CLINICAL TRIAL LITERACY: EMPOWERING NURSES TO EDUCATE HISPANIC PATIENTS

Recorded on May 1, 2025

Provided by The Leukemia & Lymphoma Society (LLS) in collaboration with the National Association of Hispanic Nurses (NAHN) and The Oncology Nursing Society (ONS).

1

WELCOME AND INTRODUCTIONS

Leah Szumita, MS, RN, CCRN, ACNS-BC
Senior Director
Clinical Trial Support Center
The Leukemia & Lymphoma Society
Washington, DC

2

LEARNING OBJECTIVES

After completing this activity, the participant should be better able to:

- Summarize the brief evolution of research in the United States and its impact on current clinical practice
- Describe the phases of a clinical trial and explain their significance in advancing medical treatments and benefiting the broader population
- Identify key barriers to clinical trial participation, particularly among Hispanic Patients
- Demonstrate effective communication techniques for educating patients about clinical trials
- Apply culturally sensitive strategies to address misconceptions and build patient trust
- Explain how LLS Clinical Trial Support Center can help you and your patients

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CE INFORMATION

Registered Nursing Credit Designation
Approval for nurses has been obtained by the National Office of The Leukemia & Lymphoma Society under provider number CEP 5832 to award 1.0 continuing education contact hour through the California Board of Registered Nursing.

- **Method of Participation**
  Learners must participate in the entire activity, complete the post-assessment with a score of 70% or higher, and complete and submit the evaluation form to earn credit. Once completed, the certificate will be generated. If you have questions regarding the receipt of your certificate, please contact us via email at ProfEducation@LLS.org.

  There are no fees for participating in or receiving credits for this activity.
- **Supporters**
  There is no commercial support associated with this activity.

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SPEAKERS

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President, Oncology Nursing Society
Assistant Vice President, Advanced Practice Providers
University of Miami/Sylvester Comprehensive Cancer Center
Miami, FL

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University of Miami/Sylvester Comprehensive Cancer Center
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DISCLOSURE INFORMATION

The Leukemia & Lymphoma Society requires all faculty to fully disclose current and recent financial relationships with commercial interests. A conflict of interest may be considered to exist if such a person has financial relationships with the grantor or any non-eligible entities (commercial interests) that may have a direct impact on the content of the program. Financial relationship is defined as being a shareholder, consultant, grant recipient, research participant, employee, and/or recipient of other financial or material support. Recent is defined as within the past 24 months.

- Jessica MacIntyre, DNP, MBA, APRN, AOCNP, has no relevant financial relationships with ineligible companies to disclose for this educational activity.
- Christopher Otero, BSc, MSN AGNP-C, has no relevant financial relationships with ineligible companies to disclose for this educational activity.
- Leah Szumita, MS, RN, CCRN, ACNS-BC, has no relevant financial relationships with ineligible companies to disclose for this educational activity.

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IN PURSUIT OF *YOUR CURE.*

Clinical Trial Literacy: Empowering Nurses to Educate Hispanic Patients

Jessica MacIntyre, DNP, MBA, APRN, NP-C, AOCNP®, FAANP

Christopher Otero, BSc, MSN, APRN, AGNP-C

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Poll Questions

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8

Poll Question 1

Provide one word that describes what research means to you?

9

Poll Question 2

Have you been involved in speaking to a patient about participating in a research study or clinical trial?

A. Yes
B. No

10

Poll Question 3

Do you feel comfortable speaking to a patient about the importance of being part of a research study or clinical trial?

A. Yes
B. No

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Poll Question 4

What would help you feel more comfortable being involved in research?

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12

Images taken from Google images

13

Basics and Background

14

Research and Common Terms

- **Study**: a **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (Protection of Human Subjects, 2017).
  - Term clinical trial related but not the same as a research study.

- According to the U.S. Food and Drug Administration (FDA): an individual who is or becomes a **participant** in research, either as a recipient of the test article or control.
  - May be referred as a study participant or human subject.

- **PI:** Principal Investigator
- **Sub PI:** Substitute Principal Investigator

- **Informed Consent:** Communication between you and your health care provider that often leads to agreement or permission for care, treatment, or services.

