



# MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of  
BRIGHAM AND WOMEN'S HOSPITAL  
and HARVARD

A horizontal row of colorful silhouettes representing a diverse group of people. The silhouettes are in various colors including purple, red, orange, yellow, green, and blue. Above each silhouette is a speech bubble of the same color, suggesting communication or dialogue.

## Integrating Health Literacy into the Informed Consent Process: Tips for Developing Understandable Consent Materials

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# Disclaimer

- The opinions expressed are those of the author(s) and/or presenter(s) and are not intended to represent the position of Brigham and Women's Hospital, Harvard University, or University of Arkansas Little Rock, Bowen School of Law.
- We have no personal conflicts of interest relevant to this presentation.

# Objectives

- By the end of the session, attendees should be able to:
  - Describe what health literacy is and its relevance to clinical research.
  - Explain how health literacy best practices can be integrated into different phases of the clinical research life cycle.
  - Identify strategies for creating clear, understandable informed consent forms that comply with the Revised Common Rule.



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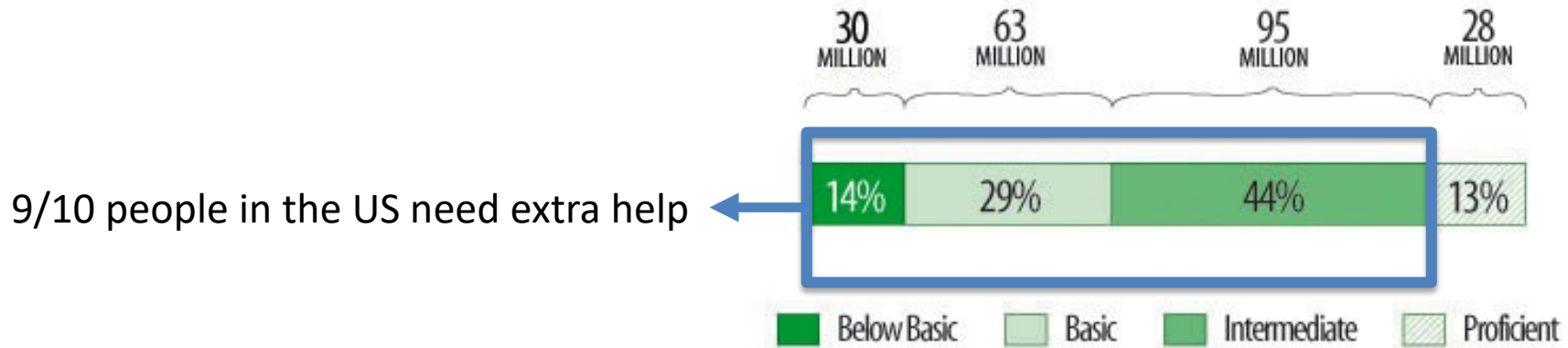
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A horizontal band across the middle of the slide features a row of colorful silhouettes of people's heads and shoulders. Above each silhouette is a speech bubble of a matching color. The colors transition from purple on the left, through red, orange, yellow, green, and finally blue on the right. A white rectangular box with a red border is superimposed over the center of this graphic.

Background

# The Health Literacy Opportunity

- Literacy levels are concerning around the world.



- A person's health literacy affects their ability to:
  - Access services and information
  - Understand and follow health-related instructions
  - Make appropriate health-related decisions

From: [https://nces.ed.gov/naal/kf\\_demographics.asp](https://nces.ed.gov/naal/kf_demographics.asp)

# The Evolving Health Literacy Definition

## Individual Skills

“Health literacy is the degree to which **individuals** have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions.”

Nielsen-Bohman L, Panzer AM, Kindig DA, Editors, Committee on Health Literacy. Health Literacy: A Prescription to End Confusion. Washington, DC: Institute of Medicine. The National Academies Press; 2004.



## Societal Responsibility

“Health literacy occurs when a **society provides** accurate health information and services that people can easily find, understand, and use to inform their decisions and actions.”

Department of Health and Human Services. Solicitation for Written Comments on an Updated Health Literacy Definition for Healthy People 2030. <https://www.federalregister.gov/documents/2019/06/04/2019-11571/solicitation-for-written-comments-on-an-updated-health-literacy-definition-for-healthy-people-2030>, 9/17/19.

