

Influential Medicine Providing Access to Clinical Trials (IMPACT) Program

Guidelines & Instructions Letter of Intent & Full Application

Effective dates: October 1, 2022 – June 30, 2023

Application Deadlines	
LOI Deadline	January 6, 2023, 3:00 PM (ET)
Invitation for Full Application Submission	January 13, 2023
Full Application due:	March 10, 2023, 3:00 PM (ET)
Grant Start date:	October 1, 2023

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.

<u>Description of Influential Medicine Providing Access to Clinical Trials</u> (IMPACT) Program

Bringing trials to the patients

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 mainly at local community oncology centers. These clinical trials will be hosted by the major cancer center (IMPACT hub) who will partner with community-based oncologists to facilitate recruitment and participation of patients at community oncology centers.

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 in the early years of funding.

LLS has a broad interpretation of what constitutes a community oncology center, but generally, it will be a non-academic center that sees patients who are far from a major academic 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 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.

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 goal 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 is no set requirement for number of IMPACT trials but should reflect a good faith effort on the part of the hub to reach the goals of the program.

Demographics of IMPACT Trials and Geographic Distribution of Community Partners
Though all patients at the 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 from a rural location, are a minority, and/or are
economically disadvantaged.

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. Any one patient may have characteristics of 1-3 of these groups.

Community oncology partners would ideally be in a broad distribution around the IMPACT hub. However, the choice of community partners can initially be chosen based on patient need as well as likelihood of IMPACT trial activity occurring at the community sites in a reasonable timeframe.

The long-term goal of IMPACT is engagement of major academic centers with community oncology centers that are distant from the major academic center. A successful long-term outcome is to have a series of IMPACT-associated community oncology centers that serve the geographic region of the major cancer center's catchment area, particularly those that are distant from the major cancer center. IMPACT trial participants should have a demographic make-up that matches the demographic make-up of the hematologic malignancy patients of the communities served by the IMPACT-associated community oncology centers.

Geographic Diversity of the Overall IMPACT Award Mechanism

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 six IMPACT programs:

- Vanderbilt University Medical Center
- Mayo Clinic Rochester
- Weill Cornell Medical College of Cornell University
- MD Anderson Cancer Center
- University of Colorado
- City of Hope National Medical Center

Though we may accept applications targeting similar geographical areas, we strongly favor those programs that will add to the overall program's geographic diversity. The bar will be high for those new applications with a geographical reach that highly overlaps with any currently funded IMPACT programs. We will not accept new applications from any institution that currently hosts an IMPACT program.

Award Amount

The maximal award value is \$250,000.00 for each year of the five-year grant, which can include up to 5% overhead costs of the total award amount requested in the proposal. Since IMPACT is meant as an infrastructure grant, all trial costs must be supported by other sources. Physician salaries may be included but must be well justified and must not comprise a large portion of the total award. Acceptable costs may include clinical trial navigators dedicated to IMPACT trials, clinical pharmacies, and other expenses related to bringing the trials to the community patients

at the community centers. Some costs for travel are acceptable but must not be a large budget item. Educational activities are welcome but should not be a large expense; note that LLS has resources that can be harnessed for this purpose. Costs related to mechanisms to increase efficiency of interaction between the hub and community centers regarding clinical trials are encouraged. A full-time coordinator (including fringe benefits) for the IMPACT program is suggested.

An additional \$150,000 *may* be provided to strong IMPACT programs with well-justified expenses. The application should include the full \$400,000, but the additional \$150,000 must be justified every year for funded IMPACT programs.

LLS IMPACT funding is for 5 years. It is expected that IMPACT awardees will work towards a goal of sustainability of the program beyond LLS funding. Success in the program, together with specific efforts of the IMPACT team, should produce opportunities for continued funding of the IMPACT program after LLS funding ends. Part of the annual evaluation by LLS (see below) will relate to efforts by the IMPACT team to achieve this sustainability.

Note: IMPACT is <u>not</u> 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.

Who Can Apply

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 IMPACT progress, appropriate disbursement of funds, and adherence to LLS policy. The IMPACT Director must be employed by, and have a primary appointment at a nonprofit, academic institution. This institution must be the IMPACT host institution.

Citizenship

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

Institution (Host Institution/Hub)

The institution (hub) must be in the United States. The hub is a nonprofit, major academic cancer center with substantial clinical research efforts in hematological malignancies. NCI-designated cancer centers will qualify. Other major cancer centers that serve many blood cancer patients and that have robust hematological malignancy clinical trial programs may also qualify, but there may be a higher burden on the applicant to prove that their institution will be an effective IMPACT hub.

