patients, members of racial and ethnic minorities, and/or the economically disadvantaged patients.
- 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 in hematological malignancies.
- The likelihood of clinical trials treating patients in a reasonable time frame.
- Demonstrated funding for the IMPACT-associated clinical trials.
- The clarity of thought and presentation**.**
- The quality and appropriateness of proposed educational and outreach activities.

Key Dates

	Date	Time
Call for Proposals	September 2021	
Letter of Intent Deadline	December 15, 2021	3:00 PM ET
Full Application Phase Deadline	February 25, 2022	3:00 PM ET
Notification of Awards	July 2022	
LLS's receipt of signed Grant Agreement and Milestones	September 1, 2022	
Funding start date	October 1, 2022	

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

The submission deadlines will be enforced. 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 submissions after the deadline has passed. **Late submissions due to technical difficulties will not be accepted.**

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 these Guidelines & Instructions in full.
2. Log in to the LLS Research Portal (https://lls.fluxx.io/) and select IMPACT. Click "Apply to IMPACT" to begin the application process (well ahead of the deadline).
    - If you have applied to LLS in the past, you do not need to create a new registration and can log-in with your username (email address associated with your account) and your password. If you forgot your password, simply click the "reset or create password" link and enter your email address. The system will send your username and a link to update your password.
    - If you are a first time user to the LLS Research Portal, please contact researchprograms@lls.org so an account can be created for you.
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.
    - Character limitations include spaces. Character and other length limitations are strictly enforced on the web form and the uploaded project description template. If character limits are not adhered to, the application may be administratively disqualified.
    - 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. Once your LOI is submitted, you will receive an automated email from the Research

Portal. This email may end up in your spam filter.

6. Once the LOI Phase has passed, you may proceed to the Full Application Phase. Click on your request, found in New or Pending, to continue with your application. Please carefully follow the instructions on the LLS Research Portal, this document, and the application template. Full Applications require completion of both the web form and a template that must be downloaded from the Project Document section of the LLS Research Portal. **Failure to follow all application instructions may result in administrative disqualification of your application.**
    - Contact researchprograms@lls.org with any questions about the application that are not addressed in the LLS Research Portal, this document, or the application template.
7. Submit your Full Application to LLS prior to the Full Application deadline. **We strongly recommend submitting well before the deadline, as site traffic on the day of and days leading up to the deadline will be heavy. There are no extensions permitted to our deadlines.**
8. Character limits include spaces. Character and other length limits are strictly enforced on the web form and the uploaded project description template. Font must be Arial 11 pt. **If character limits and font restrictions are not adhered to, or the preset margins are altered, the application may not be reviewed.**
9. To create a fair process for all applicants, all instructions must be followed. ***Do not ask for exceptions to these policies, including but not limited to exceptions to deadlines or making corrections to your document past the deadline.***

Carefully check every page of your application prior to submission. The IMPACT Diretor is ultimately responsible for this submission, even if someone else submits the 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.

IMPACT Title
100-character limit including spaces.

Summary
Provide a brief overview of your IMPACT program using the following format:
Section 1 (1 sentence): Overall question/focus of your program
Section 2 (1 to 2 sentences): High level approach you will use to address this question
Section 3 (1 to 2 sentences): Outcome/goal of your program

Note: Write as one paragraph and do not write "Section" or any other way to separate the sentences.

Brief Biography

A brief biography written for a lay audience. Approximately 1,000 characters including spaces.

Lay Abstract

Clear lay abstracts understandable by non-scientists are required. ***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 an educated, non-scientific reader is required.

Helpful hints for writing an appropriate lay abstract:

- Reduce the use of scientific/clinical terms that are specific to your field.
- When specific scientific/clinical terms are necessary, be sure to include a brief definition.
    - When in doubt, err on the side of over-explaining.
- Avoid using too many acronyms and always define acronyms before using.

Use the following list of questions as a guide for creating your Lay Abstract:

- What is the overall problem?
- What is the specific goal of your program? How does if fit into the overall problem?
- What is unique about this program?
- How will you achieve your goals?

Please spend time to write a thoughtful lay abstract that conveys your program to a lay audience. The length should be approximately 2,500 characters, including spaces, but no less than 2,000 characters. Be aware of your confidential information, as the lay abstract will be shared with others.

Brief Statement of Current Community Center Participation

1,000-character limit including spaces. Indicate if any clinical trials hosted by the hub are currently treating patients at community centers or if you are still at the planning stages; indicate the ~% patients whose trial participation is largely at the community center.

Brief Overview of the Plan to Increase Community Center Participation

1,000-character limit including spaces. Briefly indicate how you will increase the participation of patients whose trial activities occur largely at the community center.

Number of Hematology/Oncology Clinical Trials at the Cancer Center

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

Submission and Confirmation

Carefully check your work 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 LOI after you have submitted but prior to the deadline, please email these updates and/or corrections to researchprograms@lls.org.

Once your LOI is submitted, you may immediately being working on the full application.

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 limits (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 should not be changed. Only single-spaced, Arial 11 pt. font is acceptable.

