MAKE IT CLEAR:

THE USE OF LAY LANGUAGE IN RESEARCH RECRUITMENT

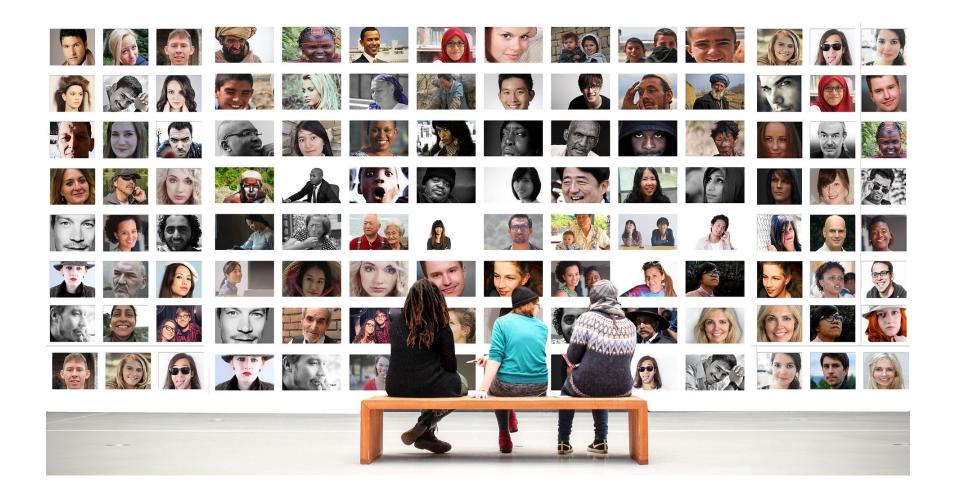


IN THE LAST TALK...

- Learned to define your audience and understand the 'customer' to sell your study.
- Acknowledged what might be of value to your participants.
- Encouraged building participant-researcher relationships.
- Addressed providing the right amount of information in sharing about your study.

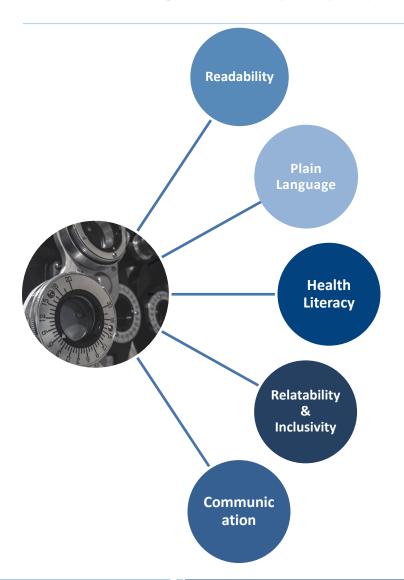


THE CHALLENGE





5 LENSES OF MAKING IT CLEAR



Materials to apply these lens:

- Print ads (flyers, brochures)
- Social Media
- Websites, digital ads
- Telephone scripts
- Email templates, letters
- Informed Consent Forms, Consent aids
- Survey instructions
- Study Documents
- Study Results



POLL: TRUE OR FALSE?

READABILITY, PLAIN
LANGUAGE AND HEALTH
LITERACY
CAN BE USED
INTERCHANGEABLY.





POLL: FALSE!

READABILITY

PLAIN LANGUAGE

HEALTH LITERACY

NOW THIS LOOKS LIKE SOMETHIN' I'D READ!

I'M UNDERSTANDIN' ALL
THIS INFO UP IN HERE!

I'M GONNA GO MAKE SOME INFORMED DECISIONS!



From Communicate Health







LENS #1: START WITH READABILITY

Readability [ree-duh-bil-i-tee]

the state or quality of being readable.

the property of materials that affects the ease with which printed matter can be read for a sustained period.

Visibility & Eye Movements

- Add white space for visual appeal.
- Present information in manageable "chunks."
- Add bullets. Can also use tables, diagrams, consent aids.

Fatigue in reading

- Use 1-2 syllable words to describe complex concepts
- Break up e-consents in multiple sections.

Rate of work (reading/skimming speed)

- Keep headings for easy to find visit info.
- Be consistent with terms throughout





What will happen if you take part in the study?

