

Recruitment and Retention

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FINANCIAL DISCLOSURE:

- No Relevant Financial Relationship Exists
- No Conflicts of Interest to Report

Clinical Trials: Diversity in Type, Phase, and Target Populations



Example 1. Imagine That Your Neighbor Linda Asks You To Help Her Find a Clinical Trial for Type 2 Diabetes.



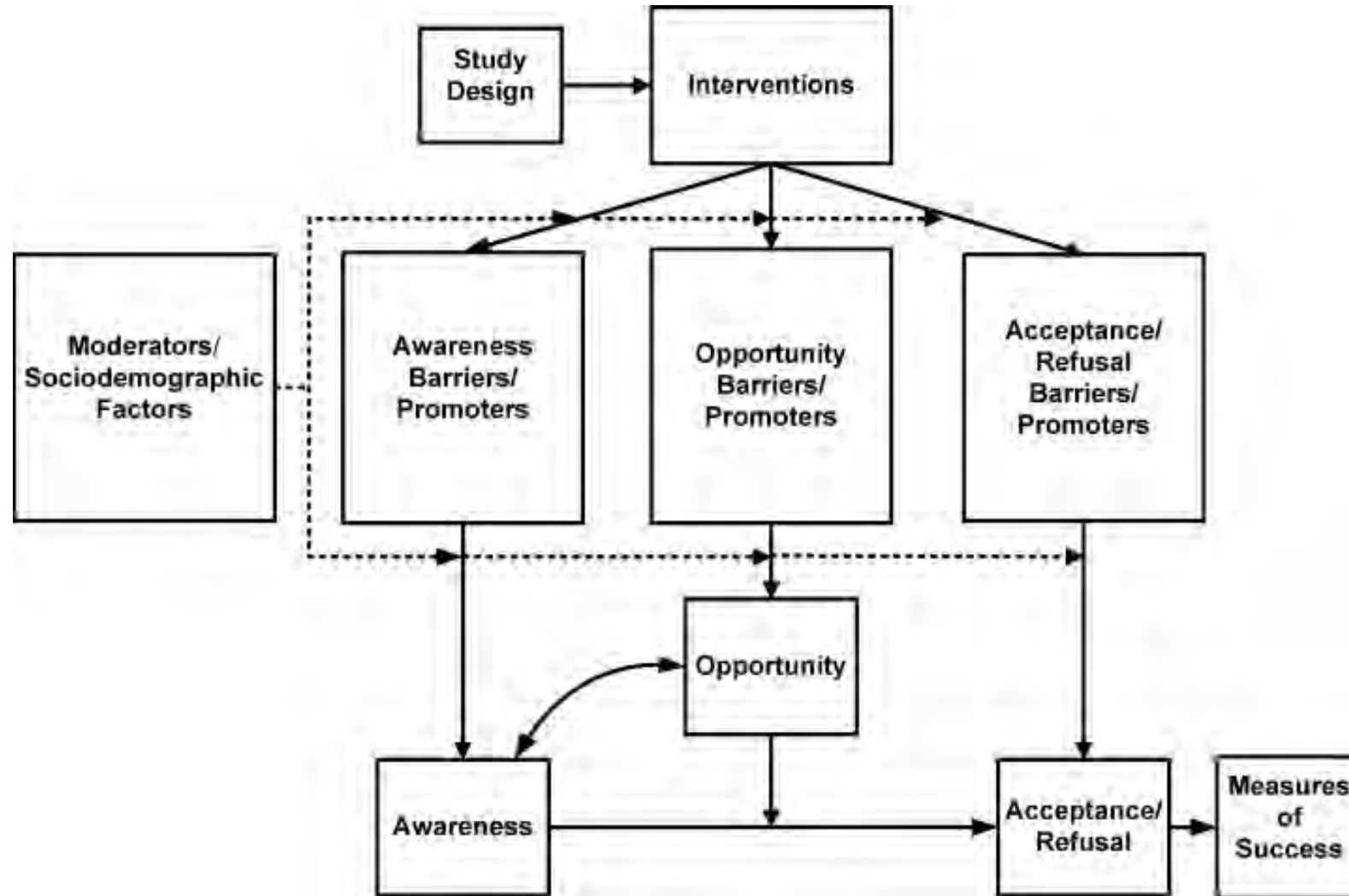
Where would you start?

