

Effective Person-centered Consent for Minoritized Populations

Natalie Dilts, MPH
Project Lead, Recruitment Innovation Center
Vanderbilt University Medical Center

October 24, 2022



VANDERBILT  UNIVERSITY
MEDICAL CENTER

CTSA Clinical & Translational
Science Awards Program

Disclosure

- The presenter for this session is:

Natalie Dilts, MPH

I have no relevant financial relationship(s) in connection with this educational activity

Funded by:

National Center for Advancing Translational Science

U24TR001579 Vanderbilt University Medical Center

07/01/2016 – 6/30/2023



CTSA Clinical & Translational
Science Awards Program

Learning Objectives

- Identify cultural considerations when consenting minoritized participants.
- Apply strategies for supporting a person-centered consent process for empowered decision making.

TRIAL **INNOVATION** NETWORK



CTSA Clinical & Translational
Science Awards Program

Research participation rates in minoritized populations

- Participation in clinical trials is particularly low among some groups, especially racial and ethnic minoritized populations.^{1,2}



Table 1. Percent Participation in Clinical Trials by Subpopulation* for New Molecular Entities and Therapeutic Biologics Approved in 2020

	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 AND OLDER	UNITED STATES
AVERAGE	56%	75%	8%	6%	11%	30%	54%

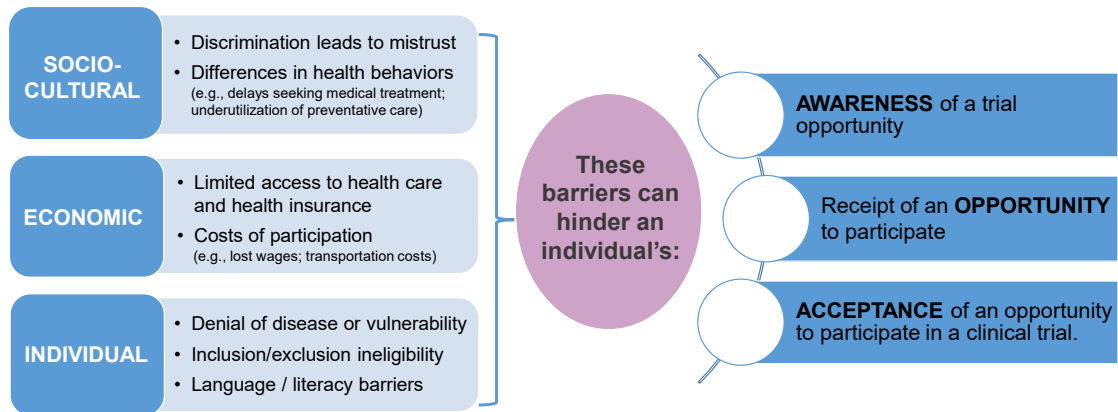
* The percentage of all other races combined (American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, Other, Unknown/Unreported) makes up to 100% of race category.
 * The percentage of Non-Hispanic and Unknown/Unreported ethnicity makes up to 100% of ethnicity category.
 * The percentage of patients from anywhere else in the world makes up to 100% of geographic category.

CTSA Clinical & Translational Science Awards Program

- People from racial and ethnic minoritized groups are underrepresented in clinical research.
- Black or African American individuals represent 12.4% of the population but only 8% of the participants in clinical drug trials.
- Hispanic or Latino individuals represent 18.7% of the population but only 11% of the participants in clinical drug trials.
- Lower participation rates may result in (Barrett, et al., 2017):
 - Inability to generalize research findings
 - Biased reporting of adverse effects
 - Unfair distribution of the benefits of the research (Belmont Report) furthering racial health disparities

Barrett NJ, Ingraham KL, Vann Hawkins T, Moorman PG. Engaging African Americans in Research: The Recruiter's Perspective. *Ethn Dis.* 2017 Dec 7;27(4):453-462. doi: 10.18865/ed.27.4.453

Clinical trial barriers for minoritized populations^{3,4}



TRIAL INNOVATION NETWORK



CTSA Clinical & Translational Science Awards Program

Notes:

Barriers to minority recruitment and participation in clinical trials include sociocultural, economic, and individual.