# A Broad View of Health Literacy

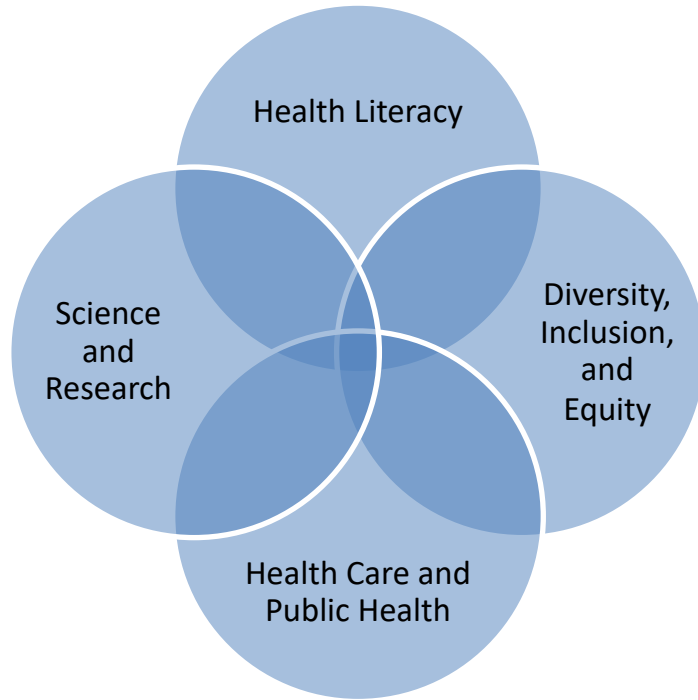




# The Potential of Applying Health Literacy Best Practices



# The Bigger Picture of Health Literacy



## Health literacy fulfills key ethical research principles

- Respect for Persons
  - A right to understand
- Beneficence
  - An effort to reduce harm
- Justice
  - Equitable access to research



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A horizontal illustration at the bottom of the slide depicts a diverse group of people. The silhouettes of the individuals are in various colors (purple, red, orange, yellow, green, blue) and are arranged in a line. Above each silhouette is a speech bubble of a corresponding color, creating a visual representation of communication and diversity.

## The Clinical Research Life Cycle

# The Clinical Trial Life Cycle

Clear communication is essential throughout the participant's clinical research journey.