15

16

Consequences of poor clinical trial participation

- Lack of access to **quality/optimal care**.
- Trial participants may receive more **comprehensive follow-up.**
- Lost opportunity to evaluate drug responses in a specific **population-differences in drug metabolism exist**.
- Poorer survival observed in minority population may be explained by **genetic factors that interact with effects of drugs**.
- Example: BiDil approved in CHF-combines isosorbide dinitrate and hydralazine hydrochloride was more effective in African Americans.
- Example: Erlotinib more effective in Asian women lung cancer patients who are non-smokers.

17

History Informs Participation

- Achieving high participant involvement in research can be challenging, especially in communities that have been historically underrepresented in research and where mistrust of researchers is common
- The privilege of conducting clinical research, and of earning and maintaining trust of those who agree to participate in that research, comes with great responsibility.

Image from: University of Miami
https://news.miami.edu/stories/2020/11/research-shows-covid-19-has-hit-hispanic-communities-hard.html

18

19

Evolution of Research

20

Evolution of Clinical Research

562 BC	• In the Book of Daniel: King Nebuchadnezzar wanted everyone to eat a meat and wine diet. • Nutritional experimentation (meat vs vegetarian)
1747	• Dr. James Lind conducted the first randomized clinical trial (1:1) • Tested different approaches to the management of scurvy
1863	• First placebo clinical study by Dr. Austin Flint • Small trial of 13 patients with rheumatism (herbal vs placebo)
1943	• First double-blind controlled study (physicians and patient were both blinded to each treatment arm and only nurses knew what each group received. • Performed in the UK with over 1K British factory workers looking at the common cold.
1946	• First curative randomized control trial of streptomycin in the treatment of pulmonary fibrosis. • Process was similar to what we use today (clear criteria, schedules, data collection, etc.)

Herzog-LeBoeuf C & Willenberg KM. The History of Clinical Trials Research: Implications for Oncology Nurses. Semin Oncol Nurs. 2020 Apr;36(2):150997. doi: 10.1016/j.soncn.2020.150997. Epub 2020 Mar 19. PMID: 32201023.

21

Importance of Ethics

- Nuremberg Code of 1947
  - Considered the first code of modern research ethics.
  - Written by American judges overseeing trials of doctors who performed "experiments" on prisoners in Nazi Germany.
  - Defined fundamental points necessary for the conduct of research to be ethical.

The Nuremberg Code

1. Voluntary informed consent.
2. Fruitful result for the good of society.
3. Prior experimentation on animals, and prior knowledge of the problem.
4. Avoidance of unnecessary physical or mental injury.
5. Banning of known lethal or disabling procedures.
6. Degree of risks should not exceed benefits.
7. Proper preparation and facilities to prevent injury or death.
8. Performance of experiments only by scientifically qualified people.
9. Participants may freely end the experiment.
10. The experiment must stop if it proves too dangerous.

Image from: https://www.renews.co.nz/

22

Importance of Ethics

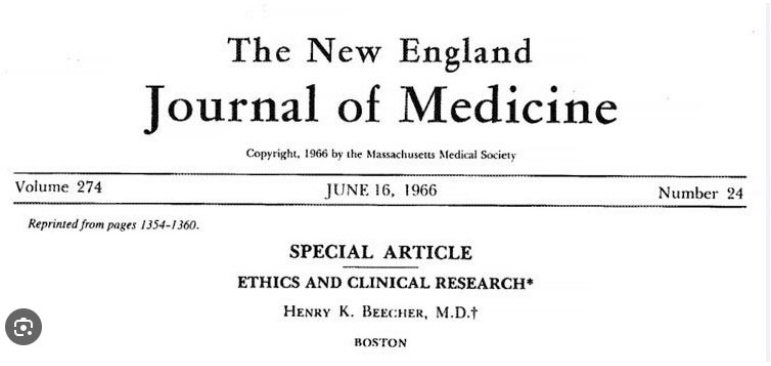
- Declaration of Helsinki
  - Drafted and adopted in 1964 by the World Medical Association.
  - Ethical guidelines for physicians.
  - Added from components of the Nuremberg Code
    - Discontinue treatment if harm to patient and withdrawal language.
    - Legal guardian consent

Image from: https://humanexperimentandethics.wordpress.com/2017/12/06/declaration-of-helsinki/

23

Ethics in Research

There was a belief that unethical and "bad" research was conducted by bad and unethical people and well-trained physicians who were acting for the good of humanity performed only good, ethically appropriate research.