- a. Nearest academic medical center
- b. ClinicalTrials.gov
- c. American Diabetes Association
- d. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
- e. Not sure

A low-angle, light blue-tinted photograph of a large statue of a man with a beard, wearing a long robe, standing in front of a classical building with columns. The image is used as a background for the slide.

Example Models for Clinical Trial Recruitment and Retention

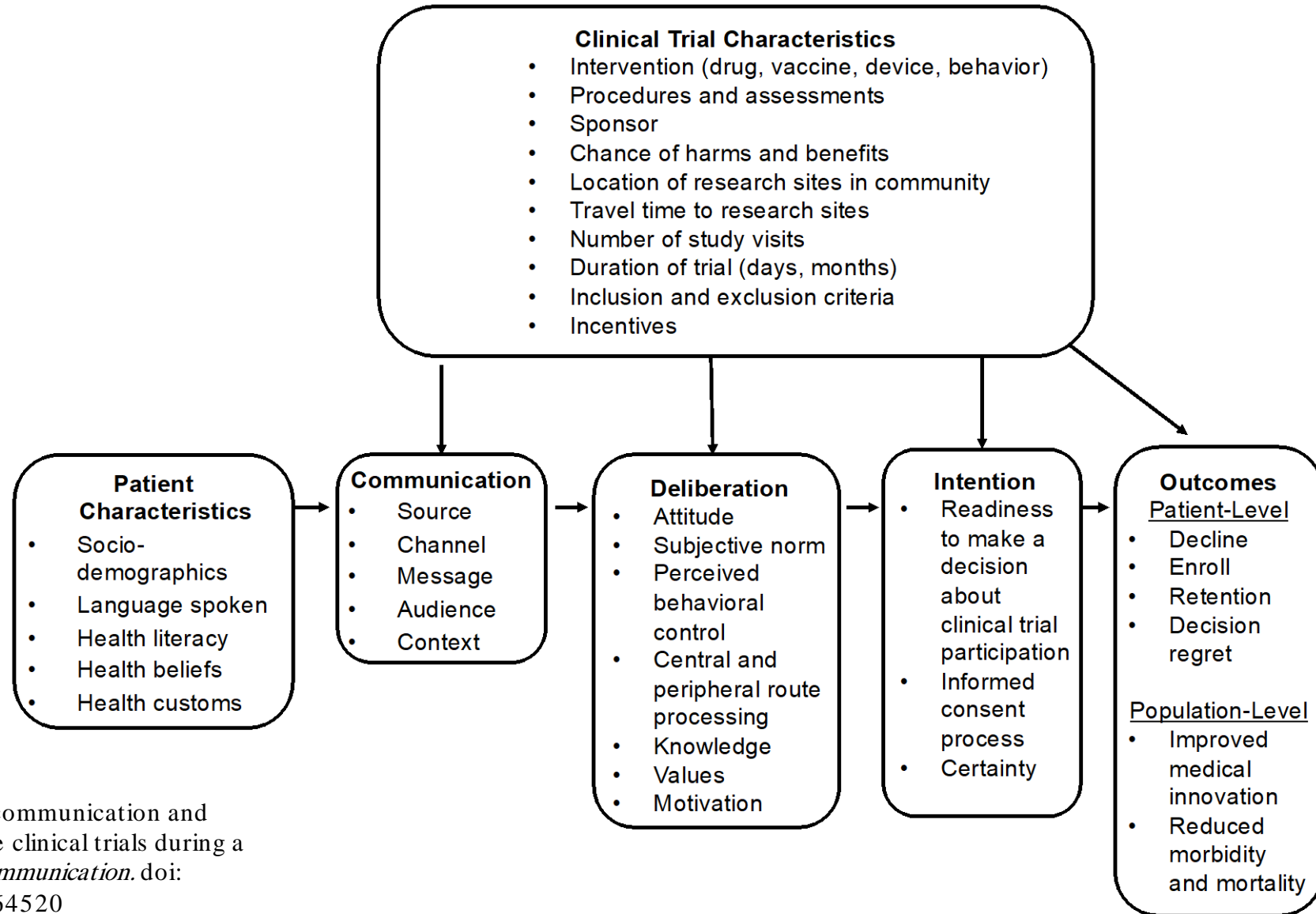
Barriers to recruiting underrepresented populations to cancer clinical trials: Conceptual framework.



Recruitment Innovation Center (RIC) continuum of participant recruitment efforts.