If you participate in this study, for three weeks you will: use FASTER daily, have three fMRI brain scans, and will come to the clinic for study visits once a week. Before treatment you will have physical exam. Details of your participation are described below.

Clinical and Health Screening: You will undergo a screening process to determine if you are eligible for the study. In order to protect you from adverse medication effects, you will be screened with a complete medication history, physical exam, and laboratory tests. During your first exam visit and again at your final visit, approximately 2 tablespoons (30 mL) of blood will be drawn to test liver an kidney function. We will also do a blood test to make sure you are not pregnant and to test medication concentration in your blood at the end of the study. The results of your physical exam and laboratory tests will appear in your UNC Health Care medical record. Your medical record will also show that you are participating in this study. During the initial screening, you will be asked questions about your past health, the complications from your surgical incisions, as well as questions about any symptoms you may be experiencing now. You will also be asked to complete questionnaires about your mood symptoms and trauma history. You may choose not to answer any or all of the questions for any reason.

Brain Imaging: You will participate in three brain imaging sessions at the UNC Biomedical Research Imaging Center. In these sessions, magnetic resonance images (MRIs) of your brain will be taken. An MRI is a picture of your brain taken with the use of strong magnetic fields. MRIs do not use x-rays or other radiation, and there are no known risks from exposure to magnetic fields and radio waves associated with MRIs. However, there is the risk of discomfort with confinement inside the imaging machine. In this study, special MRIs (called functional MRIs or fMRIs) will be taken that provide information about what areas of the brain are made active by particular kinds of stimuli. You will complete a safety questionnaire to determine whether you have any foreign iron or sto metal objects in your body, such as a pacemaker, shrapnel, metal plate, or metal debris. If you have any such objects in your body, y cannot participate in the MRI session unless it is deemed safe to do so by the fMRI team. The fMRI team at BRIC determines the safety of metal objects for potential participants on a case by case basis. For that reason, the study coordinator always contacts the fMRI team any time there is a metal object in a potential participant's body to determine if it will be safe to conduct a brain scan. The fMRI team frequently utilizes mrisafety.com and generally uses clinical procedures as a basis for determining safety. If the team is still unsure after checking the website or referencing clinical procedures, they will <mark>verify</mark> with clinical radiologists in the hospital. If the metal object is an implant, the fMRI team will check to see if there is an MRI safety indicator on the implant's card. If that information is not available, the fMRI team will contact the manufacturers of the implant to determine if the participant can be safely scanned with the implant. Additionally, before every scan, the fMRI team has a checklist for participants to fill out that asks about metal objects and surgeries to ensure that every participant is properly and thoroughly screened before being scanned in the fMRI machine. You may be asked to participate in an additional 15 minute test brain scan once it has been deemed that there are no safety concerns so that the fMRI team can ensure your brain images are free of any artifact, which is when a metal object can block a part of the brain image. This optional visit would occur before your second study visit. Please ask the experimenter if you are unsure about any metal objects in your body. During the scan, you will see a screen which will give you a simple task that you will perform by pushing a button. This task will involve a scheme in which you hypothetically win or lose money. You will have the task explained to you and will have a chance to practice it before getting into the scanner. Once you understand the task instructions, you will lie down on your back on a platform and your head will be positioned inside a helmet-like circular tube and the platform will be pushed inside the long tube of the MRI machine. The MRI technician will provide padding for your head and knees to make you more comfortable while lying down. If you are uncomfortable or feel pain because of lying down, please tell the technician immediately. You will be able to see outside of the helmet and outside the imaging machine by looking at a mirror. In this way, you will be able to watch the pictures or words displayed on a screen placed near your feet. If sounds are presented, you will hear them through earphones. It is expected that each imaging session will take approximately 2 hours.

Medication Application Procedures: Starting after your first MRI, you will initiate use of either the investigational medication or the standard medication. In either case, you will apply the topical ointment twice a day. The investigational medication is called FASTER, and contains .45mg concentration of the active agent XYZ. The standard medication is called USUAL and contains .01mg concentration of the active agent ABC as well as .5mg concentration of the active agent 123. You will use the study medication for three months and will return any unused portion to us.