These barriers can either promote or hinder an individual's 1) awareness of a trial opportunity, 2) receipt of an opportunity to participate, and 3) acceptance of a trial opportunity to participate.

Cultural considerations when consenting minoritized participants

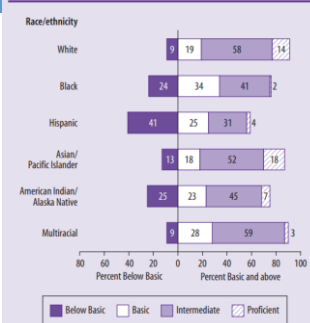
1. Health Literacy

- 36% of U.S. adults have basic or below basic health literacy skills.⁵
- Minoritized adults have lower rates of health literacy.⁶
- Healthy People 2030 recognizes that organizations have a responsibility to equitably address health literacy.⁷

TRIAL INNOVATION NETWORK



Figure 2-5. Percentage of adults in each health literacy level, by race/ethnicity: 2003



NOTE: Detail may not sum to totals because of rounding. Adults are defined as people 16 years of age and older living in households or prisons. Adults who could not be interviewed because of language spoken or cognitive or mental disabilities (3 percent in 2003) are excluded from this figure. All adults of Hispanic origin are classified as Hispanic, regardless of race. The Asian/Pacific Islander category includes Native Hawaiians. Black includes African American, and Hispanic includes Latinos. SOURCE: U.S. Department of Education, Institute of Education Sciences, National Center for Education Statistics, 2003 National Assessment of Adult Literacy.

Notes:

- Health Literacy: The degree to which individuals have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions.
- The National Assessment of Adult Literacy estimates 36% of U.S. adults have basic or below basic health literacy skills.
- Minoritized adults have lower health literacy rates.

Healthy People 2030: <https://health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/health-literacy>

Cultural considerations when consenting minoritized participants

2. Limited English Proficiency (LEP)

- 300+ languages spoken in the US.⁸
- More than 23 million Americans have Limited English proficiency (LEP).⁹
- Lack of translated consent forms for LEP participants makes it harder to understand research-related information.



CTSA Clinical & Translational
Science Awards Program

Notes:

- There are more than 300 languages spoken in the United States
- More than 23 million Americans have limited English proficiency (LEP).
- However, it is important to differentiate literacy from English-language proficiency.
- Some non-English speakers have adequate health literacy in their native language, and vice versa.
- Lack of translated consent forms for LEP participants makes it harder to understand research-related information.

Cultural considerations when consenting minoritized participants

3. Legal Concerns

- Immigration status¹⁰
- Relinquishing legal rights if something goes wrong¹¹
- Contradictory language¹²
 - “Deidentification of PHI” vs. “Risk of unintentional data sharing”
 - “Right to withdraw” vs. “Data already shared might not be retrievable”



- For immigrants and refugees, there may be concerns that immigration status will be affected if they sign the consent form.
- Belief they no longer have the right to sue the research institution if something goes wrong
- Concerns related to contradictory language:
 - Information will be deidentified vs. Risk that personal information could be unintentionally shared with someone who should not have access to it
 - Right to withdraw from biobank vs. Data already shared prior to participant withdrawal may not be able to be retrieved since they would be deidentified

Cultural considerations when consenting minoritized participants

4. Preferences for Formatting of Information¹¹

- The use of plain language in the consent forms
- Summaries at the end of each section
- The use of pictures, illustrations and large font
- Information presented in a Question-and-Answer format

TRIAL INNOVATION NETWORK



CTSA Clinical & Translational
Science Awards Program

Notes:

- Over 75% of African American and Latino adults prefer the use of plain language in the consent form.
- Over 60% of minoritized adults prefer the use of summaries and pictures in the consent document.
- Over 50% of African American and Latino adults prefer the use of large font and information presented in Q&A format.