The New England
Journal of Medicine

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Volume 274 JUNE 16, 1966 Number 24

Reprinted from pages 1354-1360.

SPECIAL ARTICLE

ETHICS AND CLINICAL RESEARCH*

HENRY K. BEECHER, M.D.†

BOSTON

24

Examples of Unethical Research

Willowbrook school picture
Taken from the College of Staten Island website

Figure 3. Dr. Walter Edmondson of the PHS drawing a blood sample from a study participant during an annual roundup in Milstead, Macon County, 1953. Reproduced from National Archives (in public domain). PHS = Public Health Service.

Picture taken from article :
Tobin, M.J. (2022).

Tobin, M.J. (2022). The Fiftieth Anniversary of Uncovering the Tuskegee Syphilis Study: The Story of Timeless Lessons, American Journal of Respiratory Critical Care Medicine, (10), 1145-1158.

Importance of Ethics

- 1974 creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
  - Charged with establishing a code of research ethics.
- Ethics of conducting and being part of a research is an important principle
  - *Belmont report*: Release in 1979.
  - Has remained the primary code underlying the conduct of ethical clinical research in the United States.
  - Provides an ethical framework for the federal regulations designed to protect human research subjects.
  - Three principles:
    1) Respect for Persons (i.e., informed consent & privacy)
    2) Beneficence (i.e., minimize harms and maximize benefits)
    3) Justice (i.e., fair selection)

Additional Safeguards

- Pure Food and Drug Act of 1906
  - Prohibited interstate commerce of contaminated and misbranded drugs.
  - Did not require investigators to demonstrate safety or efficacy of the drug.
- Federal Food Drug Cosmetic Act (FFDCA)of 1938
  - Required that drugs are to be proven safe before manufacturers are permitted to sell them in the interstate commerce.
- Kefauver-Harris Drug Amendment to FFDCA of 1962
  - Increased safety provision requiring that drug manufacturers must prove safety and efficacy.

Image from: Google Images

27

Phases of Clinical Trials

28

Clinical Trial Research

- Clinical Trials are highly controlled clinical experiments used to investigate the systemic effects of specific medications or regimens or methods of administration to determine efficacy, safety, and toxicity.

Phase 0	Examine if a drug produces a desired outcome	Pharmacodynamics, Pharmacokinetic, dosage for future studies
Phase I	Establish maximum tolerated dose by evaluating a drug's pharmacokinetics and corresponding toxicities.	Example: Drug 123GHT in all solid tumors
Phase II	Establish effectiveness in specific tumor types and validate drug properties and toxicities	Example: Drug 123GHT in colorectal cancer
Phase III	Compare agent to standard of care. Validate efficacy and quality of life	Example: Drug 123GHT in colorectal cancer in comparison to FOLFOX
Phase IV	Add to current information about risks and side effects of the new agent or regimen	Example: Drug 123GHT is now showing cardiac toxicity post trial

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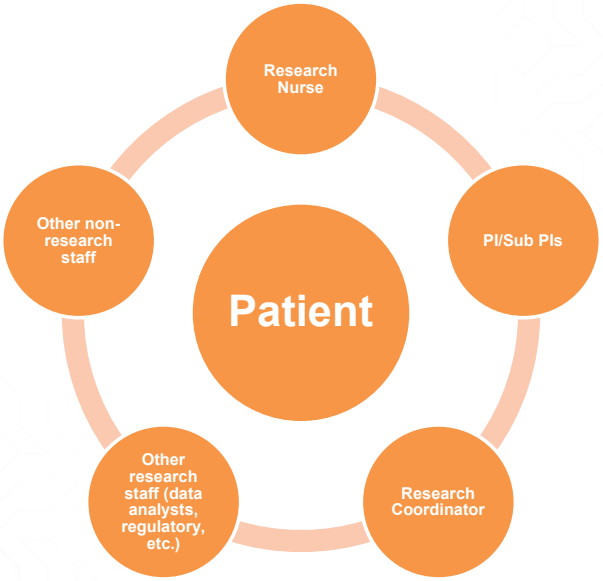
Research is a Team Approach



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Barriers to Clinical Trial Participation in Hispanic Communities

