LEUKEMIA & LYMPHOMA SOCIETY®

Equity in Access Research Program

2025 Request for Proposals

Building Evidence for Effective Interventions to Increase Therapeutic Cancer Clinical Trial Accrual: Promoting Access for Patients from Underrepresented Groups

Introduction

The Leukemia & Lymphoma Society's (LLS) mission is to cure blood cancers and improve the quality of life of patients and their families through research, policy advocacy, education, and support. We are the largest nonprofit funder of blood cancer research, investing nearly $1.8 billion in the most pioneering science worldwide since 1949. We drive policy and regulatory changes that accelerate the development of new blood cancer treatments and break down barriers to care.

This funding opportunity is part of LLS's *Equity in Access Research Program*, designed to generate evidence that will guide **changes in healthcare policy and practice** to ensure that all patients with and survivors of a blood cancer have the ability to access and utilize optimal treatment, care, and resources that can improve their quality of life and outcomes, from diagnosis through survivorship. This program is based on the concept of health equity as "the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes."[1] For LLS, a key part of advancing health equity is a commitment to reducing and ultimately eliminating health disparities that affect those with a blood cancer. We define health disparities as "a type of preventable health difference that is closely linked with social, political, economic, and environmental disadvantage."[2]

Although substantial evidence links economic and social disadvantage to avoidable illness, poor health-related quality of life, and greater untimely death, it is possible to lessen the impact of this disadvantage on health through social policy reform.[3] Moreover, **it is possible to reduce disparities in cancer outcomes through institutional and practice changes that mitigate barriers to high-quality care and treatment, and enhance access to clinical trials.**[4,5] LLS is committed not only to contributing to public awareness of and discourse about disparities in access to healthcare and clinical trials,

as well as disparities in health outcomes, but also to shaping this discourse in a meaningful way for patients with and survivors of a blood cancer.

Background

The Importance of Equity in Therapeutic Cancer Clinical Trial Participation

The opportunity to participate in a clinical trial is considered high-quality cancer care,[6,7] but access to and participation in these trials is inequitable. Approximately 20% of all cancer patients are eligible for participation in a clinical trial, yet only about 7-8% participate.[8,9] Further, it is estimated that only 15% of those participating are from racial and ethnic minoritized groups,[8,10] even though racial and ethnic minoritized groups comprise more than 40% of the U.S. population.[11] Despite factors that have contributed to mistrust, patients from racial and ethnic minoritized groups are as willing as non-Hispanic whites to participate in health research when eligible and invited to participate.[12-18]

Research also consistently shows that groups underrepresented in cancer clinical trials include people not only from ethnic and racial minoritized groups,[19-21] but also people who have low incomes,[22] people who live in rural areas,[23] people who are age 70 and older,[24-26] as well as adolescents and young adults aged 15-39.[27] Disproportionately low participation rates among these groups may perpetuate disparities in treatment outcomes.[5] Moreover, ongoing underrepresentation will continue to lead to limited generalizability for newly discovered cancer treatments.[19,28,29]

Disparities in trial access and participation among different groups do not exist independently of one another; as noted by Mishkin and colleagues, the "intersection between trial enrollment and age, race, ethnicity, and other patient characteristics such as geographic area and rurality warrants further study so that more targeted enrollment enhancement efforts can be developed that improve trial diversity across demographic groups."[25] We agree with Oh et al. who suggest that "adequate representation of diverse

populations in clinical research is not only a matter of science, but also economics and social justice."[30]

Barriers to Therapeutic Cancer Clinical Trial Participation

The literature to date has documented numerous barriers affecting cancer clinical trial participation. Addressing such barriers is critical for accelerating progress toward more effective cancer treatments and providing *all* patients with access to novel treatment approaches.[31] These barriers occur at the system, institutional, clinician/research team, and patient levels[10,28,29,31-38]; see Table 1 below.