DISCOVERY



RECRUITMENT



CONSENT



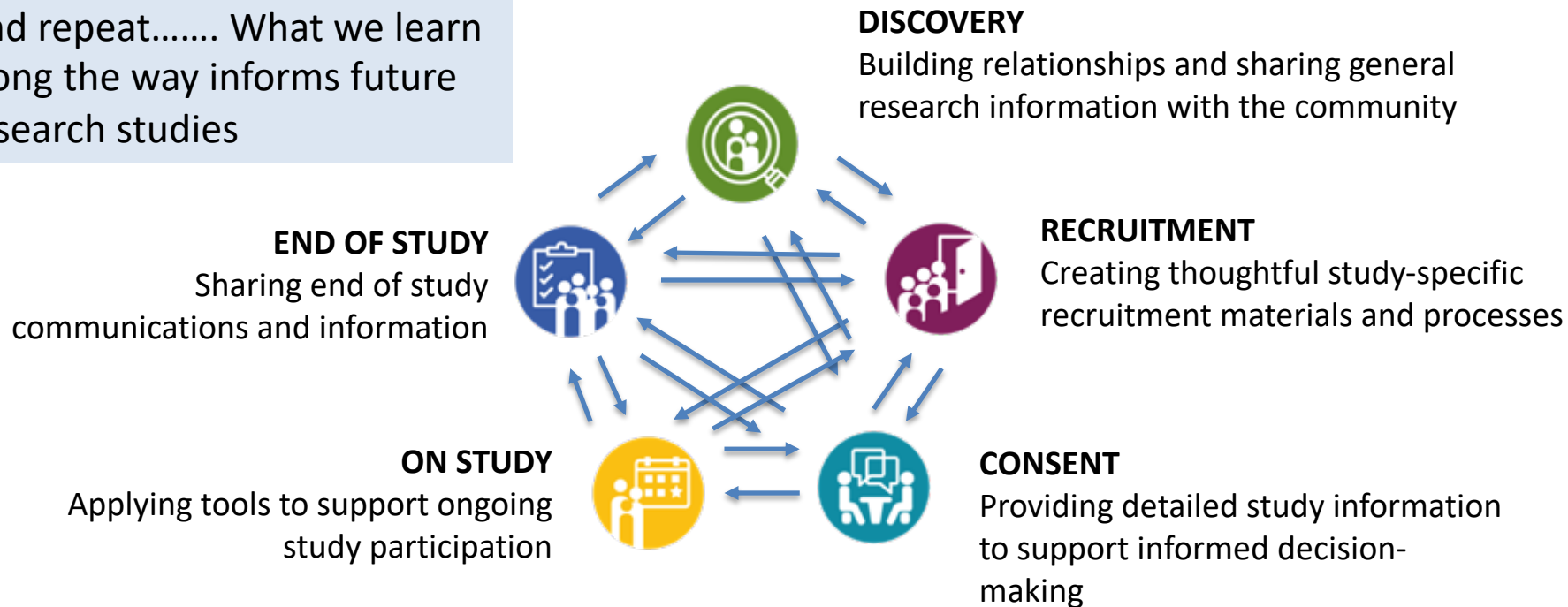
ON STUDY








END OF STUDY

# Integrating Health Literacy Principles

And repeat..... What we learn along the way informs future research studies



Stage of Journey through the Life Cycle	Examples of Clear Communication Opportunities
 <b>Discovery</b>	<ul style="list-style-type: none"> <li>- Research awareness campaigns</li> <li>- Outreach and engagement efforts to solicit patient input into study design and development</li> </ul>
 <b>Recruitment</b>	<ul style="list-style-type: none"> <li>- Advertisements</li> <li>- Recruitment scripts</li> </ul>
 <b>Consent</b>	<ul style="list-style-type: none"> <li>- Consent scripts</li> <li>- Consent forms</li> <li>- Study schedules/calendars</li> </ul>
 <b>On Study</b>	<ul style="list-style-type: none"> <li>- Study medication/intervention instructions</li> <li>- Study commitment contract</li> <li>- Adverse event reporting information</li> <li>- Participant satisfaction survey</li> </ul>
 <b>End of Study</b>	<ul style="list-style-type: none"> <li>- Instructions for coming off trial</li> <li>- Information on maintaining access to treatment options</li> <li>- Study results/summaries</li> </ul>



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## Applying Health Literacy to the Informed Consent Process



# HEALTH LITERACY IN CLINICAL RESEARCH

[START HERE](#) | [TRIAL LIFE CYCLE](#) | [BEST PRACTICES](#) | [RESOURCES BY ROLE](#)

## Consent Guide

[Home](#) > [Best Practices](#) > [Overview](#) > [Consent Guide](#)

### Applying Health Literacy to Informed Consents for Research:

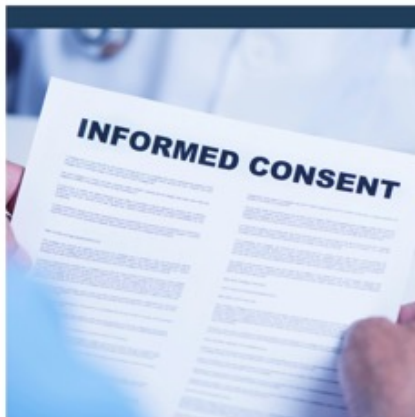
Quick Tips for Clearly Explaining the Requirements

**Adapted from original material created by:** Christopher R. Trudeau, JD

Creating consent materials that people can understand involves not only thinking about the content needed, but also how that content will be worded, ordered, and presented. Consent form content is always important, yet due to recent regulatory changes that emphasize clarity, consent forms will be reviewed more closely by Institutional Review Boards/Ethics Committees (IRB/ECs), government regulators, and, sometimes, even in courts.

Using health literacy best practices, we can do more with consent forms than simply ensuring regulatory compliance.