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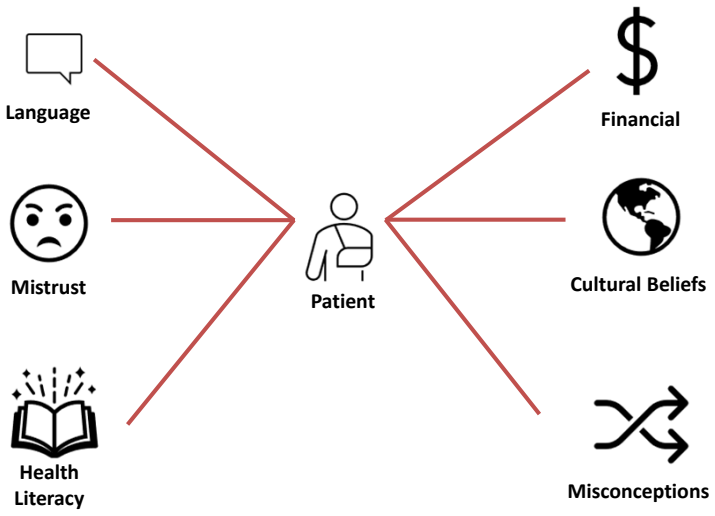
Barriers to Clinical Trial Participation in Hispanic Communities



Nearly half of Hispanic adults **(46%)** have a close friend or family member who requires a Spanish-speaking health care provider or translator, highlighting substantial language barriers in health care settings.

Patients with Limited English Proficiency are about **70%** less likely to engage in clinical trials compared to English-proficient individuals.

Hispanic Americans are more likely than other racial and ethnic groups to be uninsured, with **20%** lacking health insurance as of 2019.

In a 2013 survey of U.S. Latinx cancer patients, only **48%** were aware of clinical trials, despite **65%** expressing willingness to participate

33

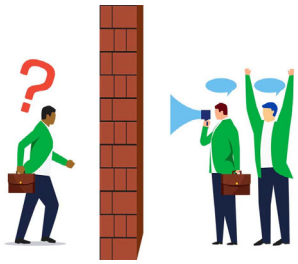
What are some areas of mistrust in healthcare?

- Experiences of discrimination and bias
- Exploitation on research with poor explanation
- Immigration status concerns
- Lack of Hispanic representation among healthcare providers and research teams

Dreyfus et al. (2023). Understanding Hispanic/Latino Participation in Clinical Trials and Observational Studies, and Strategies to Increase Participation. *Project MUSE*. Retrieved from https://muse.jhu.edu/article/882042

34

Misconceptions and Language Barriers



- Misconceptions: Research for terminal patients.
- Fear of losing autonomy.
- Language barriers hinder understanding.
- Poorly translated materials frustrate.
- Non-inclusive language disconnects culturally.

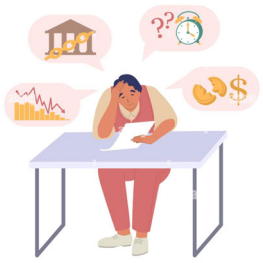
Arevalo et al. (2016). Mexican-American perspectives on participation in clinical trials: A qualitative study. *Contemp Clin Trials Commun*, 4, 52-57. doi: 10.1016/j.conctc.2016.06.009.

Why is health literacy confusing within clinical research?

- Comprehension of Clinical Complexity
- Confusion between Care Types
- Uncertainty about Risks and Benefits
- Limited Understanding without culturally tailored communication

Evans KR, Lewis MJ, Hudson SV. The role of health literacy on African American and Hispanic/Latino perspectives on cancer clinical trials. J Cancer Educ. 2012 Jun;27(2):299-305. doi: 10.1007/s13187-011-0300-5. PMID: 22203466; PMCID: PMC3712748.

Financial Concerns



- **Limited insurance**, wary of costs.
- **Lost wages** concern hourly workers.
- **Extra costs** deter participation.
- Mistrust due to **unclear compensation**.

Garza et al. (2025). Bridging the gap: Understanding Latino willingness to participate in public health and clinical trials research across diverse subgroups. *Contemp Clin Trials Commun*, 44, 101440. doi: 10.1016/j.conctc.2025.101440.

37

What do nurses have to do with this?

- Patient advocacy
- Build trusting relationships
- Bridge between research & patient care
- Language concordant care
- Patient navigation
- Protocol review boards

38

What do nurses have to do with this?