Table 1. Barriers to Therapeutic Cancer Clinical Trial Participation

Level	Examples (these are not meant to be exhaustive)
Structural/Systemic	• Restrictive inclusion or exclusion criteria[39-42] • Onerous participation requirements[39-42] • Community oncology practices not selected to participate in trials by trial sponsors[8,43] • Inadequate trial availability across different cancer types/stages[8]
Institutional	• Community oncology practices choosing not to participate in clinical trials due in part to lack of infrastructure and resources[8,43] • Trial selection process that leads to opening studies that do not fit the patients seen[31,44] • Ineffective/inconsistent patient screening and enrollment practices[12,29,30,36,45-50] • Staff/infrastructure capacity and capability[51-53] • Complex and lengthy informational materials[54,55] • Complex and lengthy processes and forms (e.g., informed consent)[56-58]
Clinician/Research Team	• Physician and other health care provider attitudes towards trials[10] • Failure to consistently offer trials to eligible patients[12,29,30,36,45,46,51,59] • Poor quality of provider-patient communication during clinical interactions[10,53,59-61] • Assumptions about patient treatment preferences, implicit or explicit biases, or stereotypes about who may be a "good" study participant[13-16,51,62-64]

Patient	• Lack of knowledge/awareness of trials as an option for treatment • Low self-efficacy, high medical mistrust, negative beliefs and attitudes[65] • Low health literacy[54,66-68] • Limited English proficiency[69-71] • Concerns about costs as compared to standard care[72] • Concerns about logistics as compared to standard care[72] • Fear of side effects[31,38,72] • Preference for control of treatment[31,38,72]

The Need to Identify Effective, Evidence-Based Approaches to Increasing Participation in Therapeutic Cancer Clinical Trials

As delineated above, there is an extensive body of literature describing the barriers that likely impede cancer clinical trial accrual, along with numerous recommendations and reports[29,36,37,73-80] about how mitigating these barriers could lead to increased accrual. However, as noted by Denicoff et al., while multiple studies have documented "successful" approaches to increasing trial accrual, few studies have rigorously tested interventions to improve clinical trial accrual.[74] In 2024, LLS commissioned a systematic review[81] (see www.lls.org/equityinaccess) which aimed to identify studies completed in the last 10 years that provide clear quantitative evidence for whether an intervention improved accrual and, if so, by how much. Studies were included if they were conducted in the United States, described single or multicomponent interventions, provided data to measure accrual relative to baseline levels, or compared accrual rates with other interventions carried out as part of the same study. The outcome of interest was change in rate of accrual, defined as the number of cancer patients enrolled in therapeutic cancer clinical trials over a specific time, or the proportion of eligible patients enrolled in trials over time.

The surprisingly small number of studies that met the criteria for inclusion **made it difficult to identify with certainty any effective, evidence-based approaches for**

increasing accrual in therapeutic cancer clinical trials. The few studies that did report positive accrual outcomes suffered from a lack of rigorous methods and a lack of detail about the resources necessary for implementation. Moreover, results for a given intervention were never replicated, limiting the strength of evidence for any one intervention and making it impossible to draw firm conclusions regarding efficacy. Now, in 2025, more than 10 years after Denicoff et al. highlighted the problem, there is still a dearth of rigorously conducted studies that have tested interventions to increase rates of cancer clinical trial accrual.[74]

Further, although barriers to clinical trial enrollment among cancer patients are multilevel and systemic, our systematic review found - as have others - that studies seeking to increase accrual have focused primarily on mitigating patient-related barriers only.[8,82] As Unger and colleagues have suggested, this emphasis suggests that patients themselves are the primary factor limiting trial enrollment.[8] However, their meta-analysis revealed that system, institutional, and clinician-level factors may have a much greater influence on patient participation; in fact, these systemic factors accounted for the non-participation of more than three out of four patients across the trials studied.[8] Based on their findings, they conclude that the root causes of low participation rates are structural and clinical barriers rather than patient attitudes. This suggests that research, interventions, and policies to improve trial participation should focus in large part on systemic, structural, and clinical barriers instead of individual patient barriers.[8] Because many of these barriers are potentially modifiable, mitigating them represents an "enormous opportunity to increase trial participation rates."[8]

In conclusion, there is a paucity of high-quality evidence to guide efforts to increase participation in therapeutic cancer clinical trials. **More evidence must be generated to identify which interventions can be effective in the current policy environment for which populations of patients, and what resources are required to replicate them.** It is imperative that interventions for increasing participation in cancer clinical trials be developed and rigorously evaluated so that these interventions can be disseminated,

access to trials can expand and become more equitable, and trial results can become more generalizable.[19,28,62,73] These interventions can enhance the speed with which clinical researchers can determine results and bring new treatments to patients who need them.