Study Visits: In total, you will attend 6 study visits across your participation. In the first, you will discuss the study with the principal investigator or a research assistant, you will provide consent, and your medical history will be assessed. This appointment will likely take 2-2.5 hours. At your second visit, the study doctor will also perform a physical exam at this visit and administer a series of questionnaires. After your exam you will have blood drawn for initial lab work. At the following three study visits you will have an fMRI done, you will complete a second task outside of the fMRI that you will perform by pushing a button, you will be given an interview and a series of questionnaires, you will be given your tube of study medication and you will have blood drawn, about 2 tablespoons (30mL). Each MRI appointment will likely take 3 hours. At each of these visits you will also be given a new tube of study medication and have blood drawn. Each of these appointments will likely take one hour. During your final appointment, you will return all study medication, compete the same interview and questionnaires as before, have a second physical exam to evaluate the progress of your healing, and have blood drawn. The last visit will take about an hour.

What will happen if you take part in the study?

If you decide to join this study you will:

- Apply a cream twice a day, for three weeks to your wounds. This will be either the new medication, FASTER, or the standard medication, USUAL.
- · have three fMRI brain scans
- come to the clinic for study visits once a week (parking vouchers provided)

Visit 1: Screening Visit, Medical History

You will come to the ABC clinic for your first appointment. You will meet with the study team to go through this document, discuss what is being asked of you for this study, and to ask any questions that you have. If you decide to join, you will sign this form and continue with the visit. A copy of this form will be placed in your medical record so that if you see another doctor while in this study, they can see that you are taking FASTER or USUAL. We will ask you to complete questionnaires about your:

- Mental health and medical history
- · Current mental health symptoms
- Current mood symptoms
- Any history of trauma

You may choose not to answer any or all of the questions for any reason. This visit should last 2-2.5 hours.

Visit 2: Screening Visit, physical exam

You will return to the ABC clinic to meet with a study doctor for:

- Physical exam. The study doctor will listen to your lungs and heart, look at the areas on your belly where you have surgical
 cuts, and ask you questions about how you are feeling.
- Blood draw. We will take about 2 tablespoons (30mL) of blood to be sure that your liver and kidneys are functioning
 properly and to be sure that you are not pregnant (if female).

The results of your exam and laboratory test results will appear in your UNC Health Care medical record. This visit should last about 2 hours.

Visits 3-5: MRI and Medication Visits

For visits 3, 4, and 5, you will go to the UNC Imaging Center to meet with the study team. Each visit will take 3 hours. At each of these visits you will:

- Have an MRI. We will ask you to get into a machine that will take a picture of your brain. This will not hurt, but you may
 ask to stop at any time if you feel uncomfortable. Some people who are afraid in small spaces may feel uneasy or scared
 during this procedure. More details about how the MRI works are included in the next section.
- Get medication. The study team will give you a tube of the study medication to use twice every day. You will not know
 which kind of medication are you are given. You will also be given instructions on how to use it.
- Blood draw. We will again ask for 2 tablespoons of blood to check your kidney and liver function. We will also check to see how much of the medication is in your blood.

Visit 6: Final Visit and Exam

For your last study visit, you will come to the ABC clinic. This visit will include:

- Return medicine. The study team will collect any study medication that you have left over.
- Answer questions. We will ask you to answer some questions about how you are feeling.
- Physical exam. The study doctor will do another exam just like the one at Visit 1.
- Blood draw. We will again ask for 2 tablespoons of blood to check your kidney and liver function. We will also check to see how much of the medication is in your blood.

This visit will last 1 hour. At the end of this visit, we will give you \$200 (gift card) to thank you for your time and effort. Your participation in the study will be over at the end of this visit.

Tools to measure Readability

in your documents

- Flesch Kincaid Scale
 (on Microsoft Word)
- Grammarly
- Hemingway App

Readability Statistic	
Counts	
Words	444
Characters	2,186
Paragraphs	24
Santancas	20

Hemingway App makes your writing bold and clear.

The app highlights lengthy, complex sentences and common errors; if you see a yellow sentence, shorten or split it. If you see a red highlight, your sentence is so dense and complicated that your readers will get lost trying to follow its meandering, splitting logic — try editing this sentence to remove the red.

You can utilize a shorter word in place of a purple one. Mouse over them for hints.

Adverbs and weakening phrases are helpfully shown in blue. Get rid of them and pick words with force, perhaps.

Phrases in green have been marked to show passive voice.

You can **format** your *text* with the toolbar.

Paste in something you're working on and edit away. Or, click the Write button and compose something new.