General Model of Clinical Trial Participation: Health Communication and Decision Making Considerations



The ASK Approach to Enhancing Clinical Trial Participation

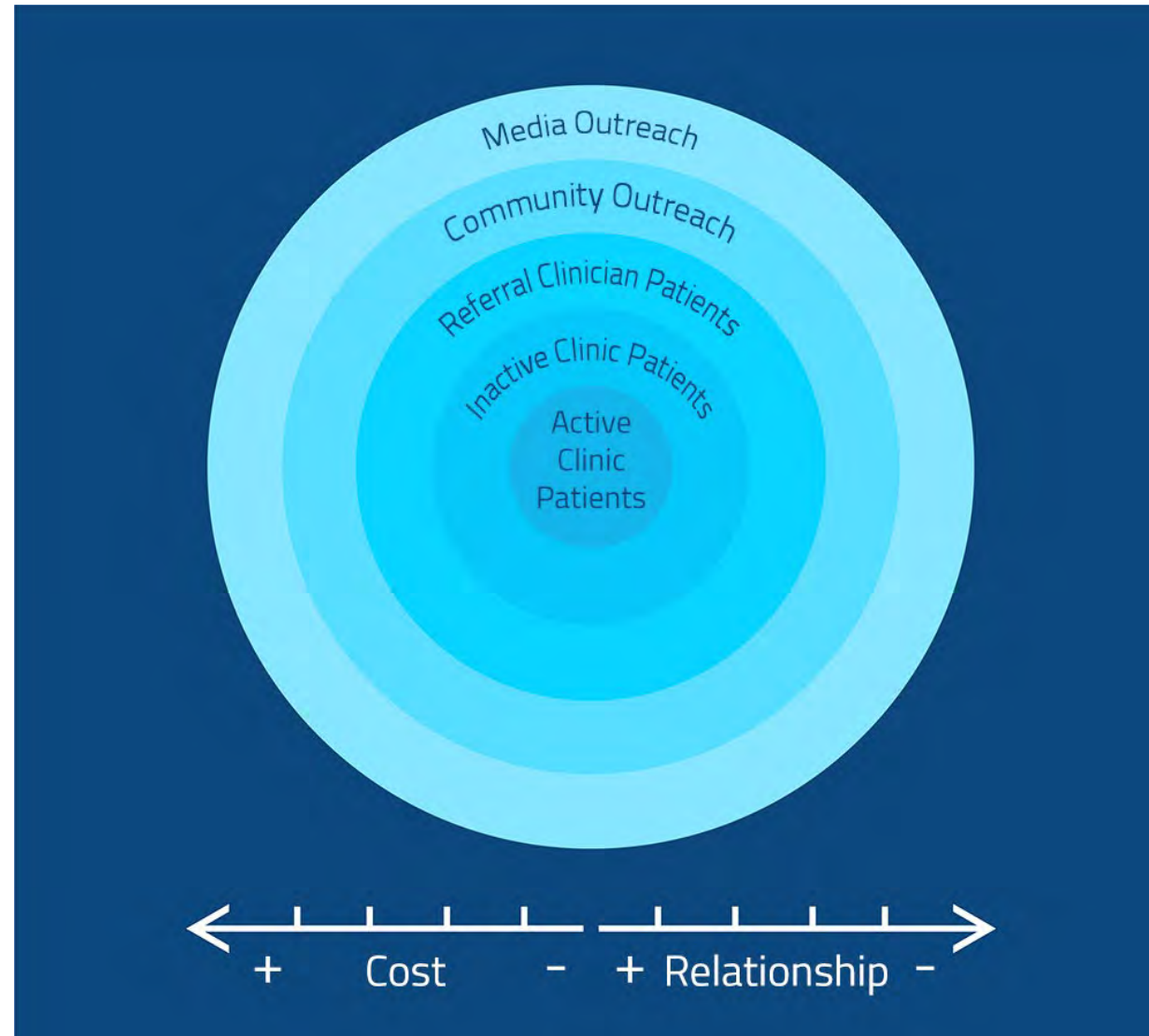
A	Assume that all patients will want to know their options.
S	Seek the counsel of stakeholders.
K	Know your numbers.

Langford AT (2021). Health communication and decision making about vaccine clinical trials during a pandemic. *Journal of Health Communication*. doi: 10.1080/10810730.2020.1864520.

