



CLINICAL TRIAL LITERACY: EMPOWERING NURSES TO EDUCATE HISPANIC PATIENTS

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).



WELCOME AND INTRODUCTIONS

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Senior Director

Clinical Trial Support Center

The Leukemia & Lymphoma Society

Washington, DC

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

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.

Approval for Nurses has been obtained by The Leukemia & Lymphoma Society under provider number 50-12996, Expires: 10/31/2026, to award 1.0 continuing education contact hour through the Florida Board of Nursing.

- **Method of Participation**

Attendees must participate in the webinar in its entirety and complete the evaluation to obtain CE credit. After completing this process, you will receive your certificate by email. 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.

SPEAKERS

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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.

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



@SylvesterCancer



Learning Objectives

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Poll Questions

Poll Question 1

Provide one word that describes what research means to you?

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

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

Poll Question 4

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



Basics and Background

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.

Importance of Hispanics & Clinical Research

- According to the United States (U.S.) Census Bureau (2022), there are 63.6 million Hispanics/Latin (of any race), living in the United States, representing 19.1% of the total U.S. Population.
- Hispanics/Latinos are the nation's second-largest racial or ethnic group after non-Hispanic whites.
- Only 11% participate in clinical trials.
- The underrepresentation of ethnic and racial minorities in clinical trials is a persistent issue in the U.S. despite the National Institutes of Health (NIH) Revitalization Act of 1993.
- Nurses have a unique opportunity to increase accrual of minority patients to clinical trials.

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.

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>

NURSES ARE THE KEY!

Nurses remain the most trusted profession, with 78% of U.S. adults currently believing nurses have high honesty and ethical standards.

-Gallup-

Evolution of Research

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.

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/>

Importance of Ethics

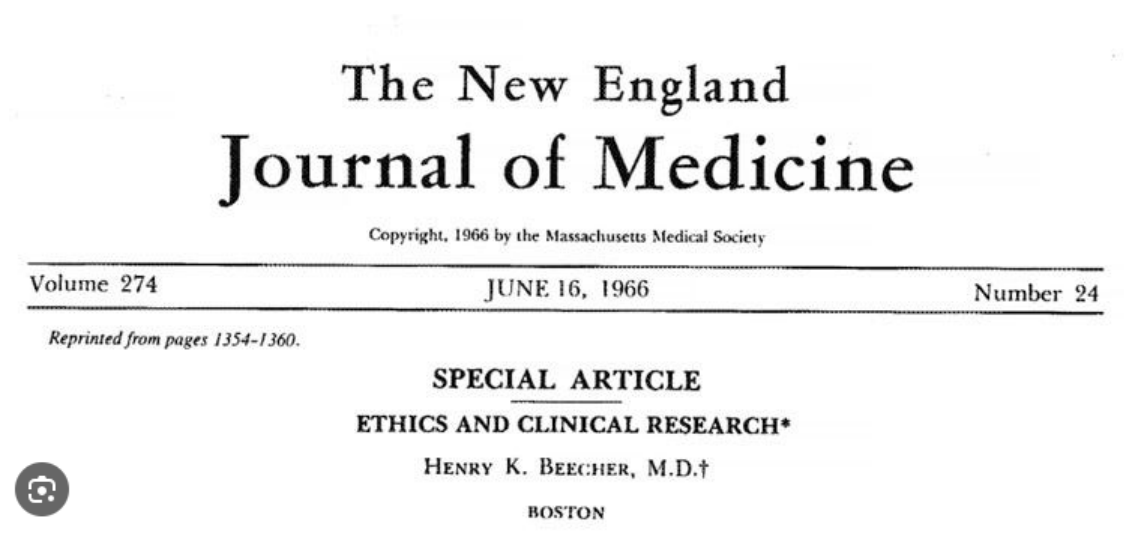
- Declaration of Helsinki
 - Drafted and adopted in 1964 by the World Medical Association.
 - Ethical guidelines for physicians.
 - Added from components of the Nuremberg Code
 - Discontinue treatment if harm to patient and withdrawal language.
 - Legal guardian consent



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

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.



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

Phases of Clinical Trials

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.