Hemingway

Readability Grade 6

Good

Letters: 610 Characters: 757 Words: 133 Sentences: 11 Paragraphs: 7

Show Less ▲

Reading time: 00:00:31

2 adverbs, meeting the goal of 2 or fewer.

1 use of passive voice, meeting the goal of 2 or fewer.

1 phrase has a simpler alternative.

1 of 11 sentences is hard to read.

1 of 11 sentences is very hard to read.

Note that readability tools are only one lens to review your materials.



LENS #2: PLAIN LANGUAGE CONTENT

Content:

- Anticipate the reader's questions, and answer them preemptively.
- Write so your readers know what is required of them.

Paragraph Structure:

- Get to the point first.
- Use active voice and a conversational tone.
- Second person point-of-view.

Words:

- Skip the jargon and extraneous words.
- 6th-8th grade reading level; "living room language"
- Avoid abbreviations and acronyms w/o explanations







Researchers at the National Institutes of Health (NIH) seek healthy volunteers to participate in a research study. The purpose of this study is to better understand how pain and emotions are processed in the human brain and influenced by psychological factors. This is an outpatient study that may involve moderate but tolerable pain. Researchers are studying how thoughts, feelings, and learning influence pain and perception. All tests will be conducted at the NIH in Bethesda, Maryland. Compensation is provided.

Participation involves:

- ▶ one screening and one study session each lasting one to three hours
- psychological questionnaires
- physiological recordings (e.g., heart rate, breathing)

You may qualify if you are:

- 18-50 years old
- in good health
- fluent in English
- available to come to NIH during daytime hours

You may not qualify if you:

- · have, or have had a medical or psychiatric condition
- suffer from a chronic pain condition
- use recreational drugs
- · are pregnant

Location: The NIH Clinical Center, America's research hospital, in Bethesda, Maryland, is conveniently located on the Metro red line (Medical Center stop). Parking is provided at no cost.

For more information call: 1-800-411-1222

TTY- 1-866-411-1010 online, www.clinicaltrials.gov Refer to study 15-AT-0132 (NO-MRI) NIH...Turning Discovery Into Health®



Influenced

Psychological

Factors

Outpatient

Moderate

Tolerable

Conducted

Screening

Physiological

Chronic

Recreational

Diagnostic Cognitive Assessments Compensation

*Consider that this audience is likely
much better versed in standard
medical terminology

AUTISM RESEARCH











Do You Love a Child with Autism?

The Rebecca Center for Music Therapy is looking for children with autism spectrum disorder (ASD) to participate in a research study to learn if music therapy could be an helpful early treatment for children with ASD.

Each child in this study will receive 10 no-cost music therapy sessions, complete diagnostic and cognitive assessments, and a musical instrument to keep. Compensation is provided for family effort.

Who is Eligible?

- Children ages 4-7
- Diagnosed with ASD
- Limited or no prior music therapy

New; Untested; not yet FDA approved How effective, how well it works

Usual doctor, family doctor

Look at, ask questions, survey, activity

Sample, the X we collected

Begin to show signs of, begin to feel X

To see if you are a good fit

Able to join; sign up

Amount, level

Payment to thank you for your time and effort

Now, right now, at this time

Belly pain, stomach cramps

Chemo

Water(s)

Stiff joints

Period; Time of the month

1 in 5 people who got tested, had disease.

Dizziness, the spins, wobbly

Blue, sad, down, feeling "off"

Feel sick, sour stomach

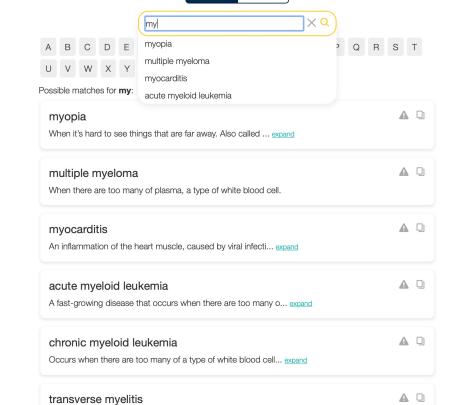
Leaking, dribble

Sugar(s)

PLAIN LANGUAGE TOOLS

for your documents review

- ☐ CDC's <u>Clear Communication</u> Index.
- □ Real Life Research ICF Edited- <u>Sample Paragraphs</u>.
- UM's <u>Plain Language Medical</u> <u>Dictionary</u>.
 - Thesaurus style live search on ways to explain big medical words.