Communication

39

Strategies for Effective Communication?

- Understanding Cultural and Health Beliefs
- Providing Empathy and Respect
- Engaging in Family Member Inclusivity
- Use of Non-Technical Language
- Acknowledgement of concerns and patience to review with family
- Teach Back Methods

Ledesma Vicioso et al. (2022). Implementation Strategies to Increase Clinical Trial Enrollment in a Community-Academic Partnership and Impact on Hispanic Representation. *JCO Oncol Pract*, 18(5), e780-e785. doi: 10.1200/OP.22.00037

40

Case Study #1

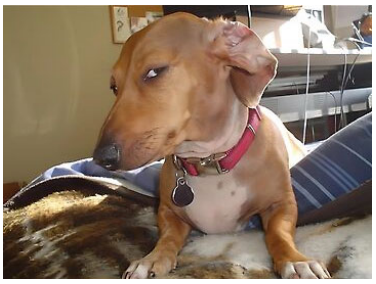
Patient Background:

- Maria Doe, a 60-year-old female with a recent diagnosis of Renal Cell Carcinoma (RCC), 6 months ago.
- She was referred to the Oncology Research Clinic after her oncologist identified her as a candidate for a clinical trial.
- She presented to the clinic with her adult daughter, who speaks English fluently and often acts as her interpreter. Maria appeared anxious and hesitant, asking, "¿Van a experimentar conmigo?" ("Are they going to experiment on me?").
- Referral Reason: Eligible for a Phase II clinical trial evaluating a novel immunotherapy agent.

Case Study #1

What barriers were identified initially with Maria Doe?

A. Language barrier with consent process
B. Financial Risks and understanding
C. Lack of Understanding Clinical Research
D. Family Member support



Case Study #1

Visit Details	Nursing Intervention
Maria **struggled to understand** the consent form, even when translated into Spanish. She was **unclear** about trial procedures, randomization, and the difference between standard care and investigational treatment. Maria depended heavily on her **daughter for translation**, which complicated sensitive health conversations. The research coordinator was not fluent in Spanish, and interpreter services were not readily available during the visit.	**Scheduled a follow-up** visit with a Research Staff Translator. Used **visual aids and the teach-back method** to explain the purpose of the trial, safety protocols, and patient rights. **Addressed Maria's fears** that could be an indication of a previous experience on a clinical research study. Review previous experience and clarify any misunderstanding. Worked with the research team to provide **Spanish-language materials** and **adapt communication** to Maria's cultural preferences.

43

Case Study #2

Patient Background:

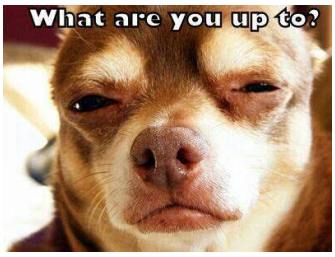
- Jorge Doe, a 63-year-old male with a recent diagnosis of Metastatic Colorectal Cancer, 12 months ago.
- He was referred to the Oncology Research Clinic by his primary Oncologist for a Phase 1 KRAS Targeting immunotherapy.
- During the initial intake, Jorge appeared reserved. Although he understood English, he continuously deferred to his wife—who spoke only Spanish—and asked to receive all information in Spanish. He voiced concerns about "research" and his unfamiliarity with it. He stated that he knows very little of clinical research from back home in Colombia. He was confused by the complex wording that was used by the clinical research coordinator.
- He stated that he would like to call his brother and sister while this study was explained.

44

Case Study #2

What barriers were identified initially with Jorge Doe?

A. Language barrier with consent process
B. Financial Risks and understanding
C. Mistrust of Clinical Research and the process of it
D. Family Member support
E. Complex Clinical Research Literacy
F. Both D&E



45

Case Study #2

Visit Details	Nursing Intervention
He was unfamiliar with **targeted therapy**, assuming all cancer treatments involved chemotherapy. Jorge **relied heavily** on his **wife** and **siblings** to help make healthcare decisions. He felt conflicted when the clinical team spoke mostly to him without addressing his family directly. Although Jorge was bilingual, he **preferred Spanish** for medical conversations to feel confident and respected. The research staff was not culturally attuned to Hispanic norms of communication and family involvement.	**Schedule** a dedicated **family consultation** with a professional interpreter present, giving space for questions from Jorge's wife and siblings. Described the trial in terms of "**personalized treatment**" rather than "experimentation," which helped reduce fear. Explained the process of informed consent in a **group format**, honoring Jorge's desire for family consensus. Ensured every encounter included verbal summaries and **repeat-back techniques** in Spanish.