Find out how to:



**Find it here:**

<https://mrctcenter.org/health-literacy/tools/overview/consent-guide/>





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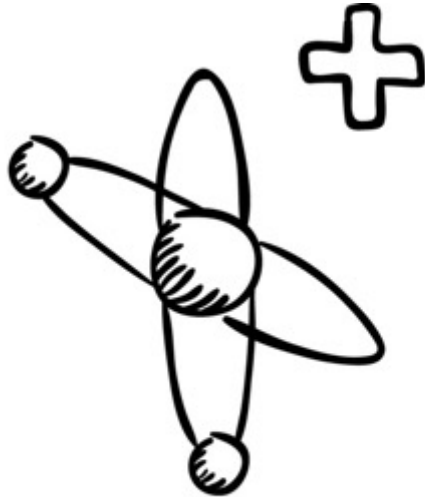
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Consent is a Process – Not Just a Form



- ✓ It is a **conversation** about whether to participate in the trial after learning the risks, benefits, alternatives, etc.
- ✓ The “informed” portion of the consent does not come from the signature indicating “consent.”

# The three ions of consent processes



POSITIVE IONS

☒ Conversation

☒ Education

☒ Documentation

## Think about the audience



What do we know about this specific study population?

Can we involve a subset of them in the creation process on the front end? User test with them after creation?

# What are the barriers to understanding?



## People in clinical trials may:

- ✓ Be worried, stressed, concerned
- ✓ Have trouble reading and processing
- ✓ Have little to no experience with clinical trials



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## Navigating the Requirements in the Revised Common Rule

Covered? Location?	Basic Requirements	Covered? Location?	If-Applicable Requirements
	1. Purpose and explanation of the research		10. That there are unknown or unforeseeable risks
	2. Risks & foreseeable discomforts		11. If and when involuntary removal from study is possible
	3. Benefits (to person & others)		12. Additional costs that may be expected by participating
	4. Alternatives that might also help the participant.		13. Consequences of early withdrawal from study
	5. Extent confidentiality will be maintained		14. If significant findings will be provided
	6. Compensation & treatment available if complications		15. Approx. number of people in the study.
	7. Contact info for questions about research		16. [new] whether clinically relevant research results will be disclosed and under what conditions.
	8. Participation is voluntary and there will be no loss of benefits if decline		17. [new] whether biospecimens might be used for commercial profits – even if identifiers are removed.
	9. [new] One of these: (a) The subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed. OR  (a) That identifiers might be removed and the de-identified information or biospecimens will be used for future research without additional informed consent.		18. [new] If biospecimens research, whether research will or might include whole genome sequencing.

People can't figure me out, they can't process me. I don't expect them to. You can't process me with the normal brain.

Charlie Sheen

 quotebay



# How do you know if something is understandable?

## ✓ Clarity matters not length.

82 Fed Reg 12 at p. 7265 & SACHRP Commentary

<https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-november-13-2018/index.html>

## ✓ Information should be understandable to a “reasonable person”

- ✓ “The prospective subject or the legally authorized representative must be provided with the information that **a reasonable person would want to have in order to make an informed decision** about whether to participate, and an opportunity to discuss that information.” (emphasis added)

82 Fed Reg 12 at p. 7265

# Who is the reasonable person?



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- A very common standard in the law – been part of clinical consent for 100+ years.
- **SACHRP:** “The reasonable person concept recognizes that it is impossible for researchers to determine what information every individual participant would consider helpful in deciding whether or not to participate.”
- “Instead, it asks researchers to include what reasonable people in the same or similar circumstances would want to or need to know.”

# How does health literacy fit in?



- ✓ Health literacy helps determine what a reasonable person would understand.
- ✓ Learn from health literacy research & practice – we know a lot more now about what people do and do not understand because of it.
- ✓ User testing should become a standard practice to determine where your study population may struggle. (Involve study pop from the beginning.)

# Consent must BEGIN with “key information”



Image: Pixabay

“Informed consent must begin with a **concise and focused presentation** of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons **why one might or might not** want to participate in the research.

This part of the informed consent must be organized and presented in a way that facilitates comprehension.”

# What must be in the beginning?



Image: Pixabay

The preamble to the new Common Rule lists the following elements to begin with:

- Consent is for research and participation is voluntary.
- Purpose, duration, and procedures to be followed.
- Reasonably foreseeable risks or discomforts.
- Alternatives to the research that might be advantageous to the subject.
- Benefits to subject or others.

# Flexibility & creativity are encouraged

Because there is great variability across clinical trials, there may be great variability in the choice and presentation of key information. Concern about variability should be balanced with recognition of the importance of flexibility. The existing system of drafting consent forms and obtaining consent has become stagnant, and it needs to improve.

Because the key information requirement will apply to a broad range of research studies being conducted with many diverse populations of research subjects, SACHRP does not believe that there are any elements of consent that would never be appropriate as an item of key information.