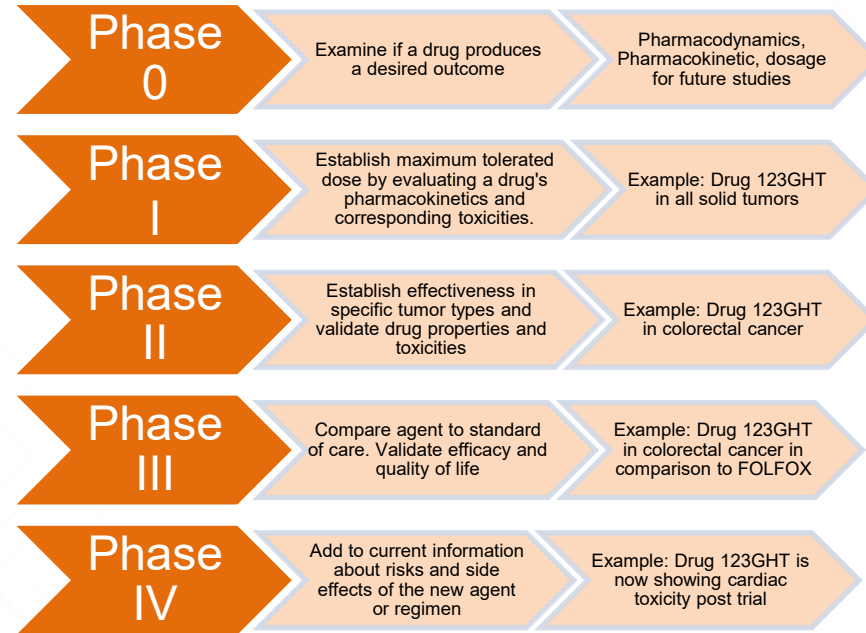
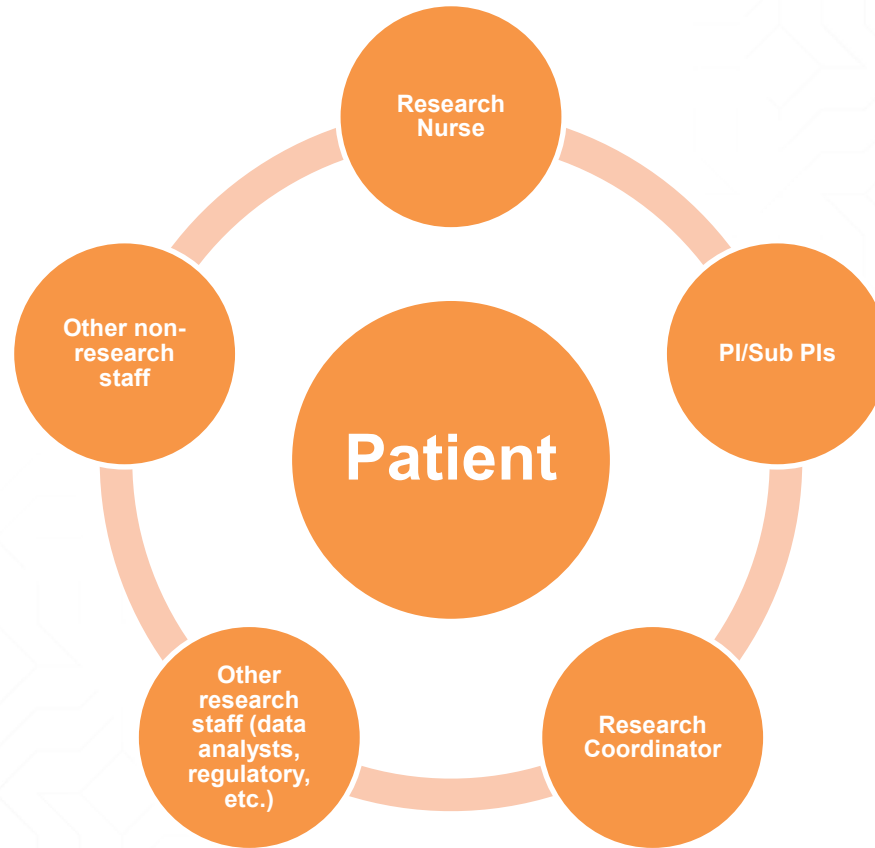