Stakeholders may include, but not limited to:

- Researchers
- Patients
- Caregivers
- Community health workers
- Community-based organizations
- Faith-based organizations
- Internal clinicians
- External referring clinicians
- Administrators
- Communication and marketing professionals
- Health information technology professionals
- Institutional review board professionals
- Pharmaceutical companies
- Media partners
- Policymakers

Concentric Circle Model of Recruitment



Potential Online Recruiting Strategies

- Social media
- Email
- Electronic health record-based methods (e.g., patient portals)
- Online survey panels (e.g. mTurks, Qualtrics, Dynata)
- Paid digital advertising
- Postings on websites
- Electronic word of mouth
- Text messaging
- Recruitment registries (ResearchMatch.org)



Make a positive impact by volunteering for research

[Join Now!](#)

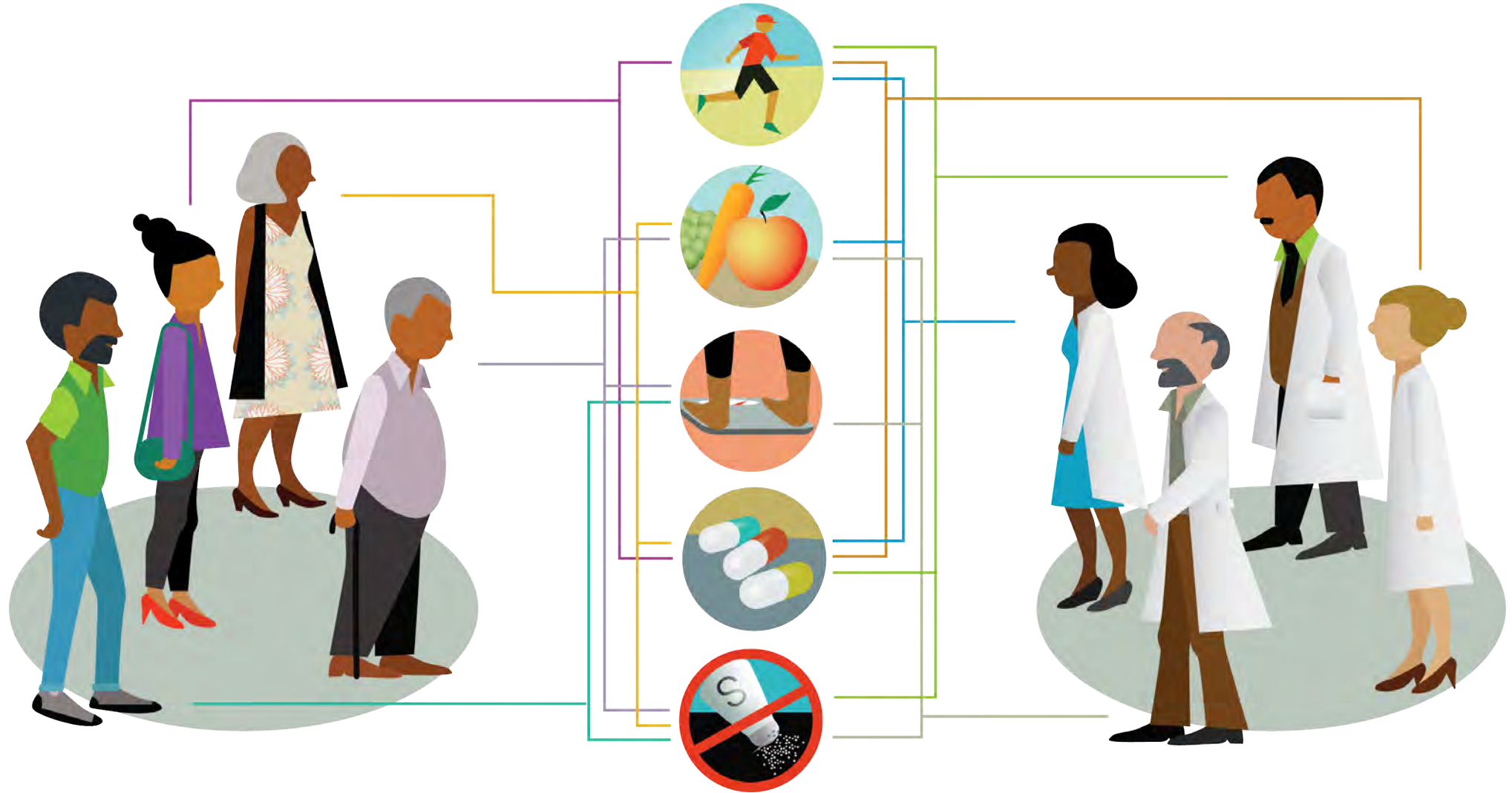
What is ResearchMatch?