# Don't ignore how being in this study will impact participants' daily lives

SACHRP further notes that existing elements of consent, and traditional approaches to consent, have emphasized benefit and risk, **but have not given similar attention to burdens or to the impact of participation in research on an individual's normal life activities....** In many cases, impact is certain, but benefits and harms are not.

**In many studies discomforts and inconveniences, rather than risks, might be key information.** Examples include, “you will have to avoid exposure to sunlight for four months,” “all of your hair will fall out,” “you will not be able to drink alcohol for six months,” “you should avoid sexual contact” or “you will have 20 study visits.”

# How do you determine this for your study?



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- 1. What are your study population's needs?**
  - ✓ Think of health literacy needs, life & health circumstances, etc.
  - ✓ Don't think about what you think is important or where you are concerned about liability – be participant-centered.
- 2. How can you involve your study population in the creation or vetting process?**



## Most Important Information Influencing Decision to Participate

	Percent Rate "Very Important"
Potential risks and benefits	83%
Purpose of the clinical research study	75%
Types of medical procedures required	73%
If my confidentiality would be protected	63%
Physical location of the research study center	60%
Potential costs and reimbursements	57%
Length of participation	56%
If I would receive a summary of the study results after my participation ended	56%
Being provided with supporting information on managing my health condition in general	53%
Being provided with supporting information on the clinical research study	54%
Duration of each study visit	50%
Number of study visits	48%
If I would have access to the study drug after my participation ended	47%

Source, CISCRP, All Respondents, Study N=12,427, 2017

# Most and Least Liked Clinical Trial Elements

<b>MOST LIKED</b>	<b>Percent of Total</b>		<b>LEAST LIKED</b>	<b>Percent of Total</b>
Helping advance science and the treatment of my disease/condition	<b>36%</b>		There was nothing I didn't like about my clinical study experience	<b>39%</b>
Helping others who may have my disease/condition	<b>27%</b>		The possibility of getting a placebo	<b>24%</b>
The compensation (money) I received	<b>26%</b>		The location of the study center was too far or not convenient	<b>23%</b>
The amount of care and attention that I received from the study doctors and staff	<b>20%</b>		The study visits were too time-consuming	<b>11%</b>
My relationship with the study staff	<b>14%</b>		The side effects of the study drug	<b>11%</b>
Access to new, cutting-edge treatment:	<b>14%</b>		The compensation (money) I received was not enough	<b>9%</b>

Source: CISC RP, Those Participated in Clinical Research Study, N=2,194, 2017

# The MRCT Center's Commitment to Health Literacy

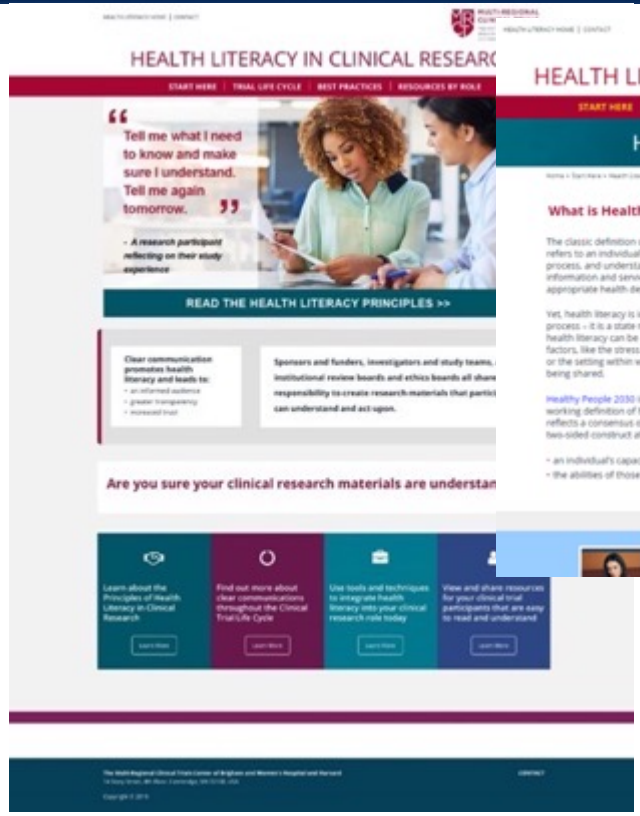
In 2019 the MRCT Center launched a publicly available website on Health Literacy in Clinical Research.