Plain Language Medical Dictionary

Application by the University of Michigan Library



Personal Favorite!

POLL: TRUE OR FALSE?

THE IRB CONSENT TEMPLATE LANGUAGE CANNOT BE CHANGED.





POLL: FALSE!

THE IRB CONSENT TEMPLATE LANGUAGE CANNOT BE CHANGED.

UNC IRB SOP 1101, section 2.2:

"The informed consent information must be presented in language that is understandable to the subject (or legally authorized representative). To the extent possible, the language should be understandable by a person who is educated to 8th grade level and layman's terms shall be used in the description of the research"





LENS #3: HEALTH LITERACY



Definition

- Personal health literacy is the degree to which individuals have the ability to find, understand, and use information and services to inform healthrelated decisions and actions for themselves and others.
- Organizational health literacy is the degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.
- Sit back and consider the health literacy for your population. How is it different for...
 - MDs
 - Adult Participants
 - Pediatric Participants



LET'S TAKE A LOOK!

This double-blind randomized clinical trial is designed to determine the safety and efficacy of an investigational topical agent called FASTER in individuals who have developed post-surgical abdominal abscesses. (grade 23)

The purpose of this randomized clinical trial is to investigate a new topical drug, called FASTER. It is not yet approved by the FDA, which is why we are conducting this study. We want to find out if it is safe and if it is more effective at healing post-surgical abdominal abscesses than current standard medication. You will get either the investigational drug or the current standard medication; neither you nor the study team will know which one you are using. (grade 11)



LET'S TAKE A LOOK!

This is a research study to learn more about a new topical drug, called FASTER. It is not yet approved by the BA, which is which is why wong this study. We want to ind worth it is a field not if it can be always to independ on the study of the standard medication. The study is the study to the study to

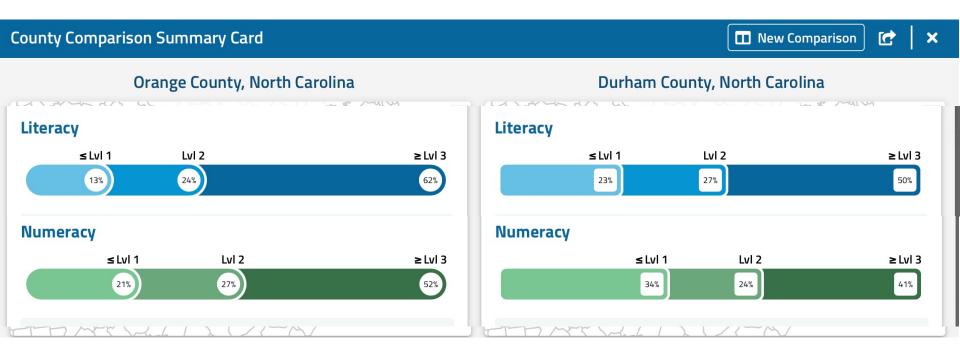
We want to learn more about a new drug, called FASTER. It is not FDA approved yet. We want to know more about how it works and if it is safe compared to usual medicine. It is for people with infected cuts from surgery on their stomachs. You will get either the new drug or the usual medicine. You will not know which one you get. (grade 4)



Tools for Health Literacy

in your documents

- ☐ CDC's <u>Health Literacy Comprehensive</u> Guide
- Boston University's Database of Validated <u>Literacy Tests by</u> <u>Disease Type</u>.
- National Center for Education Statistic's Interactive <u>Literacy</u> <u>Maps</u>, the key for <u>literacy</u> and <u>numeracy</u>.



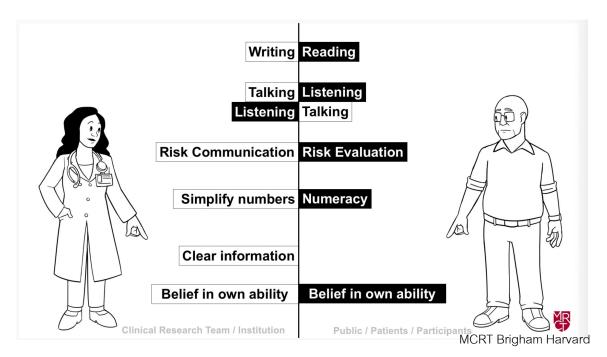
POLL: TRUE OR FALSE?

