



Health literacy considerations for clinical trial communication and decision making

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Disclosures

- No financial conflicts of interest to report

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



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One Definition of Personal 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>. Accessed 3/3/2022

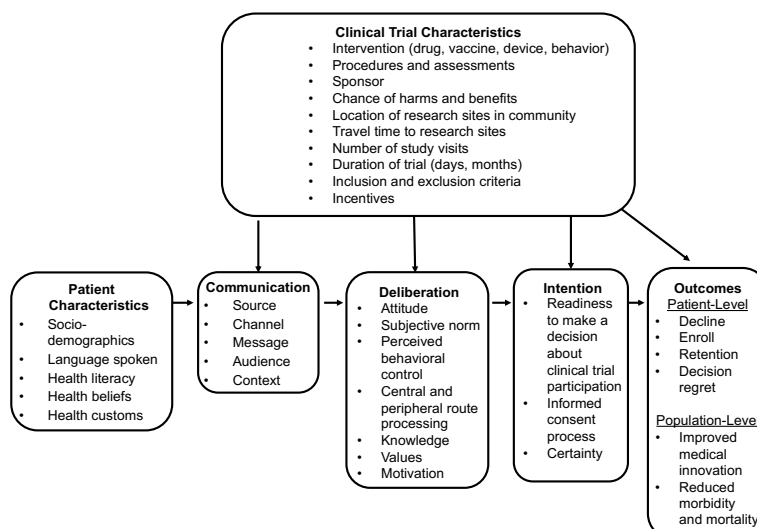
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Health

Imagine That Your Neighbor Dave Asks You To Help Him Find a Clinical Trial for Alzheimer's Prevention



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



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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



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

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.



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. Strelakova, 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.com/journalsPermissions.nav
DOI: 10.1177/1740774515571139
ctj.sagepub.com


 NYU Langone Health

Cancer

Original Article  Free Access

Racial/ethnic differences in clinical trial enrollment, refusal rates, ineligibility, and reasons for decline among patients at sites in the National Cancer Institute's Community Cancer Centers Program

Aisha T. Langford PhD, MPH , Ken Resnicow PhD, Eileen P. Dimond RN, MS, Andrea M. Denicoff MS, RN, Diane St. Germain RN, MS, Wortia McCaskill-Stevens MD, MS, Rebecca A. Enos RN, MPH, Angela Carrigan MPH, Kathy Wilkinson RN, BSN, OCN, Ronald S. Go MD, ... **See fewer authors** ^

First published: 10 December 2013 | <https://doi.org/10.1002/cncr.28483> | Citations: 56

- A higher grade level score for consent form readability (OR = 0.9, 95% CI = 0.83-0.97) was significantly associated with lower refusal rates.
- Consent page length ≥ 20 was significantly associated with lower odds of “no desire to participate in research” among CT decliners (OR = 0.75, 95% CI = 0.58-0.98).

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O' Sullivan et al. *Trials* (2021) 22:544
<https://doi.org/10.1186/s13063-021-05493-1>

Trials

RESEARCH

Open Access

An evaluation of the process of informed consent: views from research participants and staff



Lydia O' Sullivan^{1,2*}, Laura Feeney¹, Rachel K. Crowley^{1,3}, Prasanth Sukumar¹, Eilish McAuliffe⁴ and Peter Doran^{1,2}

- Research staff (n=116) and research participants (n=169) from Ireland and the UK
- Survey about perceptions of the informed consent process

“Research participants were predominantly positive about the informed consent process but highlighted the importance of having sufficient time and the value of providing follow-up once the study concludes, e.g. providing results to participants.”



O' Sullivan et al. *Trials* (2021) 22:544
<https://doi.org/10.1186/s13063-021-05493-1>

Trials

RESEARCH

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“Most staff (74.4%) staff reported that they felt very confident or confident facilitating informed consent discussions, but 63% felt information leaflets were too long and/or complicated, 56% were concerned about whether participants had understood complex information and 40% felt that time constraints were a barrier.”



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

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

Page 1 of 20



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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.

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



Group Question: What Would Make You Feel Confident That a Parent Has Made a Truly Informed Decision About Having Their Child Participate in a Clinical Trial?