General Eligibility

IMPACT Director applicants must hold an MD or equivalent degree and must be affiliated with a non-profit institution at the time funding commences and for the duration of the award. The award must remain with the institution identified as the cancer center hub in the application. If the IMPACT Director leaves the institution, LLS must be notified immediately. A new IMPACT Director must be identified by the 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. **Modifications to leadership of funded awards must be approved by LLS in order for funding to continue.**

Post-Award Management

Annual Goals

Annual goals are required at the start of funding. These goals will be the number of community oncology center partners, number of clinical trials open in the community, and number of patients participating in trials at community sites. Each year, these goals will be updated to reflect changes from the prior year as well as new goals. In addition, updates on this progress will be provided to LLS four times a year.

Both LLS and the IMPACT Director must agree on the goals. These are due by the funding agreement due date and must be updated yearly in the progress report.

Annual Assessment

After the final quarterly report of the year (which is called the annual progress report), LLS staff will assess the quality of the IMPACT award and the progress made on the specific annual goals as well as the overall goals of the program. The major goal of IMPACT is *bringing trials to patients*, with most trial activity for those patients occurring at their local community oncology center. *Therefore, this goal should be the clear focus for this 5-year grant.* While we recognize that getting trials open in the community and getting patients actively participating in trials will take time, continued funding depends on sufficient progress in getting these patients on trials at the community centers. After the annual 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. If progress is not sufficient, a warning will be provided, which may result in future funding being reduced or eliminated if progress does not improve. After this assessment, LLS may ask the IMPACT Director for modifications of their future goals.

Annual Reports

In addition to quarterly discussions, there are Intellectual Property and Progress Reports that are due annually, Financial Reports that are due semi-annually and Publications Reports that are due quarterly. The Progress Report is the fourth quarter report and will contain progress in meeting the annual goals (see above). The Progress Report evaluation by LLS may or may not require a brief meeting with LLS staff. This report is essential for LLS scientific staff evaluation of progress. Release of the next payment is contingent on the receipt, review, and approval by LLS of all satisfactory reports (and quarterly 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 virtually or in person at least quarterly to discuss progress and results.

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, hub capabilities, and any new information for those that submitted IMPACT applications previously.

Full Application

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

Review Criteria

Priority Score

- The likelihood that the IMPACT program will substantially increase clinical trial participation of those patients whose trial participation will be mainly at community oncology settings.
- Quality and feasibility of the long-term goal of engaging multiple community centers that represent the geographic range of the hub's catchment area.
- Quality of the plan to increase patient participation of those who live in rural areas, are
 members of racial and ethnic minorities, and/or are economically disadvantaged; this
 effort should seek to match the demographics of the hematological malignancy patient
 population of the community centers served.
- The likelihood of the clinical trials to significantly advance outcomes for clinical trial participants.
- The qualifications of the IMPACT Director and the IMPACT team.
- The quality of the hub and its ability to support multiple clinical trials in hematological malignancies.
- The likelihood of IMPACT clinical trials treating community patients in a reasonable time frame, with this participation occurring mainly at the community centers.
- The clarity of thought and presentation.
- Quality of the IMPACT sustainability plan.
- A minor consideration will be how the applicant's IMPACT program will add to the geographic diversity of the currently funded IMPACT programs.

Key Dates

	Date
Call for Proposals	October 2022
LOI Deadline	January 6, 2023; 3:00 PM ET
Invitation for Full Application Submission	January 13, 2023
Full Application Phase Deadline	March 10, 2023; 3:00 PM ET
Notification of Awards	June 2023
Funding start date	October 1, 2023

^{*}LLS's Funding Agreement Terms & Conditions are available on www.lls.org.

<u>The submission deadlines will be enforced.</u> 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 <u>LLS Research Portal</u> automatically shuts down 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 these Guidelines & Instructions in full.
- 2. Log in to the <u>LLS Research Portal (https://lls.fluxx.io/)</u> and select IMPACT. Click "Apply to IMPACT" to begin the application process (well ahead of the deadline).
 - o 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.
 - o If you are a first time user to the <u>LLS Research Portal</u>, please fill out the <u>Account Request Form</u> 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 <u>researchprograms@lls.org</u> if you submit in error (must be before the deadline).
- 5. Once your LOI is submitted, you will receive an automated email from the <u>LLS Research Portal</u>. This email may end up in your spam filter.
- 6. Applicants who are invited to submit a full application will have access 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 <u>researchprograms@lls.org</u> with any questions about the application that are not addressed in the <u>LLS Research Portal</u>, 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 may be heavy.
- 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 be administratively disqualified.
- 9. Line spacing is preset in the Word document. Do not change the setting. Pasting text from another document into the template may result in a change in the line

spacing. Check the line spacing in the template before pasting, and if there is a change after pasting, return the line spacing to the original setting.