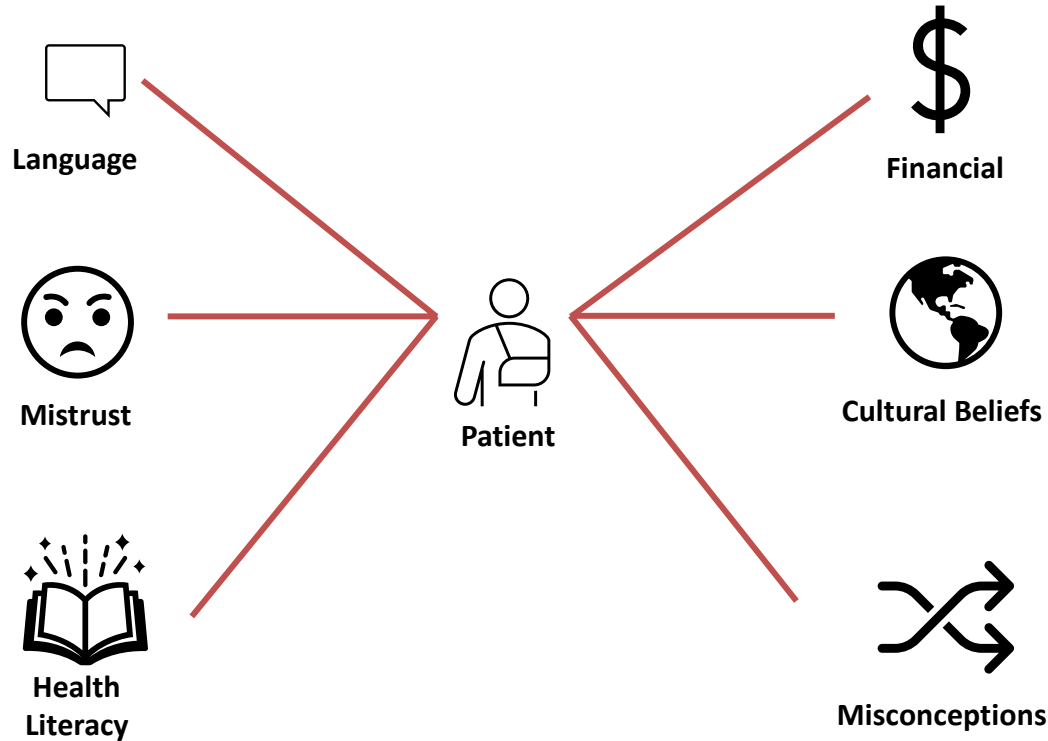
Image obtained from Google Images

Research is a Team Approach



Barriers to Clinical Trial Participation in Hispanic Communities

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

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>

Misconceptions and Language Barriers



Misconceptions: Research for terminal patients.

Fear of losing autonomy.

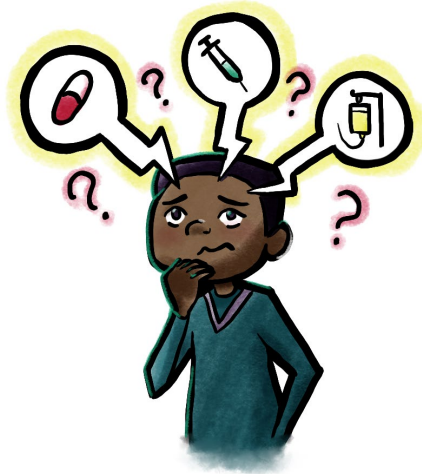
Language barriers hinder understanding.

Poorly translated materials frustrate.

Non-inclusive language disconnects culturally.

Alvares 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

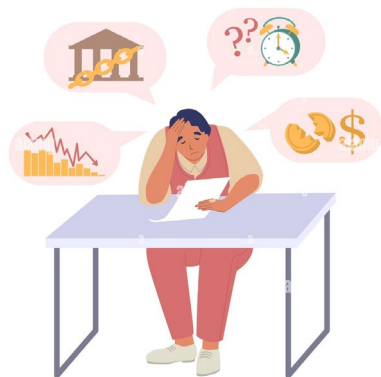
Confusion between
Care Types

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.

What do nurses have to do with this?