Developed by a multi-stakeholder workgroup

Designed for research professionals

Provides ways to take action in your own clinical research role

[www.mrctcenter.org/health-literacy](http://www.mrctcenter.org/health-literacy)



## Health Literacy in Clinical Research Principles

Clear communication with potential, enrolled, and past research participants supports understanding and decision-making that aligns with their values. Health literacy focuses on a person's ability to access, process, and understand health information to make informed health decisions. Clear communication, however, requires the communicator to share information in ways that the participant and their family, friends, and/or caregivers can understand and act upon. As such, clear communication is both respectful and ethically responsible, and important throughout the clinical research study life cycle - from access, recruitment, and informed consent to the end of a trial and the sharing of results. The MRCT Center Health Literacy in Clinical Research workgroup has developed foundational principles to help guide the adoption and integration of health literacy practices into clinical research. These are intended to support sponsors and funders, investigators and study teams, and institutional review boards and ethics committees in their communications with potential, enrolled, and past participants.

1. All clinical research communications should be clear and easy to understand.
2. Clear communication is necessary throughout the clinical research life cycle.
3. All clinical research stakeholders share an ongoing responsibility for ensuring research communication is clear and easy to understand.
4. Clinical research communications should be developed by partnering with the intended audience(s).
5. Cultural respect is an integral part of communicating appropriately about clinical research.
6. Clinical research materials for participants should integrate health literacy practices, including plain language, numeracy, clear design techniques, and cultural considerations.
7. Clinical research materials for participants should be evaluated to ensure the intended audience(s) can understand the information.
8. In-person communication with the intended audience(s) should encourage dialogue and confirm understanding.
9. All clinical research stakeholders should support the development and implementation of organizational policies that integrate health literacy into clinical research.
10. Integration of health literacy into clinical research requires proactive planning to develop, test, modify, and confirm understanding of clinical research communications.



## Clinical Trial Life Cycle Overview

Home > Trial Life Cycle > Overview

**Health literacy can support the participant throughout the clinical trial journey.**



### 1. DISCOVERY

Public awareness of, education about, and access to clinical research



### 2. RECRUITMENT

Targeted, relevant, written and verbal invitations to join research



### 3. CONSENT

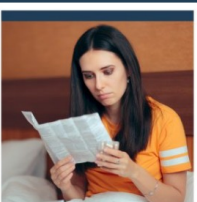
Clear written and verbal conversations about informed consent to research participation



### 4. ON STUDY

Clear information about ongoing research procedures, data collection and reporting

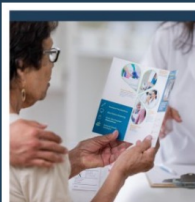
[www.mrctcenter.org/health-literacy](http://www.mrctcenter.org/health-literacy)



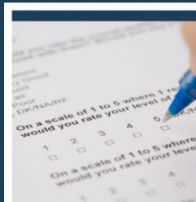
**PLAIN  
LANGUAGE  
Resources**



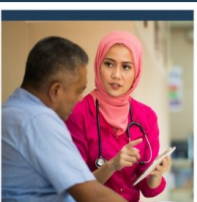
**NUMERACY  
Resources**



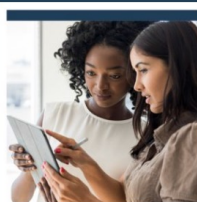
**CLEAR DESIGN  
Resources**



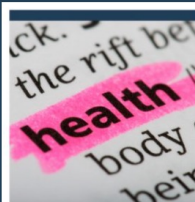
**USABILITY  
TESTING  
Resources**



**CULTURAL  
CONSIDERATIONS  
Resources**



**INTERACTIVE  
TECHNIQUES  
Resources**



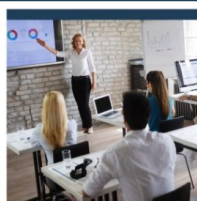
**GLOSSARY  
Resources**



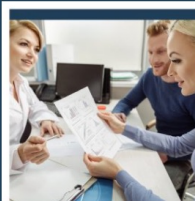
**CONSENT GUIDE  
Resources**



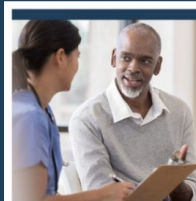
**CASE STUDY  
LIBRARY  
Resources**



**EDUCATION &  
TRAINING  
Resources**



**RETURN OF  
RESULTS  
Resources**



**RESEARCH  
PARTICIPANTS'  
Resources**

[HOME](#)[ABOUT](#)[GLOSSARY WORDS](#)[CONTACT US](#)

## Clinical Research GLOSSARY

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## Helping you understand clinical research

Welcome to the Clinical Research Glossary. This glossary is a list of research words and their meanings. Use this glossary to learn more about words that are used in research studies.