10. To create a fair process for all applicants, all instructions must be followed.

Carefully check every page of your application prior to submission. The IMPACT Director 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 <u>LLS Research Portal</u>, 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 <u>LLS Research Portal</u>, please contact researchprograms@lls.org.

Letter of Intent Phase Instructions

The Letter of Intent (LOI) is non-competitive; however, LLS reserves the right to reject an LOI when it is determined that the IMPACT Director and/or the Institution is not appropriate for this program. This may include (but is not limited to) inadequate hematological malignancy clinical research operations or overlap with existing IMPACT programs.

Information for the Letter of Intent will be entered on the web form in the LLS Research Portal.

IMPACT Title

125-character limit including spaces.

Project Summary

For funded applications, we post awardee information on our website. Together with the applicant's biographical information, there is a short Project Summary of the applicant's research. From there, a reader may choose to look at the longer Lay Description. Therefore, please provide a 3-5 sentence Project Summary describing your program. The total of all sentences should be no more than 500 characters, including spaces. Use this guide to structure the short paragraph:

- Overall question/focus of your program (1 sentence)
- High-level approach you will use (1 to 2 sentences)
- Outcome/goal of your program (1 to 2 sentences)

The overall goal is to provide a succinct overview of your program in a short, cohesive paragraph.

Brief Biography

Provide a brief, professional biography introducing the IMPACT Director to a lay audience. **1,000 characters maximum, including spaces.**

Lay Description

The Lay Description should clearly describe your program using non-technical language that is easily understood by the lay community. Scientific/Greek characters or symbols must not be

used. The Lay Description is essential for LLS to continue successful fundraising to support our current and future grantees, including the later years of *your* award, should it be funded. Thus, we require a well-written Lay Description, with sufficient detail and suitable language for non-scientists. Be aware of your confidential information, as the Lay Description (and Project Summary) will be shared with others. The Lay Description has a minimum of 2,000 characters and a maximum of 2,500 characters, including spaces.

Helpful hints for writing an appropriate Lay Description:

- Consider how you would describe your program to a friend or family member who is educated *but is not a physician nor a scientist*.
- Limit 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 Description:

- What is the overall goal of your program?
- What is unique about this program?
- How will you achieve your goals?

Certification of Lack of Overlap with Currently Funded IMPACT Programs

Current IMPACT programs are located at:

- Mayo Clinic Rochester
- Vanderbilt
- Cornell
- MD Anderson
- University of Colorado
- City of Hope

We will not accept new applications from these institutions nor with any institution closely affiliated with them.

Description of Changes from Prior Application

1,000-character limit including spaces (this information will also be asked for in the full application). For those who have previously submitted an IMPACT application, provide updates on how (and if) your proposal has evolved since the prior submission.

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 and include the percentage of these patients that are hematological malignancy patients. Provide specific numbers of active trials implemented (at least in part) at the community center as well as numbers of participating patients.

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 a community center.

Number of Hematologic Malignancy Clinical Trials at the host Cancer Center (IMPACT hub)

Number of Suitable Hematologic Malignancy Clinical Trials for Implementation at Community Oncology Settings

IMPACT Director Biosketch and Other Support form

A Biosketch and Other Support form must be provided and must follow the guidelines provided by the NIH. Please refer to the NIH guidelines for questions on how to fill out these documents. An eRA Commons Username is not required. The Other Support document *must* be a document separate from the biosketch. You do not need to switch to a new version should the NIH update any format during the application process. Therefore, use the most recent format as of October 1 of this application cycle (though you may use a later version if you wish and if one becomes available).

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 <u>researchprograms@lls.org</u>.

Full Application Phase Instructions

Applicants whose LOIs were approved may move to the Full Application Phase. **Information provided in the LOI phase will carry through to the full application and must not be changed.** The following information is required for full application submission and must be provided on the <u>LLS Research Portal</u>.

Project Template

Download the project template. 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 limitations. Margins are preset at 0.5 inches on each side and must not be changed. Line spacing is preset and may change if information is pasted into the document. Check line spacing before and after any pasting and restore to the preset values. Only single-spaced, Arial 11 pt. font is acceptable.

- 1. Application Information.
- **2. Prior Applications.** For those who have applied to IMPACT previously, describe any changes in your program since the prior application submission.
- **3.** Cancer Center Hub Statement. Describe the overall clinical trial infrastructure of the cancer center with an emphasis on clinical trials of hematologic malignancies.