The purpose of this Request for Proposals (RFP) is to fund research studies that will increase our understanding of effective interventions for increasing accrual in therapeutic cancer clinical trials, particularly among underrepresented populations. **For this RFP, accrual means a patient's agreement to participate in a clinical study as indicated by signed informed consent**.[83,84]

We seek to fund proposals that will implement and evaluate interventions designed to a) mitigate barriers to therapeutic clinical trial accrual for underrepresented groups, and b) quantitatively measure the impact of these interventions on patient accrual. With this RFP, LLS will support research that will guide changes in evidence-based practice and policy. LLS is particularly interested in proposals that address **systemic, institutional, and/or clinician-related barriers that impede clinical trial participation. In particular, we encourage submission of proposals that focus on implementing and evaluating interventions related to clinical trial decentralization, addressing social determinants of health, utilizing digital technology (including artificial intelligence), modifications to trial eligibility criteria, and/or other modifications to or additions of institutional procedures that facilitate accrual.**

Proposed research studies must:

- Study interventions to increase accrual by addressing barriers at the structural/systematic, institutional, clinician/research team, and/or patient levels. Multi-level interventions are strongly preferred. Single-level interventions are less likely to be funded. Selected interventions cannot be only at the patient level.
- Be designed in a way that allows for assessment of both the independent and combined effects of interventions conducted to increase accrual, as relevant; the

statistical analysis plan should explicitly measure independent and combined intervention effects on accrual.

- Measure change in the rate of accrual to therapeutic clinical trials over time among one or more underrepresented groups as the **primary outcome**; applicants may choose to focus on a subset of trials or populations.
- Document that the institution(s) involved in the proposed research provide clinical care to a patient demographic where at least 30% of patients represent underrepresented groups (e.g., *patients from racial/ethnic minoritized groups, those residing in rural areas, patients with Medicaid, those over age 70, and/or adolescents and young adults)*. The 30% threshold can be met through any one group or a combination of these groups.
- Include interventions and outcomes related to blood cancer therapeutic trials (leukemias, lymphomas, myeloma, myelodysplastic syndromes, and/or myeloproliferative neoplasms). Interventions and outcomes may also include therapeutic trials for other cancers.
- Test interventions that are based on promising preliminary intervention data; preliminary data can be internal or external and may be published or unpublished. This grant mechanism is not intended to fund pilot projects.
- Collect outcomes data that allow for a direct comparison, such as comparing accrual before and after an intervention is implemented or between two interventions alongside a control group.
- Involve key study stakeholders in shaping and executing the research (e.g., community oncologists, patients, clinical research staff, patient navigators).

Research Areas of Interest

Examples of research questions that address barriers at different levels include the following (this is not meant to be exhaustive but simply illustrative):

- To what extent does addressing social determinants of health (e.g., transportation, housing, food insecurity, child/dependent care) impact accrual rates?

- Can decentralized trial models (e.g., allowing trial services to be delivered/performed at local sites, telemedicine) increase accrual rates?
- How can digital technology, such as artificial intelligence, be leveraged to enhance accrual rates?
- How does ensuring systematic pre-screening and screening of patients who are starting or changing treatment increase accrual rates?
- To what extent does increasing the number of trial sites and opening trials that are better matched to the patient population (e.g. with respect to inclusion/exclusion criteria) increase accrual rates?
- How does building staff and infrastructure capacity for community-based trial delivery enhance accrual rates?
- To what extent do trial protocols that allow for trial services to be delivered during non-traditional working hours (e.g., after 5 pm, on weekends) affect accrual rates?
- What is the impact of modifying enrollment procedures and forms (e.g., permitting virtual initial eligibility screening appointments or improving informed consent) on accrual rates?
- How does establishing institutional expectations for clinicians to communicate about clinical trials as a treatment option impact accrual rates?