46

Common Tips to Connect with Hispanic Patients

Build	**Build Personalismo (Personal Connection)** Take time for warm, respectful small talk before diving into medical discussions. Davis et al, 2019)
Respect	**Respect Familismo (Family Involvement)** Encourage Family participation if patient desires, invite family members into clinical and research conversations. (Joachim-Celestin et al, 2024)
Engage in	**Engage in Cultural Humility** Treat each patient as a cultural expert and ask open-ended questions about their care beliefs and preferences.
Recognize and Address	**Recognize and Address Mistrust** Recognize experiences that may cause mistrust and be clear about procedures, risks, and benefits.

47

Why is Clinical Research important?

- May improve patient's quality and quantity of life
- Advance medical knowledge and practice
- Development of tailored medicine
- Early access to innovative therapies
- Contributions to Public Health
- Patient empowerment
- Optimizes current and potential practice
- Further expand on the "Known"

48

Resources

Non-profit Organizations

Clinical Trial Support Center

Work one-on-one with an LLS Clinical Trial Nurse Navigator who will help you find clinical trials and personally assist you throughout the entire clinical-trial process.

REQUEST CLINICAL TRIAL SUPPORT

For more information, please visit: www.LLS.org/CTSC

American Cancer Society

ACS ACTS: Finding the right clinical trial for you.

We understand the challenges of finding the right clinical trial, navigating your treatment options, and accessing the support you need. The American Cancer Society is here to guide you every step of the way.

American Cancer Society ACTS

NIH National Library of Medicine
National Center for Biotechnology Information

ClinicalTrials.gov

World Health Organization

International Clinical Trials Registry Platform (ICTRP)

Academic Organizations

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49

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53

Gracias!

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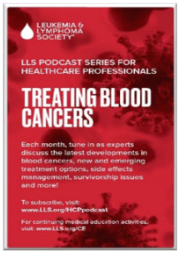
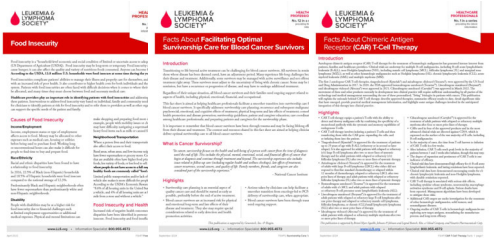
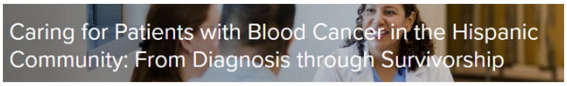
54

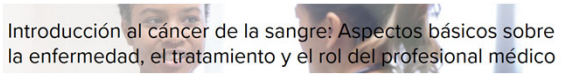
FREE LLS RESOURCES FOR HEALTHCARE PROVIDERS



- ❑ CME & CE courses: www.LLS.org/CE
- ❑ Fact Sheets for HCPs: www.LLS.org/HCPbooklets
- ❑ Videos for HCPs: www.LLS.org/HCPvideos
- ❑ Podcast series for HCPs: www.LLS.org/HCPpodcast
- ❑ LLS Research Grant Programs: www.LLS.org/Research or email researchprograms@LLS.org







CE Webinar – Blood Cancer 101
Now available in English and Spanish

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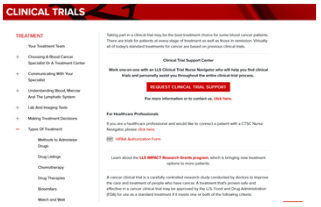
FREE LLS RESOURCES FOR PATIENTS AND CAREGIVERS

- ❑ **Webcasts, Videos, Podcasts, booklets**:
  - www.LLS.org/Webcasts
  - www.LLS.org/EducationVideos
  - www.LLS.org/Podcast
  - www.LLS.org/Booklets
- ❑ **www.LLS.org/clinicaltrials**
- ❑ **Support Resources**
  - Financial Assistance: www.LLS.org/Finances
    - Urgent Need
    - Patient Aid
    - Travel Assistance
  - Other Support: www.LLS.org/Support
    - LLS Regions
    - Online Weekly Chats Facilitated by Oncology SW
    - LLS Community Social Media Platform
    - First Connection Peer to Peer Program