1. **Table of Contents**

2. **Application Information**

3. **Cancer Center Hub Statement.** Describe the overall clinical trial infrastructure of the cancer center with an emphasis on clinical trials of hematological cancers. Include the number of blood cancer patients seen at the center as well as the number of blood cancer patients currently in clinical trials.

4. **Cancer Center Hub Patient Numbers.** Provide numbers on hem/onc activity and hem/onc patients at your cancer center.

5. **Current Community Cancer Center Involvement**. Describe the current coordination with community centers for hematological malignancy clinical trials, if any.

6. **Current Community Cancer Center Patient Numbers**. Provide numbers on hem/onc activity and hem/onc patients at community cancer centers that you are currently involved with.

7. **Plan to Increase Community Center Involvement.** Describe how IMPACT funding would be used to increase the direct community center involvement in blood cancer clinical trials.

8. **Future Community Cancer Center Involvement: New Partnerships.** Provide numbers on hem/onc activity and hem/onc patients at community cancer centers that you are planning future involvement with. Do not list centers listed in prior sections.

9. **Community Cancer Center: Goals.** Provide a goal for the number of hem/onc clinical trial participants that will have a majority of their trial participation done at the community cancer center itself.

10. **Community Cancer Center: Underrepresented Patient Goals.** Provide goals for the number of hem/onc clinical trial participants who are traditionally underrepresented that will have a majority of their trial participation done at the community cancer center itself. Provide patient characteristics (minority, socioeconomic status, and rural location).

11. **Eligible Clinical Trials.** Describe 5-10 clinical trials (currently enrolling or projected to open within one year of IMPACT funding start) that will be appropriate for community center participation. The clinical trials must have the intent to provide significant new information with high patient impact.

12. **Education and LLS Resources.** Describe current education outreach to community centers and how this will be enhanced with IMPACT funding. Include a discussion of how LLS resources may be used to enhance this outreach. These may include LLS's Information Resource Center and LLS's Clinical Trials Navigation Service.

13. **Overall Structure of Proposed IMPACT Program.** Describe the proposed structure of the IMPACT Program. Include information on how the program will be organized and the key personnel running the program. This should include a dedicated coordinator as well as a brief description of clinicians involved, the latter being described more fully in the next section. Provide a timeline for implementation. Include information of how patients' clinical trial activities will be coordinated, particularly for the trial activities performed at the community oncology centers. Provide details of who will have oversight of the IMPACT clinical trials and the nature of that oversight.

14. **Key Clinical Personnel.** There should be one cancer center clinician who oversees the IMPACT as the Program Director. There can be sub-Directors (Program Leaders) that are overseeing different aspects of the program, such as different disease focus areas. These clinicians must be the PI on at least one of the IMPACT trials. NIH biosketches for each should be attached at the end of the template.

15. **Institutional Commitment.** A key review criterion will be the level of institutional commitment to the IMPACT Program. Institutional commitment may be in the form of auxiliary or additional funding for the program, release time for program leaders, logistical or administrative support or other types of institutional contributions that directly benefit the IMPACT program. Any financial commitment should be described in detail and may include salary support for clinical or non-clinical personnel. Such salary support should be well justified based on new responsibilities associated with the IMPACT Program. A responsible institutional representative must submit a commitment letter with the application describing the institutional support of this program.

16. **References.**

17. **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 should be kept at a minimum as further described below.

Permissible Direct Costs
These are costs that 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.
3) Support for educational and outreach activities associated with the IMPACT program

Permissible Indirect Costs (often referred to as Institutional overhead, IDC, M&A, G&A or pooled costs).
These are 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
These include (but are not limited to) research, research supplies, membership dues, tuition, books, journals, and publication costs.

18. Signature Page
Provide all requested signatures.

19. 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). ***Do not have any partnership letters with any LLS employee or department.***
- Letter from Institutional Official concerning institutional commitment.
- 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).

  <u>Human Subjects</u>
  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 documents described above 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 without review.

IMPACT Clinical Trials
Fill out the clinical trial details on the Excel sheet provided. Add more columns if needed to describe diseases, drugs, and/or drug companies. Abbreviate the disease names (e.g. "AML"). Use the generic/chemical name for the drug, not the trade/brand name of the drug. For example, use "daratumumab" (spelled out; not "dara").

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, email researchprograms@lls.org and we will help you upload the correct document if you are unable to delete the incorrect document. ***This email must be received, with the correct document, prior to the deadline; there are no exceptions to this rule.***

Check the application prior to final submission. The applicant is ultimately responsible for the submission, regardless of who is uploading information on the LLS Research Portal. Every year, LLS has a small number of people that notice problems with their application after the deadline. Applicants will avoid this problem by carefully checking their application prior to final submission. Submitting well ahead of the deadline is also beneficial.

Once the deadline has passed, only the following updates may be made:

- 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 are accepted for publication; the following must be provided via email to researchprograms@lls.org:
  - Complete list of authors as they appear on the accepted manuscript
  - Manuscript title
  - Journal

    - Date of publication or online ahead of print (if known)
    - A copy of the acceptance letter from the journal
- Updates regarding any transfers to a new institution (see Transfers Section in Eligibility).