In addition to these areas of interest, we encourage the utilization of the LLS Clinical Trial Support Center to augment proposed interventions. https://www.lls.org/support-resources/clinical-trial-support-center-ctsc.

We will **not fund studies** that focus primarily on:

- Understanding patient barriers to accessing cancer clinical trials
- Understanding patient perspectives, preferences, and unmet needs around cancer clinical trials
- Patient or community attitudes, knowledge, awareness about clinical trials, or willingness to participate in trials

- Physician or provider attitudes, knowledge, awareness about clinical trials, or willingness to refer patients to trials

However, data on patient, provider and community knowledge, attitudes, and perceptions may be collected as part of overall assessment efforts.

Funding Available

- Maximum project period is 5 years, and the maximum funding amount per year is $500,000.
- Total budget, including indirect costs, should not exceed $2.5 million for a 5-year project period.
- Indirect costs are limited to 11.1% of the total direct costs during the Research Funding Term.

Applicants should request the amount of funding they will need to complete the proposed research and disseminate findings. The review process will include an evaluation of the appropriateness of the funding request in light of study aims and methods to achieve the aims.

Applicant Eligibility

The application will require a Principal Investigator who is responsible for proposal submission and conduct of the study, including adherence to all stipulations made by LLS in this document, and in a Funding Agreement. Study teams may also include one or two Co-Principal Investigator(s) and multiple Co-Investigators. Study teams must also include at least one stakeholder (e.g., community oncologists, patients, clinical research staff, patient navigators).

LLS welcomes Principal Investigators at all stages of their careers as well as Principal Investigators who have not previously conducted research in the area of blood cancer. However, if the Principal Investigator is an early investigator, a more experienced Co-

Principal Investigator is required. Principal Investigator(s) must also meet the following eligibility criteria:

- The Principal Investigator(s) must be affiliated with a public or nonprofit institution (tax exempt under Section 501(c)(3) of the Internal Revenue Code).
- The sponsoring institution must be based in the United States or its territories.
- The Principal Investigator must have a PhD, MD, DO, ScD, JD, or equivalent doctoral degree.

The Principal Investigator and other study team members may come from a variety of disciplines, including but not limited to medicine/oncology, nursing, social work, public health, health services research, economics, sociology, health communication, epidemiology, and biostatistics. **We strongly encourage multi-disciplinary teams.**

Consistent with LLS's commitment to diversity, equity, and inclusion, we encourage applications that have investigators and/or research team members from backgrounds historically underrepresented in research disciplines as a result of their race, ethnicity, socioeconomic status, disability, or other factors.

How to Apply

All application materials for this RFP must be submitted via the LLS Research Portal at https://lls.fluxx.io/. It is recommended that you familiarize yourself with this portal well in advance and that you submit early, at least 2 days before the due date. This competitive proposal process has two phases: a Letter of Intent and an invited full proposal.

Registration

If you are a first-time user of the LLS Research Portal (https://lls.fluxx.io/), please complete the registration form using this link: Account Creation Request to create an account. **Please register at least one week before the Letter of Intent due date** to ensure

submission of the Letter of Intent by the specified deadline. If you do not hear back in one week after completing the registration form, please email researchprograms@lls.org.

If you have applied to LLS in the past, you do not need to create a new registration and can login 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. For login issues, please email researchprograms@lls.org.