ResearchMatch is a nonprofit program funded by the National Institutes of Health (NIH). It helps to connect people interested in research studies with researchers from top medical centers across the U.S.

Get connected to research on many different health conditions - through ResearchMatch.



Example 2. Hypertension Management in Black Adults



A low-angle, light blue-tinted photograph of a large statue of a man with a beard, wearing a long robe, standing in front of a classical building with columns. The statue is the central focus of the background.

Health Literacy Considerations for Clinical Trial Communications and Informed Consent


One Definition of Health Literacy

Personal health literacy is the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.

Healthy People 2030. <https://health.gov/our-work/national-health-initiatives/healthy-people/healthy-people-2030/health-literacy-healthy-people-2030/history-health-literacy-definitions>

Health Literacy and Informed Consent

Perceptions of Clinical Trial Participation Among Women of Varying Health Literacy Levels

👤 Allison C. Burks Aubrey Doede Shayna L. Showalter Jessica Keim-Malpass 

📁 Clinical Trials Communication Patient Education

ONF 2020, 47(3), 273-280 DOI: 10.1188/20.ONF.273-280

Linguistic Strategies for Improving Informed Consent in Clinical Trials Among Low Health Literacy Patients

Janice L. Krieger ✉, Jordan M. Neil, Yulia A. Strekalova, Melanie A. Sarge

JNCI: Journal of the National Cancer Institute, Volume 109, Issue 3, March 2017, djw233, <https://doi.org/10.1093/jnci/djw233>


Published: 29 October 2016 Article history ▼

Ethics

Simplification improves understanding of informed consent information in clinical trials regardless of health literacy level

Eun Jin Kim and Su Hyun Kim

**CLINICAL
TRIALS**

Clinical Trials
2015, Vol. 12(3) 232–236
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sagepub.co.uk/journalsPermissions.nav
DOI: 10.1177/1740774515571139
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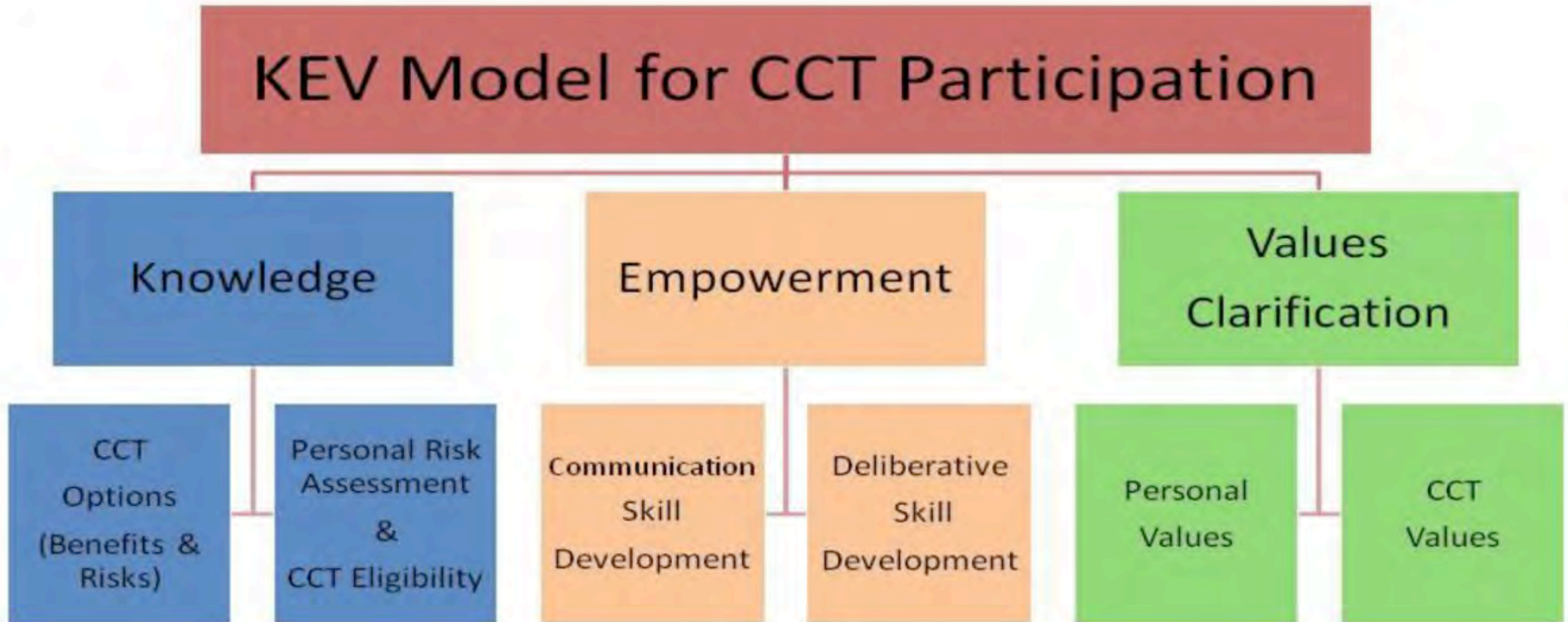
Journal of Cancer Education