EDUCATION IS THE ONLY THING THAT DETERMINES A PERSON'S HEALTH LITERACY.



Poll: False!

EDUCATION IS THE ONLY THING THAT DETERMINES A PERSON'S HEALTH LITERACY.







LENS #4: RELATABILITY & INCLUSIVITY

"Sometimes when I tell them I'm deaf, they give me a piece of braille paper." --Journal Community Health 2017

Think about your people

- Consider larger font in consent forms.
- Create materials in various languages for participants.

Use terms that are relatable.

 No one says "I'm going to the pharmacy to pick up my contraception."

Identify language that may be offensive.

- Women who are advanced maternal age → 'If you're over 35...'
- Failure to thrive →
 'Requiring attention to growth, protein-intake...'

Evaluate demographics routinely

Learn your IRB Short Form



Tools for Relatability & Inclusivity

- ☐ Use <u>LanguageLine</u> for interpreter or translation services.
- **EthnoMed**-Integrating Culture into Clinical Practice.
- Request a <u>consultation</u> with TraCS community engagement or inclusive sciences group.
- □ Do the work!

WHAT THE DANGIN' HECK? I'M ONLY 36!



From Communicate Health



LENS #5:

COMMUNICATION

Communication

Review your documents and practice, practice, practice!

Start with questions.

• Script: How are you? I'm calling from Dr. Smith's office about a research project we're doing. Have you done one before?

Allow for a conversation.

- Active listening.
 - Mirror back words that the participant uses to describe things
 - Anticipate their questions!
 - Speak slowly and simply, pause between "chunks" of information. Use analogies.

Allow for questions

- "Do you have any questions" is not good enough.
- TeachBack Method

"I gave you a lot of information, and want to make sure I didn't miss anything. Can you tell me what I explained so far? What questions do you have?"



TIPS FOR COMMUNICATIONS

- ☐ Ascertain their mindset.
 - Ask them, their care team.
- Watch for behaviors.
 - Illiteracy or lack of understanding.
- ☐ Schedule a consult to practice!

TABLE 1

Behaviors Suggestive of Inadequate Health Literacy Skills

Asking staff for help

Bringing along someone who can read

Inability to keep appointments

Making excuses ("I forgot my glasses.")

Noncompliance with medication

Poor adherence to recommended

interventions (e.g., changes to decrease acid reflux, such as elevating the head of the bed)

Postponing decision making ("May I take the instructions home?" or "I'll read through this when I get home.")

Watching others (mimicking behavior)

Safeer & Keenan, 2005

Shame & Guilt in Medicine

People may be ashamed to speak up when they don't understand research. 50% could remember a time when a doctor's visit made them feel ashamed. May feel guilt to decline research as well. –adapted from Darby & Harris (2009)



POLL: TRUE OR FALSE?

YOU ONLY NEED TO REVIEW CONTENT FOR LAY LANGUAGE IN YOUR RECRUITMENT MATERIALS AT THE BEGINNING OF YOUR STUDY.





Poll: False!

YOU ONLY NEED TO REVIEW CONTENT FOR LAY LANGUAGE IN YOUR RECRUITMENT MATERIALS AT THE BEGINNING OF YOUR STUDY.

Lay Language practices can be used for retention and study fidelity.



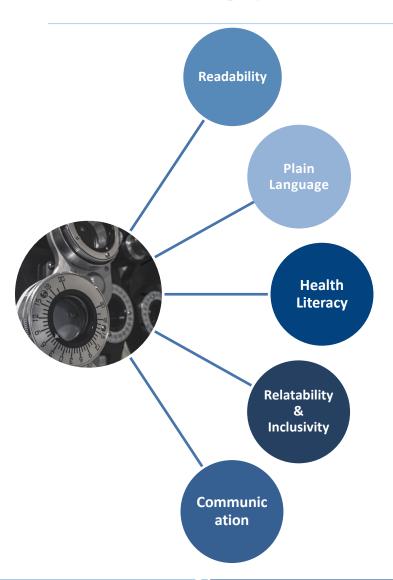


FINAL THOUGHTS

- A lot of you got into research to help people and make a difference.
- It takes a special level of skill to be able to speak about research in jargon and in lay language!
- Everyone wants recruitment success and understanding.
- Combat mistrust and pre-conceptions, improves transparency.
 Think about the domino effect of successful engagement.
- Continue checking in with your audience and learning cultural contexts.
- This was a lot of information. Give yourself grace!