Cultural considerations when consenting minoritized participants

5. Preferences for Delivery of Information¹¹

- Taking information home
- Having more than one meeting
- Talking to someone who is participating in the trial
- Having a family member or friend in the consent discussion
- The use of videos and other media

TRIAL INNOVATION NETWORK



CTSA Clinical & Translational
Science Awards Program

Notes:

- Over 60% of African American and Latino adults prefer to take information home, have more than one meeting, and talk to someone who is participating in the trial.
- Over 50% of minoritized adults prefer to have a family member or friend in the consent discussion.
- Participants preferred the use of use of videos, pictures, illustrations, and large font to deliver study information

Recommended Culturally sensitive consent methods



- Use 5th or 6th grade language level
- Use simple language, short sentences, define technical terms
- Present important information first and repeat throughout
- Supplement instruction (e.g., video, flip charts)
- Utilize IRB-approved short forms for low literacy (not just for non-English speaking)

Healthy People 2030 emphasizes an organization's responsibility to equitably address health literacy⁷

Study teams can use this guidance when creating consent forms and engaging in the informed consent process

TRIAL INNOVATION NETWORK



The Attributes of a Health-Literate Organization¹³

1. Has **leadership that makes health literacy integral** to its mission, structure, and operations.
2. **Integrates health literacy into planning**, evaluation measures, patient safety, and quality improvement.
3. **Prepares the workforce to be health literate** and monitors progress.
4. **Includes populations served in the design**, implementation, and evaluation of health information and services.
5. Meets the needs of populations with a range of health literacy skills while **avoiding stigmatization**.
6. **Uses health literacy strategies** in interpersonal communications and confirms understanding at all points of contact.
7. **Provides easy access to health information** and services and navigation assistance.
8. Designs and distributes **print, audiovisual, and social media content that is easy to understand** and act on.
9. **Addresses health literacy** in high-risk situations, including care transitions and communications about medicines.
10. **Communicates clearly** what health plans cover and what individuals will have to pay for services.

- The average adult reads at the 8th or 9th grade level, and 20% read at the 5th grade level or below.
- To ensure wide understanding, it is best for materials to be written at the 5th or 6th grade level (<https://www.ahrq.gov/health-literacy/improve/precautions/tool11.html>)

The Attributes of a Health-Literate Organization: <https://nam.edu/perspectives-2012-ten-attributes-of-health-literate-health-care-organizations/>




Recommended Culturally sensitive consent methods

Address LEP

- Provide translated forms and pre-test them for comprehension
- Offer live translation and interpreter services
- Provide training to interpreters for person-centered consent
- Demonstrate any study procedures
- Use universal healthcare symbols in the physical environment

Address Legal Concerns

- Hire racially and culturally congruent staff
- Expand the verbal portion of the consent process
- Clarify immigration status will not be affected by participation
- Partner with community agencies to address deportation concerns
- Facilitate discussions with current and former participants
- Utilize NIH-issued Certificates of Confidentiality

CoC Protections	
	CoCs protect all copies of identifiable, sensitive information collected by a CoC recipient
	Information protected by a CoC is immune from the legal process and is not admissible as evidence (unless participant consents to this disclosure)
	CoC protections last in perpetuity

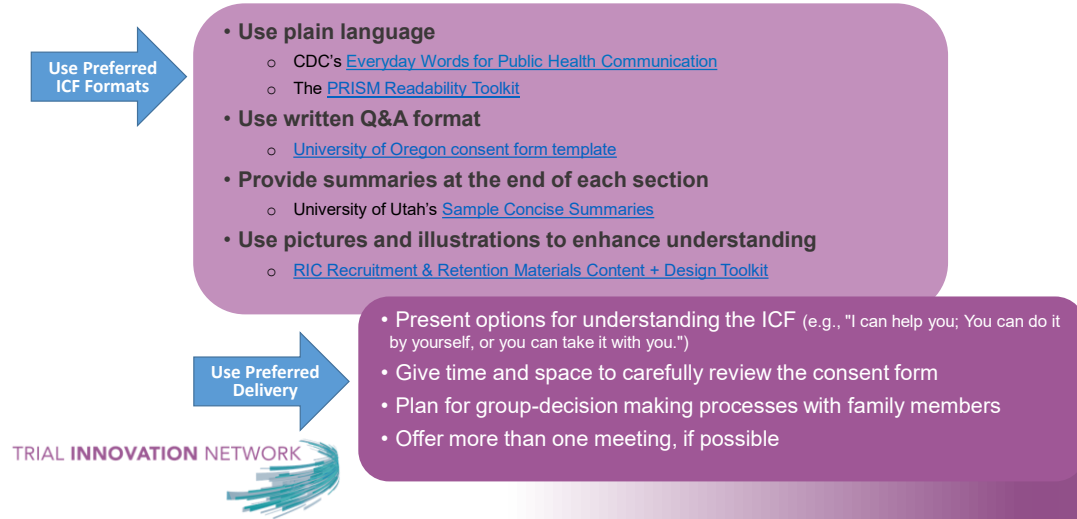


CTSA Clinical & Translational Science Awards Program

NIH Certificates of Confidentiality:

<https://grants.nih.gov/policy/humansubjects/coc.htm>

Recommended Culturally sensitive consent methods



CDC Everyday Words for Public Health Communication:

<https://www.cdc.gov/other/pdf/everydaywords-060216-final.pdf>

The Prism Readability Toolkit:

https://www.research.chop.edu/sites/default/files/web/sites/default/files/irb/IRB_prism_readability_toolkit.pdf

University of Oregon consent form template:

https://research.uoregon.edu/files/2020-01/template_guidance_-_informed_consent.pdf

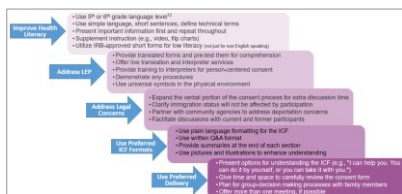
University of Utah's sample concise summaries:

https://irb.utah.edu/resources/documents/pdf/Concise_Summary_Examples_2019.pdf

RIC Recruitment & Retention Materials Content + Design Toolkit:

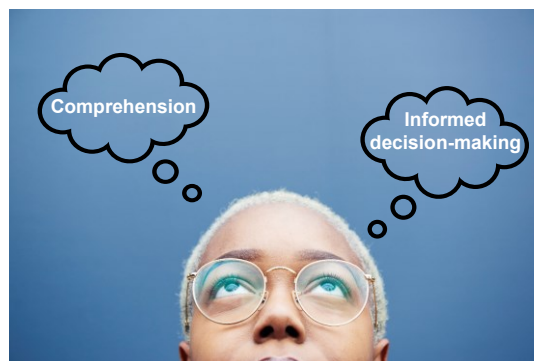
<https://trialinnovationnetwork.org/material-details/?ID=156>

Achieve person-centered consent



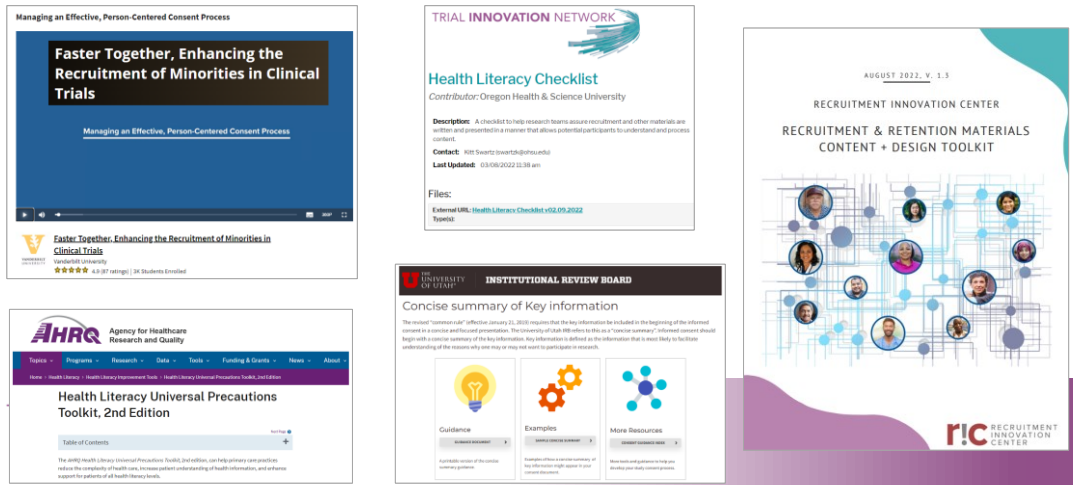
Tips to Ensure Comprehension

- Train staff to engage minoritized populations in the consent process.
- Use the 'teach-back' method (ask participants to explain their understanding of the research)
- Ask questions that begin with "How" and "What," rather than closed-ended Yes/No questions