[Published: 09 February 2019](#)

Development of a Plain Language Decision Support Tool for Cancer Clinical Trials: Blending Health Literacy, Academic Research, and Minority Patient Perspectives

[Aisha T. Langford](#) , [Sarah T. Hawley](#), [Sue Stableford](#), [Jamie L. Studts](#) & [Margaret M. Byrne](#)

Fig. 1



KEV model for CCT participation

Building and Maintaining Trust

“Trust, mistrust, and distrust influence people's ability to utilize critical resources and make decisions that are best for their health and well-being. Trust is necessary for optimizing health research, eliminating healthcare disparities, and achieving health equity, but efforts to build trust to increase healthcare utilization and research participation may have little effect on attitudes or behaviors that are rooted in distrust or mistrust.”

Griffith DM, Bergner EM, Fair AS, Wilkins CH. Using Mistrust, Distrust, and Low Trust Precisely in Medical Care and Medical Research Advances Health Equity. *Am J Prev Med.* 2021;60(3):442-445. doi:10.1016/j.amepre.2020.08.019

Enhancing trust and building effective partnerships with patients and community stakeholders must consider the variability in dimensions of trust and characteristics of researchers who are trustworthy

Trust Dimensions/Content Areas

Honesty*: Integrity and openness in a relationship

Communication*: Quality and nature of information exchange

Confidence*: Belief in reliability of parties

Confidentiality: Maintaining privacy of personal information

Competence: Qualifications, reputation, and perceived ability to provide services

Fairness*: Perceived treatment of disadvantaged and vulnerable groups

Fidelity: Duty to help partners/participants beyond self-interest

Safety: Perceived consequences of participation

System trust: Belief in institutions, processes and policies of the research system

**Dimensions of trust more relevant to patients and community members involved in advanced research roles*

Characteristics of trustworthy researchers

Accessible: easily reached

Approachable: welcoming, easy to talk to

Attentive: observant, listens carefully; responds to concerns

Empathetic: able to understand others feelings

Honest: truthful and open

Humble: assumes own importance no more than others

Respectful: regards others and their perspectives as valuable



Strategies to Enhance and Engender Trust

Balance power dynamics

Be transparent about goals, motivations

Create infrastructure and policies to community stakeholders meaningful involvement

Develop cultural humility

Equitably distribute resources

Effectively communicate, in all directions

Establish pattern of fulfilling trust

Share decision-making among partners

Value different resources and assets (such as the lived experience)



Original Investigation | Equity, Diversity, and Inclusion



July 19, 2023

The Effect of Racial Concordance on Patient Trust in Online Videos About Prostate Cancer

A Randomized Clinical Trial

Stacy Loeb, MD, MSc^{1,2,3}; Joseph E. Ravenell, MD, MS²; Scarlett Lin Gomez, MPH, PhD⁴; Hala T. Borno, MD^{4,5}; Katherine Siu, MS^{1,2}; Tatiana Sanchez Nolasco, MPH^{1,2}; Nataliya Byrne, BA^{1,2}; Godfrey Wilson, MPA⁶; Derek M. Griffith, PhD⁷; [Rob Crocker](#)⁶; Robert Sherman, BA⁶; Samuel L. Washington III, MD, MAS⁴; Aisha T. Langford, MPH, PhD²

» [Author Affiliations](#) | [Article Information](#)

JAMA Netw Open. 2023;6(7):e2324395. doi:10.1001/jamanetworkopen.2023.24395

Key Points

- Participants were randomized to watch the same video script about either prostate cancer screening or clinical trials presented by 1 of 4 speakers: a Black physician, a Black patient, a White physician, or a White patient, followed by a questionnaire.
- The primary outcome was a published scale for trust in the information
- In this randomized clinical trial of 2904 US men and women, Black adults were significantly more likely to trust videos with a Black vs a White presenter, whereas among White adults, there was no significant association between trust and race of the presenter.