Accessible version: <https://www.cdc.gov/healthliteracy/developmaterials/plain-language-communication.html>

PLAIN LANGUAGE

Communication your audience understands the first time

Organize to serve the audience

- ☑ Know your audience and purpose before you begin
- ☑ Put the most important message first
- ☑ Present other information in order of importance to the audience
- ☑ Break text into logical chunks and use headings

Choose words carefully

- ☑ Write in the active voice
- ☑ Choose words and numbers your audience knows
- ☑ Keep sentences and paragraphs short
- ☑ Include "you" and other pronouns

Make information easy to find

- ☑ Use headings and text boxes
- ☑ Delete unnecessary words, sentences, and paragraphs
- ☑ Create lists and tables



Centers for Disease Control and Prevention
Agency for Toxic Substances and Disease Registry

CS236091-8



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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](#)



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Patient Education and Counseling

Volume 104, Issue 2, February 2021, Pages 422-426



Short Communication

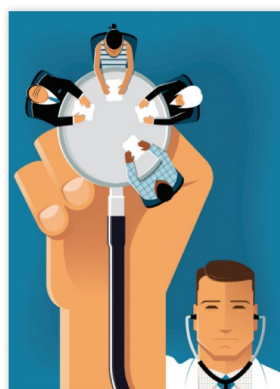
Improving knowledge and decision readiness to participate in cancer clinical trials: Effects of a plain language decision aid for minority cancer survivors

Aisha Langford ^a, Jamie L. Studts ^{b, c}, Margaret M. Byrne ^{d, e}

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This model can make patients true partners in improving care for themselves and others.



Patient Advisory Councils:

Giving Patients a Seat at the Table

Anjana E. Sharma, MD, Lucia Angel, and Quynh Bui, MD

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Sharma A, Angel L, Bui Q. Patient Advisory Councils: Giving Patients a Seat at the Table. *Fam Pract Manag.* 2015 Jul-Aug;22(4):22-7. PMID: 26176505.



An electronic health record-based strategy to recruit for a Patient Advisory Council for Research: Implications for inclusion

Nassira Bougrab¹, Dadong Li², Howard Trachtman¹, Scott Sherman¹, Rachel Thornton¹ and Aisha T. Langford¹

¹NYU Clinical and Translational Science Institute Recruitment and Retention Unit, NYU Langone Health, New York, NY, USA and ²Clinic Informatics, Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA

Table 1. Patient advisory council for research characteristics*

	Year 1 PACR members who joined in 2017 (n = 19)	Year 1 PACR members who joined in 2018 (n = 15)	PACR members as of January 1, 2019 (n = 25)**
Sex			
Female	7 (35)	9 (60)	14 (56)
Male	12 (63)	6 (40)	11 (44)
Race/Ethnicity			
Asian	2 (11)	1 (7)	2 (8)
Black	6 (32)	8 (53)	12 (48)
Hispanic	5 (26)	2 (13)	3 (12)
White	6 (32)	4 (27)	8 (32)
Age group, years			
18-36 years	2 (11)	4 (27)	6 (24)
37-55 years	6 (32)	2 (13)	3 (12)
56-74 years	7 (37)	7 (47)	12 (48)
>75	4 (21)	2 (13)	4 (16)

PACR, Patient Advisory Council for Research.

*These numbers include those who initially responded and agreed to be on the council. Actual attendance varied by meeting date.

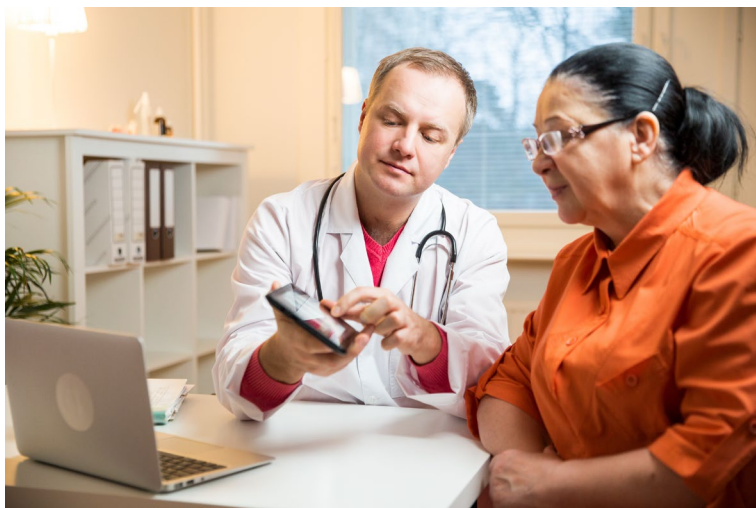
**Current PACR members as of January 1, 2019 include members from Year 1 who agreed to serve another year and new members invited in Year 2.