CTSA Clinical & Translational
Science Awards Program

Recommended person-centered consent tools



Faster Together Course (Module 7: Managing an Effective, Person-Centered Consent Process): <https://www.coursera.org/lecture/recruitment-minorities-clinical-trials/managing-an-effective-person-centered-consent-process-1GEwN>

Health Literacy Universal Precautions Toolkit, 2nd Edition:
<https://www.ahrq.gov/health-literacy/improve/precautions/toolkit.html>

Health Literacy Checklist for Research Communication:
<https://trialinnovationnetwork.org/material-details/?ID=153>

Informed consent concise summary templates: <https://irb.utah.edu/informed-consent/concise-summary.php>

RIC Recruitment & Retention Materials Content & Design Toolkit:
<https://trialinnovationnetwork.org/material-details/?ID=156>

References

1. FDA 2020 Drug Trials Snapshots Summary Report: <https://www.fda.gov/media/145718/download>
2. 2020 US Census Bureau: <https://www.census.gov/library/stories/2021/08/improved-race-ethnicity-measures-reveal-united-states-population-much-more-multiracial.html>
3. Swanson GM, Ward AJ. Recruiting minorities into clinical trials: toward a participant-friendly system. J Natl Cancer Inst. 1995 Dec 6;87(23):1747-59. doi: 10.1093/jnci/87.23.1747.
4. Durant RW, Wenzel JA, Scarinci IC, Paterniti DA, Fouad MN, Hurd TC, Martin MY. Perspectives on barriers and facilitators to minority recruitment for clinical trials among cancer center leaders, investigators, research staff, and referring clinicians: enhancing minority participation in clinical trials (EMPaCT). Cancer. 2014 Apr 1;120 Suppl 7(0 7):1097-105. doi: 10.1002/cncr.28574.
5. Cutilli CC, Bennett IM. Understanding the health literacy of America: results of the National Assessment of Adult Literacy. Orthop Nurs. 2009 Jan-Feb;28(1):27-32; quiz 33-4. doi: 10.1097/01.NOR.0000345852.22122.d6.
6. The Health Literacy of America's Adults: Results From the 2003 National Assessment of Adult Literacy. <https://nces.ed.gov/pubs2006/2006483.pdf>
7. Office of Disease Prevention and Health Promotion. (n.d.). Social determinants of health – Health literacy. Healthy People 2030. U.S. Department of Health and Human Services. <https://health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/health-literacy#cit6>
8. United States Census Bureau. 2009-2013 American Community Survey: Detailed Languages Spoken at Home and Ability to Speak English for the Population 5 Years and Over: 2009-2013. <https://www2.census.gov/library/data/tables/2008/demo/language-use/2009-2013-acs-lang-tables-nation.xls>
9. Center for Health Care Strategies, Inc. What is Health Literacy Fact Sheet: https://www.chcs.org/media/CHCS_Health_Literacy_Fact_Sheets_2013_1.pdf
10. George S, Duran N, Norris K. A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders. Am J Public Health. 2014 Feb;104(2):e16-31. doi: 10.2105/AJPH.2013.301706. Epub 2013 Dec 12.
11. Quinn SC, Garza MA, Butler J, Fryer CS, Casper ET, Thomas SB, Barnard D, Kim KH. Improving informed consent with minority participants: results from researcher and community surveys. J Empir Res Hum Res Ethics. 2012 Dec;7(5):44-55. doi: 10.1525/jer.2012.7.5.44
12. Sedig, L.K., De Loney, E.H., Bailey, S.B., Spector-Bagdady, K., Ghita, B., Krienke, L.K. and Hutchinson, R. (2022), Perspectives from a Predominantly African American Community about Biobank Research and a Biobank Consent Form. Ethics & Human Research, 44: 26-33. <https://doi.org/10.1002/eahr.500134>
13. Brach, C., D. Keller, L. M. Hernandez, C. Baur, R. Parker, B. Dreyer, P. Schyve, A. J. Lemerise, D. Schillinger. 2012. Ten Attributes of Health Literate Health Care Organizations. NAM Perspectives. Discussion Paper, National Academy of Medicine, Washington, DC. <https://doi.org/10.31478/201206a>

TRIAL INNOVATION NETWORK



CTSA Clinical & Translational
Science Awards Program