Points to Consider

Key Concept	Key Question (s)	Examples/ Suggestions
Community Engagement	Have you identified the communities that you would like to engage?	Participants and their family members; community centers.
Barriers to participation	What are the barriers to participation and how will you address them?	Time off work, transportation costs; not wanting to change current medical treatment.
Benefits to participation	What are the benefits to enrolling in this clinical research study, from the perspective of potential participants?	Work with communities through focus groups, interviews, and surveys to develop a list of benefits.

Points to Consider

Key Concept	Key Question (s)	Examples/ Suggestions
Informational materials	Will study materials account for different levels literacy and cognitive abilities?	Use clear and simple language in informational materials.
Planning and Timeline	What is a realistic recruitment timeline?	Prior local studies may provide parameter estimates of the percent of eligible participants.
Recruitment Strategies	What mechanisms will you use to encourage recruitment?	Make sure all staff who communicate with potential participants receive proper training.

Points to Consider

Key Concept	Key Question (s)	Examples/ Suggestions
Retention Strategies	<p>How will you retain participants?</p> <p>How will you monitor retention?</p>	<p>Be flexible when scheduling appointments.</p> <p>Obtain several phone numbers so that you can follow up with participants easily.</p> <p>Send participants small tokens of appreciation that will remind them of the study: birthday cards, refrigerator magnets, pens, etc.</p>

Points to Consider

Key Concept	Key Question (s)	Examples/ Suggestions
When the study has been completed	<p>How will you thank participants?</p> <p>How will you disseminate the research results to all communities involved?</p> <p>How will you maintain the relationships that you have forged with the communities?</p>	<p>Send thank you notes to participants and other communities that were involved in the study.</p> <p>Report research results in formats most useful to the different communities involved (e.g., participants, families of participants, and referring practitioners).</p>

Example Gift of Appreciation for Being in a Clinical Trial



Your courage wrote history

Today, it's more clear than ever that our survival depends on one another. When you became a clinical trial volunteer for the first COVID-19 vaccine to be approved, you joined tens of thousands to bring light to a darkened world.

In honor of your pursuit of hope, we offer this keepsake.



In Pursuit of Hope

Name _____

joined the Pfizer-BioNTech COVID-19 vaccine landmark clinical trial

on _____

Date

at _____

Study site

in _____

Location

My Participation in Pfizer's Phase 1 COVID Vaccine Clinical Trial

Study #: S20-00515
Version date: 05/20/2020

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Research Subject Informed Consent Form (Stage 1)

Title of Study: A Phase 1/2, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Describe the Safety, Tolerability, Immunogenicity, and Potential Efficacy of SARS-CoV-2-RNA Vaccine Candidates Against COVID-19 in Healthy Adults
S20-00515

Principal Investigator: Mark J. Mulligan, MD
Division of Infectious Diseases and Immunology
430 E. 29th Street, 3rd Floor
New York, NY 10016
212-263-5182

Emergency Contact: Mark J. Mulligan, MD
646-799-0778

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.