NYU's CTSI Patient Advisory Council for Research

Gives feedback on . . .

- Perceived burden of the study
- Comprehensibility of materials
- Appropriate reimbursement
- Recruitment materials
- Concerns and potential challenges
- Advertising the study

Understanding Your Target Population



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What is Health Marketing?

- Health Marketing involves creating, communicating, and delivering health information and interventions using customer-centered and science-based strategies to protect and promote the health of diverse populations (CDC, 2005).

<https://www.cdc.gov/healthcommunication/toolstemplates/WhatsHM.html>. Accessed 3/2/2022



The Four Ps of Marketing

- **Product:** the item, good or service that is being provided that delivers benefits to those who consume it; includes quality, packaging, design and brand name
- **Price:** monetary and non-monetary costs to the market
- **Place:** channels and locations where the product can be obtained
- **Promotion:** direct communication, publicity and advertising

<https://www.cdc.gov/healthcommunication/toolstemplates/Basics.html>, Accessed 3/2/2022



Choosing a Target Market

- A 'target market' is a specific group of people who have similar needs, preferences, and behaviors
- Once a target market is selected by the marketer, a **marketing plan** is developed to match the characteristics of the target market

<https://www.cdc.gov/healthcommunication/toolstemplates/Basics.html>, Accessed 3/2/2022



Potential Ways to Segment the Market

- Age
- Gender
- Race
- Ethnicity
- Geography
- Health problem
- Marital status
- Use of technology
- Health goals
- Education level
- Income level
- Risk factors
- Interests/activities
- Employment
- Caregiver roles
- Attitudes/beliefs



JAMA Network | **Open**

Original Investigation | Diversity, Equity, and Inclusion

February 14, 2022

Comparison of Racial, Ethnic, and Geographic Location Diversity of Participants Enrolled in Clinic-Based vs 2 Remote COVID-19 Clinical Trials

Jenell Stewart, DO, MPH¹; Meighan L. Krows, BA¹; Torin T. Schaafsma, MPH¹; **Kate B. Heller, MS¹**; Elizabeth R. Brown, ScD^{1,4}; Jim Boonyaratankornit, MD, PhD^{2,4}; Clare E. Brown, MS¹; Hannah Leingang, MPH¹; Caroline Liou, MA¹; Anna Bersteyn, PhD¹; Mark D. Schwartz, MD⁵; Vaidehi Agrawal, PhD⁶; DeAnna Friedman-Klabanoff, MD⁷; Stephen Eustace, BA¹; Helen C. Stankiewicz Karita, MD⁸; Michael K. Pasache-Orlow, MD, MA, MPH⁹; Patricia Kossinger, PhD¹⁰; Sybil G. Hosenk, PhD¹⁰; Helen Y. Chu, MD, MPH^{12,11}; Connie Cetani, MD, MPH^{1,2,11}; Jared M. Baeten, MD, PhD^{1,2,11,12}; Anna Wald, MD, MPH^{2,4,13,14}; Christine Johnston, MD, MPH²; Ruane V. Barnabas, MBChB, MSc, DPH^{1,2,11}

> Author Affiliations | Article Information

JAMA Netw Open. 2022;5(2):e2148325. doi:10.1001/jamanetworkopen.2021.48325

“This cohort study was a secondary analysis of 1410 participants enrolled in 3 COVID-19 studies conducted in 2020 during the early COVID-19 pandemic and found that remote clinical trials with online recruitment had increased racial, ethnic, and geographic location diversity among study participants.”