Phase 1: Letter of Intent

As the first step in the application process, please submit a Letter of Intent through the LLS Research Portal at https://lls.fluxx.io/. As part of the submission, you will need to upload a single PDF document in the **Project Description & Supporting Documentation** section that includes all of the following information, with each section clearly labeled in the order below. **Please note that submitting some duplicate information in pre-set webform fields and the PDF document will be necessary. Character limits and other length limits are enforced on the webform.**

The Letter of Intent must use at least 11-point font [Arial], 1-inch margins, and single spacing. Documents must also be left justified; fully justified text is not permitted. Letters of Intent that do not comply with these guidelines will not be considered:

1. Project title: (maximum 150 characters including spaces)
2. Lay Abstract: brief summary that clearly states the relevance of your research to the purpose of this RFP and describes your proposed research using non-technical language that is easily understood by the lay community. Be aware of your confidential information, as the Lay Abstract will be shared with the public.
3. Principal Investigator(s) and other Key Personnel
    - Names and affiliations of Principal Investigator, Co-Principal Investigator(s), and Co-Investigators

- Names and affiliations of other key personnel
- A one-paragraph biography for **Principal Investigator and Co-Principal Investigator(s)** as relevant that highlights why these individuals are particularly qualified to undertake this work (maximum 1,500 characters each, including spaces). Biographies for other co-investigators and/or collaborators/personnel are not required for the Letter of Intent.

4. Name and location of sponsoring institution
5. Name and location of any subsites or any additional institutions that will be involved in the study
6. Project Summary **(no more than 2 pages; references do not count in the 2-page limit. Proposals exceeding the 2-page limit will not be reviewed and will be automatically disqualified)**:
    a. Specific aims, which must identify barriers to be addressed and interventions that will be implemented to increase therapeutic clinical trial accrual rates, particularly of underrepresented patient populations.
    b. Potential for the study to generate new evidence for effective, replicable interventions to increase accrual rates
    c. Brief description of pilot and/or previous related work conducted by the investigators or others on the interventions or aspects of the interventions proposed (can be published and unpublished, internal or external)
    d. Brief description of how the proposal builds on prior related work to inform and support innovative approaches, methods, or tools that address the goals of the RFP
    e. Clear description of the intervention(s) to be implemented
    f. Overview of study design and methods, which must include:
        i. key outcomes, with change in the rate of accrual to therapeutic clinical trials over time among one or more underrepresented groups included as the **primary outcome**

ii. analytic methodologies to be used, **<u>including method(s) that will allow you to determine the independent and combined effects of multiple interventions, as relevant</u>**

iii. sites of care that will be involved

iv. cancer type(s) of focus for this proposal

v. a brief description of how stakeholders (e.g., community oncologists, patients, clinical research staff, patient navigators) will be meaningfully involved in the proposed study. Indicate the types of stakeholders and their anticipated roles.

7. **Site-level table: The following information should be provided in a table (see sample below). The table does not count in the 2-page Project Summary limit. In addition to the table, you may provide a brief narrative within the 2-page Project Summary describing any additional context, challenges, or strategies pertaining to the information presented in the table, as relevant**:
    a. percentage that the underrepresented population(s) of focus with the disease type(s) of focus comprise at the proposed study sites, among cancer patients treated in a year with that disease type; please present each site separately
    b. therapeutic clinical trial accrual rates for the most recent year available across clinical trials only for the disease types (including blood cancer clinical trials) and demographic groups that will be of focus in the study
    c. the approximate number and type of therapeutic clinical trials that will be included, as known at present
8. Proposed start and end dates: The start date for this award is July 1, 2026. The end date can be no later than 5 years after the start date; the latest possible end date is June 30, 2031.
9. Requested award amount (approximate); see Full Application Guidelines & Instructions at LLS.org/EquityinAccess for permissible costs. **A detailed budget and justification are not required at the LOI phase.**