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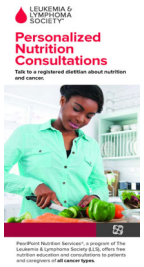
FREE LLS RESOURCES FOR PATIENTS

- **Nutrition Education Services Center (NESC)** – one-on-one **free** nutrition education and consultations to patients of all cancer types with RDs who have expertise in oncology nutrition www.LLS.org/Nutrition
- **Information Specialists** (IRC) – Personalized assistance for managing treatment decisions, side effects, and dealing with financial and psychosocial challenges.
- **Reach out** **Monday–Friday, 9 am to 9 pm ET**
  - Phone: 800.955.4572
  - Live chat: www.LLS.org/IRC
  - Email: LLS.org/ContactUs
  - HCP Patient Referral Form: www.LLS.org/HCPreferral



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CLINICAL TRIAL SUPPORT CENTER (CTSC)

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58

THE CLINICAL TRIAL SUPPORT CENTER TEAM

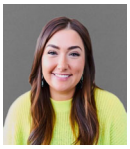
Leah Szumita
MS, RN, ACNS-BC
Senior Director, CTSC

Kelly Laschinger
CPNP, MSN, RN, CPHON
Director, CTSC

Melissa Komlosi Melendez
MSN, RN, CPNP
Senior Clinical Trial Nurse Navigator

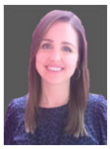
Ashley Giacobbi
DNP, RN, ACNS-BC, AOCNS, OCN
Senior Clinical Trial Nurse Navigator

Beth Davison
MSN, APRN, CNM, FAACM
Clinical Trial Nurse Navigator



Christen Hawthorne
RN, BSN, BMT-CN
Clinical Trial Nurse Navigator

Kelly Stackhouse
BSN, RN
Clinical Trial Nurse Navigator



Whitney Meeks
MSN, RN, CHPN, CNL
Clinical Trial Nurse Navigator

Sloane Cammock
MSN, RN, CPNP
Clinical Trial Nurse Navigator

Elise Curry
BA, BSN, RN, OCN
Clinical Trial Nurse Navigator

Meghan McGrath
MSN, RN, AGACNP-BC
Clinical Trial Nurse Navigator

Melanie Fyfe
MSN, APRN, AGCNS-BC, OCN, BMTCN
Clinical Trial Nurse Navigator

Michelle Bibo
CTSC Operations Specialist

59

HOW TO ACCESS THE CLINICAL TRIAL SUPPORT CENTER (CTSC)

Information Resource Center (IRC) 1-800-955-4572

Patient, Caregivers, or Healthcare Providers can complete an online referral form to refer themselves, a loved one, or a patient:

https://www.lls.org/support-resources/clinical-trial-support-center-ctsc

Email: CTSC@lls.org

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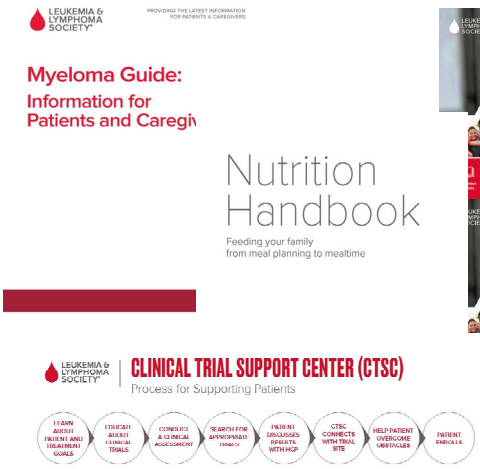
FREE LLS RESOURCES FOR YOUR PATIENTS



BOOKLETS AND FACT SHEETS

English – www.LLS.org/Booklets
Spanish – www.LLS.org/Materiales

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QUESTIONS?

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Thank you for participating!

Please complete the post-assessment and program evaluation.

For a list of our CME and CE activities, podcasts and fact sheets, please visit: www.LLS.org/CE.

Questions or concerns, please contact ProfEducation@LLS.org

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63