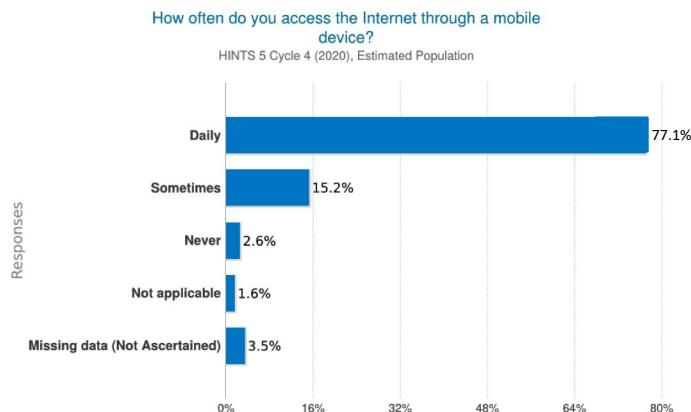
Analyze Each Segment

- Try to find existing sources of market research
- If needed, consider surveys, focus groups and other methods of collecting data directly from the target market

<https://www.cdc.gov/healthcommunication/toolstemplates/Basics.html>, Accessed 3/2/2022



Using Available Data: Example 1 Health Information National Trends Survey (HINTS)



<https://hints.cancer.gov/>, Accessed 3/3/2022





Short Communication

Correlates of knowledge of clinical trials among U.S. adults: Findings from the 2020 Health Information National Trends Survey

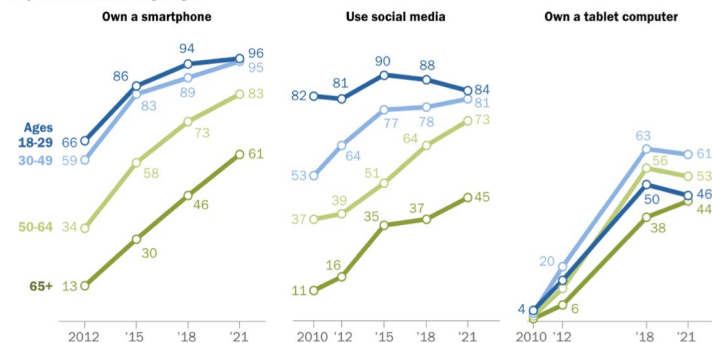
Aisha T. Langford ^a, Kerli T. Orellana ^a, Nancy Buderer ^b



Using Available Data: Pew Research Center

Smartphone ownership and social media use among older adults continue to grow

% of U.S. adults who say they ...



Note: Respondents who did not give an answer are not shown.
Source: Survey of U.S. adults conducted Jan. 25-Feb. 8, 2021.

PEW RESEARCH CENTER

<https://www.pewresearch.org/fact-tank/2022/01/13/share-of-those-65-and-older-who-are-tech-users-has-grown-in-the-past-decade/>, Accessed 3/2/2022



Top 10 Social Media Recruitment Rules



<https://edgeforscholars.org/top-10-social-media-recruitment-rules/>, Accessed 3/2/2022

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Top 10 Social Media Recruitment Rules

- Follow IRB guidelines
- Create your online persona
- Research demographics
- Seek out training
- Budget appropriately
- Plan your social media strategy and calendar
- Have support
- Control comments
- Track and measure success
- Use [ResearchMatch.org](https://www.researchmatch.org/)

<https://edgeforscholars.org/top-10-social-media-recruitment-rules/>, Accessed 3/2/2022

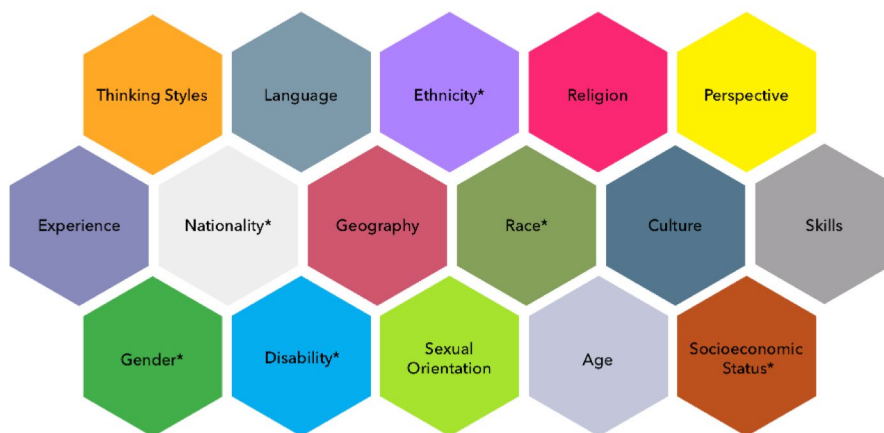
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Conceptualizing diversity, equity, & inclusion among research participants and the biomedical workforce