Patient
advocacy

Build trusting
relationships

Bridge between
research &
patient care

Language
concordant
care

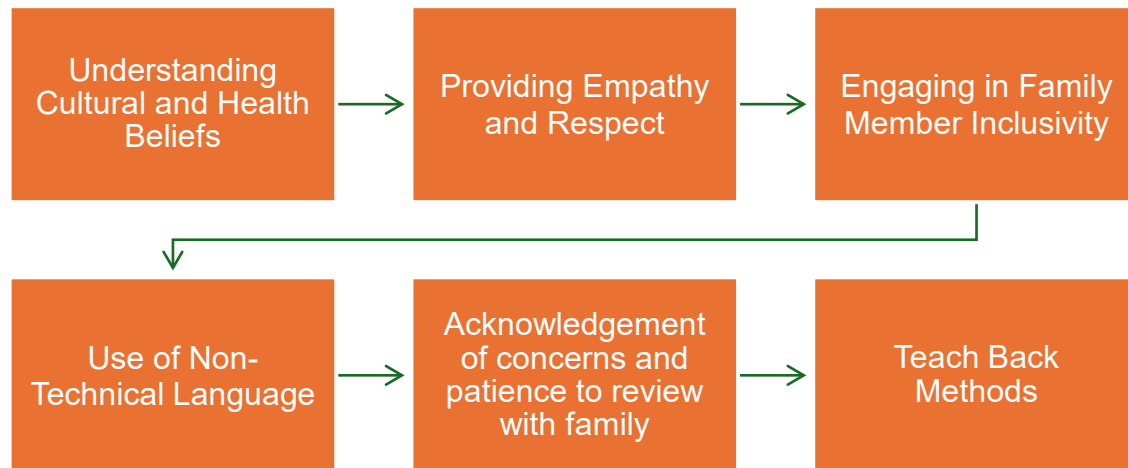
Patient
navigation

Protocol review
boards

What do nurses have to do with this?

Communication

Strategies for Effective Communication?

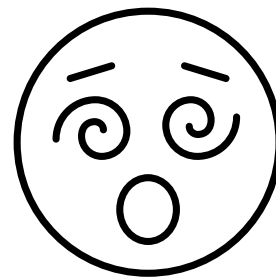


Ledesma Vicioso et al. (2022). Implementation Strategies to Increase Clinical Trial Enrollment in a Community-Academic Partnership and Impact on Hispanic Representation. *JCO Oncol Pract*, 18(5), e780-e785. doi: 10.1200/OP.22.00037

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

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.

Nursing Intervention

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.

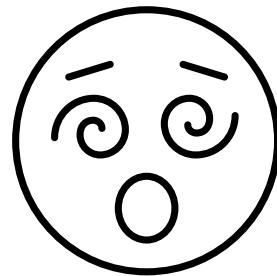
Addressed Maria's fears that could be an indication of a previous experience on a clinical research study. Review previous experience and clarify any misunderstanding.

Worked with the research team to provide **Spanish-language materials** and **adapt communication** to Maria's cultural preferences.

Case Study #2

Patient Background:

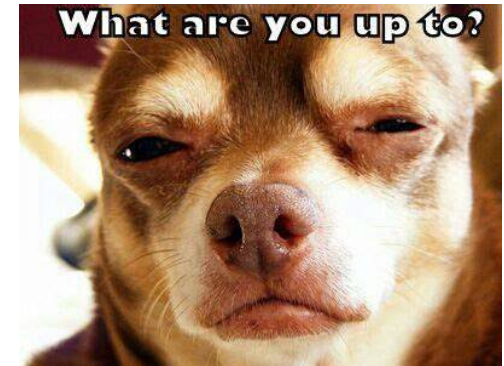
- Jorge Doe, a 63-year-old male with a recent diagnosis of Metastatic Colorectal Cancer, 12 months ago.
- He was referred to the Oncology Research Clinic by his primary Oncologist for a Phase 1 KRAS Targeting immunotherapy.
- During the initial intake, Jorge appeared reserved. Although he understood 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.



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



Case Study #2

Visit Details

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.

Nursing Intervention

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.

Common Tips to Connect with Hispanic Patients

Build	Build Personalismo (Personal Connection) Take time for warm, respectful small talk before diving into medical discussions. <div>Davis et al, 2019)</div>
Respect	Respect Familismo (Family Involvement) Encourage Family participation if patient desires, invite family members into clinical and research conversations. <div>(Joachim-Celestin et al, 2024)</div>
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.

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"

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



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.



National Library of Medicine
National Center for Biotechnology Information

ClinicalTrials.gov

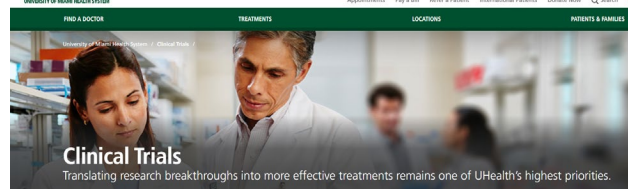


World Health
Organization

**International Clinical Trials Registry Platform
(ICTRP)**



Academic Organizations



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Special Thanks!



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Gracias!