Filter News by Category

Search News



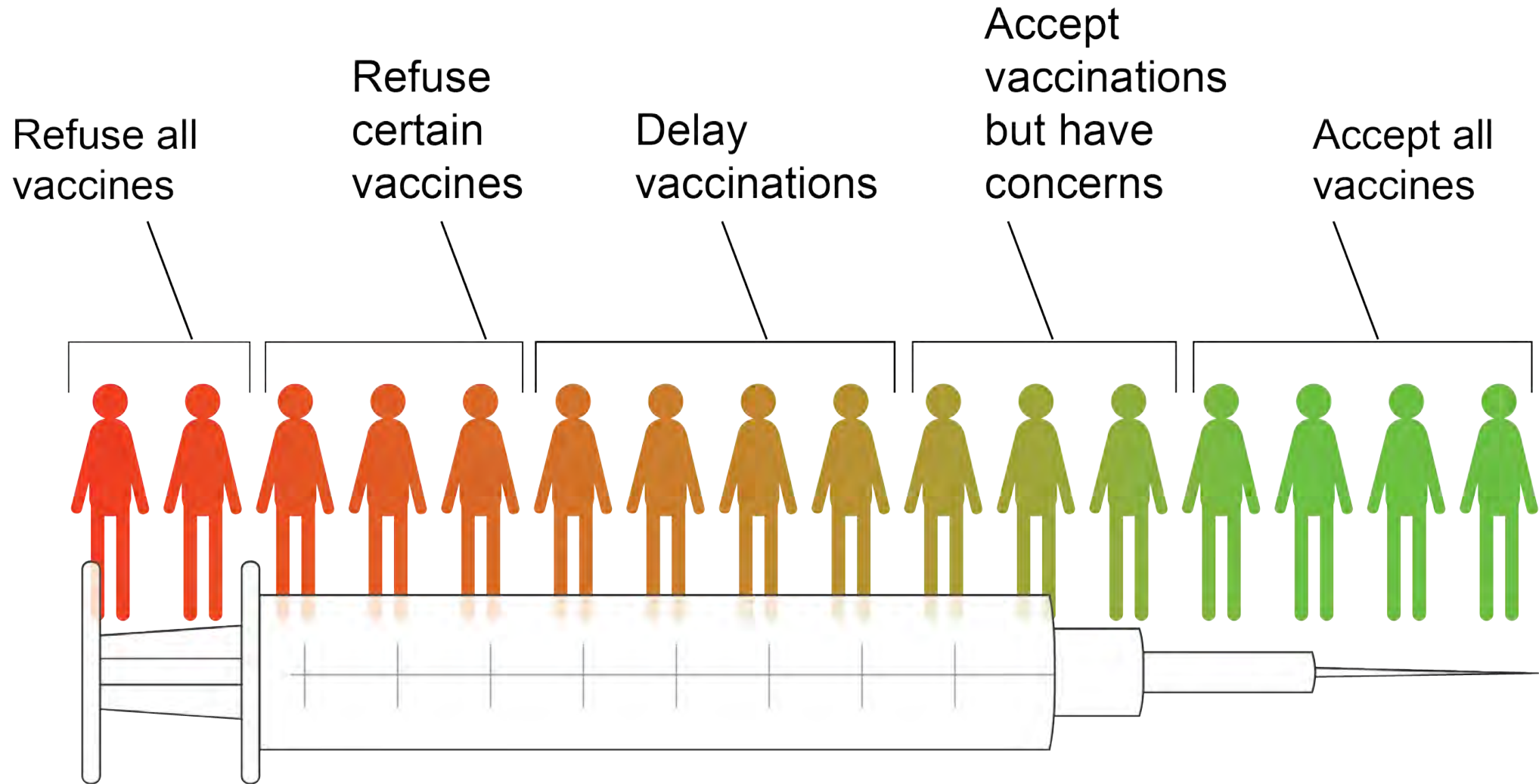
RESEARCH, PATIENT CARE, TRANSLATIONAL MEDICINE | NYU LANGONE HEALTH NEWS, NYU LANGONE HEALTH NEWS SUMMER 2021

'I Was One of the First People in the World to Get the Pfizer Vaccine. Here's What I've Learned.'



With a master's degree in epidemiology and behavioral science and a doctorate in health education and health behavior, Dr. Aisha Langford has long championed public health. PHOTO: TONY LUONG

Continuum of Vaccine Acceptance



Example 3: Low Pathogenicity Avian H10N7 Influenza Virus in a Healthy Human Challenge Model

- ClinicalTrials.gov ID NCT05436444
- Sponsor: National Institute of Allergy and Infectious Diseases



<https://clinicaltrials.gov/study/NCT05436444?cond=flu%20challenge&locStr=Maryland&country=United%20States&state=Maryland&aggFilters=status:rec&rank=1>. Accessed 10/10/2024

Example 3: Low Pathogenicity Avian H10N7 Influenza Virus in a Healthy Human Challenge Model

Background: Influenza, also called flu, is a virus. It can cause mild symptoms such as fever, cough, sore throat, and aches. Sometimes, flu can cause serious complications. Researchers want to see how people's immune systems respond to the flu.

Objective: To find the smallest dose of influenza H10N7 virus that may cause an uncomplicated mild to moderate flu infection in healthy people. This dose will be used in the future to test how well new flu vaccines work.

Group Questions:

1. Where would you recruit people for the Avian H10N7 Influenza Virus Study?
2. What challenges, if any, do you anticipate?





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