- **4.** Cancer Center Hub Geographical Service Area. Describe the geographical area served by your cancer center. Include information about the population overall, as well as information about hematologic malignancy prevalence in this area.
- Cancer Center Hub Geographical Service Area Graphics. Provide 1 or 2 graphical representations of the cancer center hub's catchment area and locations of planned community partners.
- **6.** Cancer Center Hub Hematologic Malignancy Activity. Provide numbers on hematologic malignancy activity and hematologic malignancy patients at your cancer center.
- 7. Current Community Cancer Center Involvement. Describe any current coordination with community centers to provide hematological malignancy clinical trials at those centers.
- **8.** Current Community Cancer Center Details. Provide information on community cancer centers that you are currently involved with.
- 9. Plan to Increase Community Center Involvement. Describe how IMPACT funding would be used to increase community center involvement in hematologic malignancy clinical trials. IMPACT funding supports infrastructure development and maintenance; clinical trial costs must come from other sources. Note that IMPACT seeks to increase participation of patients whose trial activity is done mostly at the community cancer centers. Describe specifics about the infrastructure that will support trial activity occurring at the community oncology centers.
- **10. Future Community Cancer Centers: New Partnerships.** Provide information on community cancer centers that you are planning future involvement with.
- **11. Community Cancer Centers: Goals.** Provide goals for the number of hematologic malignancy clinical trial participants that will have a majority of their trial participation done at the community cancer center should IMPACT be funded.
- 12. Community Cancer Centers: Underrepresented Patients. Describe how IMPACT trials will include patients traditionally underrepresented in clinical trials (low socioeconomic status, racial/ethnic minority, and/or rural patients). IMPACT trial participation should seek to match the demographics of the hematologic malignancy patient population seen at the associated community centers, and these centers should generally reflect the geographic area served by the hub.
- **13. Eligible Clinical Trials.** Describe 10 *interventional* clinical trials that will be appropriate for participation of patients whose trail activity is mainly at the community oncology center. The clinical trials must have the intent to provide significant new information with high patient impact.
- **14. 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. 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. Identify the management structure of the IMPACT program overall.
- **15. IMPACT Implementation Timeline.** Provide a timeline for implementation of IMPACT activities. Use the Gantt chart provided.
- **16. IMPACT Fund Usage.** Describe how IMPACT funding would be used to achieve the goals of the program. Group common themes and provide an overall cost for each theme (do not provide a line item of each expense).
- 17. Institutional Commitment. A key review criterion will be the level of <u>direct</u> institutional commitment to the IMPACT Program. A separate commitment letter from a responsible institutional official must be included with the application. The financial commitment should be described in this section and may include salary support for non-physician personnel. Salary support for IMPACT-associated physicians may be included but should be well justified based on new responsibilities associated with the IMPACT Program; this should not be a substantial portion of the budget nor of the institutional commitment for IMPACT. The institutional commitment should clearly and directly affect patient participation in IMPACT trials at the community oncology centers.
- **18. IMPACT Sustainability.** Briefly describe your plans to continue IMPACT activity beyond the IMPACT funding period. Describe any efforts that will be used to identify a funding plan for IMPACT sustainability.
- 19. References.
- **20.** Budget. 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.
- 21. Budget Justification. Describe how IMPACT funding would be spent to achieve the goals of the program. Justify each expense as to the overall goal of the IMPACT Program. Personnel that clearly contribute to the program can be included, and may include clinical coordinators, patient navigators, etc., as well as an IMPACT manager. Physician salaries may be included but must be well justified based on new responsibilities associated with the IMPACT Program and cannot consume a large portion of the budget. Other expenses that directly affect clinical trial participation at community centers are encouraged, including clinical pharmacy expenses. Mechanisms to increase efficiency between the hub and community centers regarding clinical trial implementation/activity are encouraged. Lastly, some travel and educational resources may be requested, but these should be a smaller part of the budget. All expenses must clearly contribute to the overall goal of bringing trials to the patients at community centers.

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:

- Personnel expenses including salary, wage, or stipend and fringe benefits; physician salaries may be included but must be well justified and not a major portion of the budget.
- Support for educational and outreach activities associated with the IMPACT program; this support may not be a large portion of the overall budget.
- Support for travel associated with the IMPACT program; this support may not be a large portion of the overall budget.
- 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). 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 the total budget requested.

Impermissible Costs

These include (but are not limited to) clinical trials, research, membership dues, tuition, books, journals, and publication costs.

22. Signature Page

Provide all requested signatures.

23. Appendix

This section should include, in this order:

- Table of contents.
- Letter from Institutional Official concerning institutional commitment.
- IMPACT Director/Applicant and Key Physician Personnel Biosketches and Other Support forms.
- Community Center Partnership Letters. Do not include any letters from LLS personnel.

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.

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.

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:

- Manuscripts that are accepted for publication; the following must be provided via email to <u>researchprograms@lls.org</u>:
 - 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 personnel changes