Jessica MacIntyre

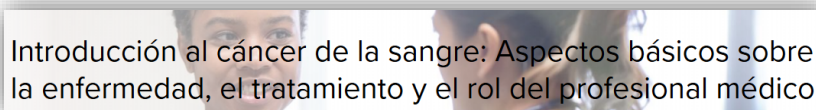
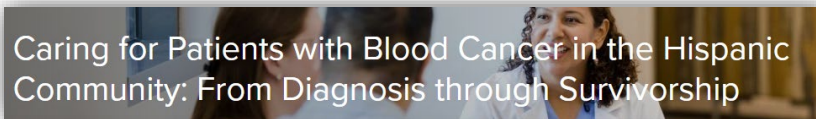
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FREE LLS RESOURCES FOR HEALTHCARE PROVIDERS

- ❑ 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



FREE LLS RESOURCES FOR PATIENTS AND CAREGIVERS

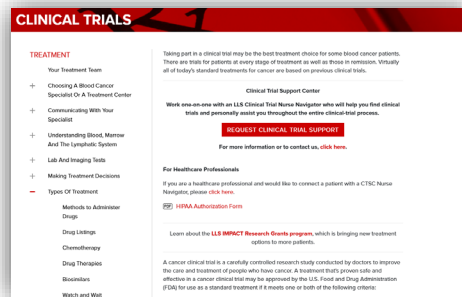
❑ Webcasts, Videos, Podcasts, booklets:

- 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

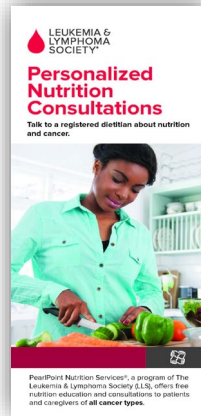


Clinical Trials & Blood Cancers: Searching For Cures



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



CLINICAL TRIAL SUPPORT CENTER (CTSC)

CTSC PROCESS FOR SUPPORTING PATIENTS

Learn about patient &
treatment goals



Educate about clinical
trials



Conduct a clinical
assessment



Search for appropriate
clinical trials



Patient & HCP discuss
results



Connect with trial sites



Address barriers to
enrollment



Patient enrollment



THE CLINICAL TRIAL SUPPORT CENTER TEAM



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



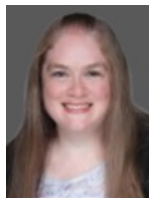
Kelly Laschinger
CPNP, MSN, RN,
CPHON
Director, CTSC



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Melendez
MSN, RN, CPNP
Senior Clinical Trial
Nurse Navigator



Ashley Giacobbi
DNP, RN, ACNS-BC,
AOCNS, OCN
Senior Clinical Trial
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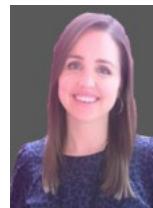
Beth Davison
MSN, APRN, CNM,
FAACM
Clinical Trial Nurse
Navigator



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



Kelly Stackhouse
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Elise Curry
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Melanie Fyfe
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OCN, BMTCN
Clinical Trial Nurse
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Michelle Bibb
CTSC Operations
Specialist

HOW TO ACCESS THE CLINICAL TRIAL SUPPORT CENTER (CTSC)

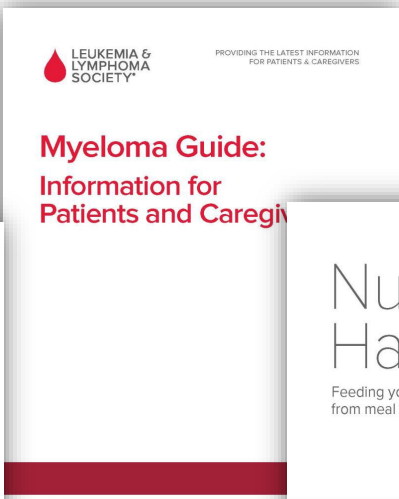
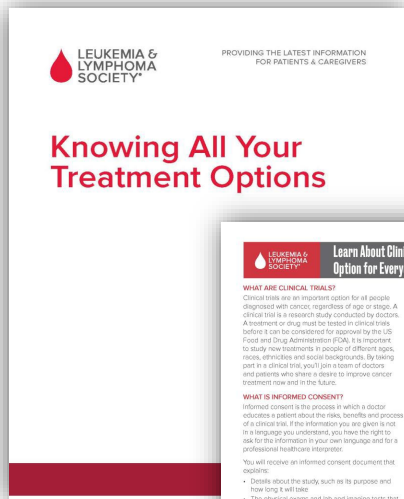
Information Resource Center (IRC) 1-800-955-4572

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

FREE LLS RESOURCES FOR YOUR PATIENTS



BOOKLETS AND FACT SHEETS

English – www.LLS.org/Booklets

Spanish – www.LLS.org/Materiales



QUESTIONS?



INSTRUCTIONS FOR CREDIT

Participants must complete the evaluation to receive credit.

After completing this process, your certificate will be sent via email.

Questions or concerns, please contact ProfEducation@LLS.org