SUMMARY: MAKE IT CLEAR



1. Readability

 Review recruitment materials for visual appeal (white space, bullets, tables) and use words with fewer syllables. Use readability programs.

2. Plain Language

 Review content, paragraph structure and word choice for simple, upfront language. Ensure content is at 6th-8th grade reading level.

3. Health Literacy

 Recognize your audience's understanding of medical jargon and adapt materials accordingly. Use words and examples that are familiar in everyday life.

4. Relatability & Inclusivity

 Use terms that are relatable and identify language that may potentially be offensive.

5. Communication

 Ascertain the mindset and behaviors of your audience. Speak slowly, pause for questions and practice, practice, practice!



5 WAYS TO CELEBRATE HEALTH LITERACY MONTH

October 1st-31st, 2021

- 1. Watch this 7-min video by Harvard Brigham on Health Literacy in Clinical Research while waiting in line for your coffee.
- 2. You've heard of Henrietta Lack's and maybe have read Rebecca Skloot's book but what's happening now? Watch the 8-min <u>Ted Talk by Lack's family</u>.
- 3. Need a gut check? Stuck on a 11th grade reading level? Have someone look over your documents for lay language? Request a free review and 30 min meeting here.
- 4. Utilize your free UNC LinkedIn Learning subscription and <u>take this course on Plain Language</u> (42 min) instead of that extra episode on your Netflix binge!
- 5. Register for Research For Me and consider signing up for a research study yourself! See what it is like to be on the other side!

RECRUITMENT SERIES

Important dates and notes.

Today's Lecture:

- How did you like this talk? Consider completing our survey.
 - https://reports.tracs.unc.edu/surveys/?s=3RPC3DNKPMTK9JYC
- Slides will be sent out later this week.
- Recording of this talk will linked to our site.

Upcoming weeks:

- October 6th: Designing Effective Recruitment Materials (12-1PM, <u>link</u>)
- October 13th: Material Design Workshop (12-1PM, <u>link</u>)
- October 20th: Recruitment Office Hours (12-2PM, via zoom)





RESOURCES & FURTHER READINGS

for your continued education (1/2)

Reada	bility
	Grammarly or Hemingway, an app for readability and grammar.
	The territory more than the territory of
	Readable's What is Flesh Kincaid Readability?
Plain L	anguage
	History of Plain Language in the US Government (Plain Language Act of 2010)
	CDC's Clear Communication Index.
	Plain Language Medical Dictionary. UM's thesaurus style live search on ways to
	explain big medical words.
	Real Life Research ICF Edited- <u>Sample Paragraphs.</u>
Relata	bility & Inclusivity
	Article on Content being <u>Inclusive, Accessible, Fun.</u>
	Quick Read on <u>Hard to Reach Populations.</u>
	Quick Read on <u>Cultural Competence</u>
	Quick Read on <u>Speaking to your Elders.</u>
	Quick Read on <u>'Target Audience'</u>
	Perspective piece on Shame in Physician-Patient interaction by Harris & Darby (2009).



RESOURCES & FURTHER READINGS

for your continued education (2/2)

Health Literacy

- ☐ Publication on Health Literacy for <u>Healthy People 2030</u> (Nov 2021)
- ☐ Publication on Health Literacy gaps between Physicians and Patients.
- ☐ UNC's <u>Health Literacy Library</u> Guide
- ☐ CDC's <u>Health Literacy Comprehensive</u> Guide
- ☐ Journal of Public Health Management & Practice's <u>Podcast on Health Literacy</u> (Apr 2021)
- ☐ Boston University's Database of Validated <u>Literacy Tests by Disease Type</u>.
- □ National Center for Education Statistic's Interactive <u>Literacy Maps</u>, the key for <u>literacy</u> and <u>numeracy</u>.



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Research Recruitment and Retention

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Register with NC TraCS for newsletters, educational series and funding opportunities: tracs.unc.edu or request a consultation for any of our programs at tracs.unc.edu/consultation