Sample table

Study Site	Underrepresented Population of Focus with the Disease Type(s) – Number and % of Annual Cases at Site	Anticipated Number of Therapeutic Clinical Trials to Be Included (by Disease Site)	Therapeutic Clinical Trial Accrual Rate for Underrepresented Population of Focus (Most Recent Year)
Site A	African American: lymphoma, 20 (**10%)** lung, 18 **(9%)** colorectal, 14 **(7%)** Hispanic/Latino: lymphoma, 10 **(5%)** lung, 12 **(6%)** colorectal, **6 (3%)**	**15** (10 lymphoma, 3 lung, 2 colorectal)	African American: lymphoma, **12%** lung, **10%** colorectal, **8%** Hispanic/Latino: lymphoma, **7%** lung, **3%** colorectal, **9%**
Site B	African American: leukemia 16 **(8%)** prostate, 28 **(14%)** Hispanic/Latino: leukemia, 10 **(5%)** prostate, 8 **(4%)**	**23** (12 leukemia, 11 prostate)	African American leukemia, **15%** prostate, **5%** Hispanic/Latino leukemia, **13%** prostate, **7%**

Special Requirement for Resubmissions to this RFP

Applicants who are resubmitting a research concept that was previously submitted to the Equity in Access Research Program and underwent full review must include a cover letter providing a high-level overview of how the revised proposal will address the critiques provided by reviewers. Please place the cover letter before the Letter of Intent. The cover letter will not be counted in the Letter of Intent page length. We have included the cover letter as a requirement for resubmissions as it will provide valuable context and show the evolution and enhancement of the research concept since its initial submission. Unless you are resubmitting, **cover letters should not be included.**

Phase 2: Invited Full Proposals

Selected Phase 1 applicants will be invited to submit a full 12-page proposal, accompanied by a detailed budget justification and additional required information. Submitted full proposals will undergo rigorous peer review by external subject matter experts. See Full Application Guidelines & Instructions at LLS.org/EquityinAccess.

Review Criteria for Full Proposals

The panel will consider the following criteria in reviewing proposals:

- Significance to the Field: Extent to which the study addresses critical, unanswered questions and increases our understanding of effective interventions for increasing the rate of accrual to therapeutic cancer clinical trials, particularly among underrepresented populations.
- Preliminary Data: Strength of pilot and/or previous related work conducted by the investigators or others on the interventions or aspects of the interventions proposed; preliminary data can be internal or external and may be published or unpublished.
- Innovation: The extent to which the study examines innovative intervention approaches, methods, or tools to increase therapeutic cancer clinical trial accrual, particularly among underrepresented groups, with a clear explanation of how the innovation represents a meaningful advancement beyond current practice or knowledge.
- Methodology: Strength of the methodological plan for bringing the research to fruition; methodologies, patient populations, and data sources must be described in detail and be appropriate for and available within the timeframe of the study. Applications must describe how key stakeholders will be meaningfully involved in the shaping and execution of the research. Applications must also describe how the independent and combined effects of interventions conducted to increase accrual will be demonstrated, as relevant.

- Investigators and Study Team: Experience, expertise, and qualifications of the Principal Investigator(s) and strength of the study team. It is critical that the investigator team has all relevant expertise and time commitment needed to bring the study to successful completion.
- Institutions: The infrastructure, capacity, and commitment of the applying institution(s) to carry out the proposed interventions and to maximize the likelihood of success.
- Dissemination Plan: Strength of a stated plan for timely, wide dissemination of findings to relevant stakeholders, including beyond academic and scientific communities.
- Feasibility: Feasibility of the study within the budget and timeframe.

Key Dates and Deadlines

The deadline to submit all Letters of Intent is **September 11th, 2025, at 3:00 PM ET** via the LLS Research Portal. If an application does not meet the RFP goals, scope, or guidelines, it may be administratively disqualified. Applicants will be notified whether they are invited to submit a full proposal or whether their Letter of Intent was declined. We will only be inviting full proposals that will be competitive.

Action	Date
• Webinar for prospective applicants	• June 18, 2025
• Deadline to submit Letters of Intent	• September 11, 2025 (3:00 p.m. ET)
• LLS notifies applicants whether they are invited to submit a full proposal	• October 31, 2025
• Deadline for receipt of full proposals and associated documents (invited applicants)	• January 29, 2026 (3:00 p.m. ET)
• Notification of awards	• April/May 2026
• Grant start date	• July 1, 2026

For questions about this Request for Proposals, please contact researchprograms@lls.org.

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