Many Types of Diversity



•A diversity of perspectives and lived experiences is fundamental to achieving research and training excellence.

³⁴ <https://diversity.nih.gov/toolkit> & <https://www.sshrc-crsh.gc.ca/funding-financement/nfrf-fnfr/edi-eng.aspx#3>, accessed 3/2/2022



Equity: One (of many) definitions

- The removal of systemic barriers and biases enabling all individuals to have equal opportunity to access and benefit from the program.

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<https://www.sshrc-crsh.gc.ca/funding-financement/nfrf-fnfr/edi-eng.aspx#3>, accessed 3/02/2022



Inclusion: One (of many) definitions

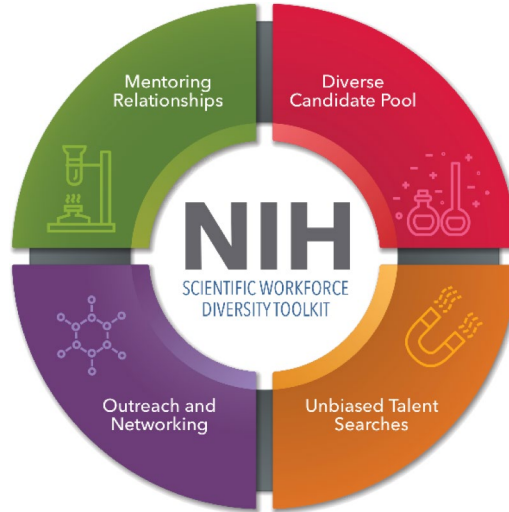
- The practice of ensuring that all individuals are valued and respected for their contributions and are equally supported

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<https://www.sshrc-crsh.gc.ca/funding-financement/nfrf-fnfr/edi-eng.aspx#3>, accessed 3/2/2022



Strategies to Enhance Scientific Workforce Diversity



37 NIH Scientific Workforce Diversity Toolkit. https://diversity.nih.gov/sites/coswd/files/images/SWD_Toolkit_Interactive-updated_508.pdf, accessed 3/2/2022



Unintended Effects of Unpaid Internships

Ryan Ken
@Ryan_Ken_Acts

The t is many unpaid internships are the grooming period for the abuse you will endure as an employee. It's a period of testing your limits. The internship itself can be an assessment of how willing you are accept financial abuse. Pennies sound like a lot after working for free.

8:29 PM · Mar 2, 2021 · Twitter for Android

Ryan Ken
@Ryan_Ken_Acts

Replying to @Ryan_Ken_Acts

Some of my mentors saw me as ungrateful for opportunities, but it was financially impossible for me to devote hours to free labor. These systems were designed for ppl with money and the pressure to "perform" wealth can produce compound financial obstacles for working class ppl

9:07 PM · Mar 2, 2021 · Twitter for Android



Lessons Learned from Conducting Recruitment and Retention Consultations

- Assess grade level readability
- Use plain language
- Challenge assumptions
- Pay attention to design features
- Provide training for staff
- Use teach-back to confirm understanding
- Adequate compensation / incentives



Start Local: Concentric Circle Model of Recruitment



<https://www.wcgclinical.com/insights/clinical-trial-operational-excellence/unlocking-the-full-potential-of-your-patient-recruitment-roi>
Accessed 3/2/2022



Emerging Questions

- How can organizations support health literacy
- Handling uncertainty in clinical trials
- How to best explain randomization
- Which, if any, audio-visual supports are most helpful for improving informed consent



Thank You

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