[VIEW ALL WORDS](#)

Use the "search" menu to find a word's meaning and other information.

[HOME](#)[ABOUT](#)[GLOSSARY WORDS](#)[CONTACT US](#)

## Informed consent

The process of learning and discussing the details of a research study before deciding whether to take part.

How to say: ⓘ Informed consent

Click image to enlarge



### USE IN A SENTENCE

**Informed consent** helps people understand what will happen if they become a **participant** and what their rights are.

### MORE INFO

**Informed consent** is an ongoing conversation before someone can participate in a study and information about the study changes.

**Informed consent** is a process to make sure that all information from a potential study participant have been reviewed.

A **consent form** is used as part of the **informed consent** process.

#### WORDS RELATED TO INFORMED CONSENT

consent

consent form

#### WORDS OPPOSITE TO INFORMED CONSENT



#### OTHER RESOURCES

- FDA Resource for Patients: "Informed Consent for Clinical Trials"

If you know of another resource that could help explain this term, please contact us!

## Randomization

A way to use chance to place study participants into different study treatment groups.

How to say: ⓘ Randomization

Click image to enlarge



### USE IN A SENTENCE

Researchers use **randomization** to make sure that study groups are chosen fairly and similar.

### MORE INFO

Every **participant** has a chance to be put into one of the study groups. No one can choose which group a participant is placed in, because it is done by a computer program.

**Randomization** helps make sure the study groups can be compared against each other at the end of the study. This is a way to avoid bias.

#### WORDS RELATED TO RANDOMIZATION

bias

blinded

random assignment

randomize

randomly assigned

study arm

#### WORDS OPPOSITE TO RANDOMIZATION



#### OTHER RESOURCES

- Explaining Randomization in Clinical Trials
- Randomization and Bias in Cancer Clinical Trials

If you know of another resource that could help explain this term, please contact us!

# HEALTH LITERACY IN CLINICAL RESEARCH

START HERE | TRIAL LIFE CYCLE | BEST PRACTICES | RESOURCES BY ROLE

## IRB

Home > Resources by Role > Overview > IRB

### Are you sure that the participant-facing materials you review and approve are clear to participants?

The MRCT Center has developed two health literacy resources specifically for Human Research Protection Programs (HRPPs) and Institutional Review Boards (IRBs).

- Health Literacy **Training** for IRBs
- Health Literacy **Checklist** for IRBs

IRBs can play an important role in supporting research study participants by applying health literacy best practices to their reviews of participant-facing materials.

**NOTE: These materials are currently being piloted. If you have feedback please email [mrct@bwh.harvard.edu](mailto:mrct@bwh.harvard.edu), and check back soon for updated versions!**



## Health Literacy in Clinical Research: IRB Training Facilitator's Guide



INTRODUCTORY HEALTH LITERACY TRAINING  
FOR HRPP AND IRB MEMBERS AND STAFF



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## Health Literacy in Clinical Research: IRB Checklist



A HEALTH LITERACY CHECKLIST FOR THE REVIEW OF  
PARTICIPANT-FACING CLINICAL RESEARCH MATERIALS



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Consent Example

# An example of making something more understandable

## Before:

We are conducting a research study in order to determine the current status of the psychosocial and health problems due to SARS-CoV-2 (COVID-19) faced within our patient community and to implement a brief online intervention based on Cognitive Behavior Therapy techniques and measure its effect. Study subjects will be assessed by completing a battery of psychological tests at various timepoints throughout the study.

## After:

In this research study we want to learn more about what kinds of health and wellness problems people are having due to COVID-19.

We also want to know whether a few short mental health lessons offered on the internet could help with any of these problems.

We will use some surveys during the study to find out if people in the study start to feel better after viewing the lessons.



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## Key Takeaways

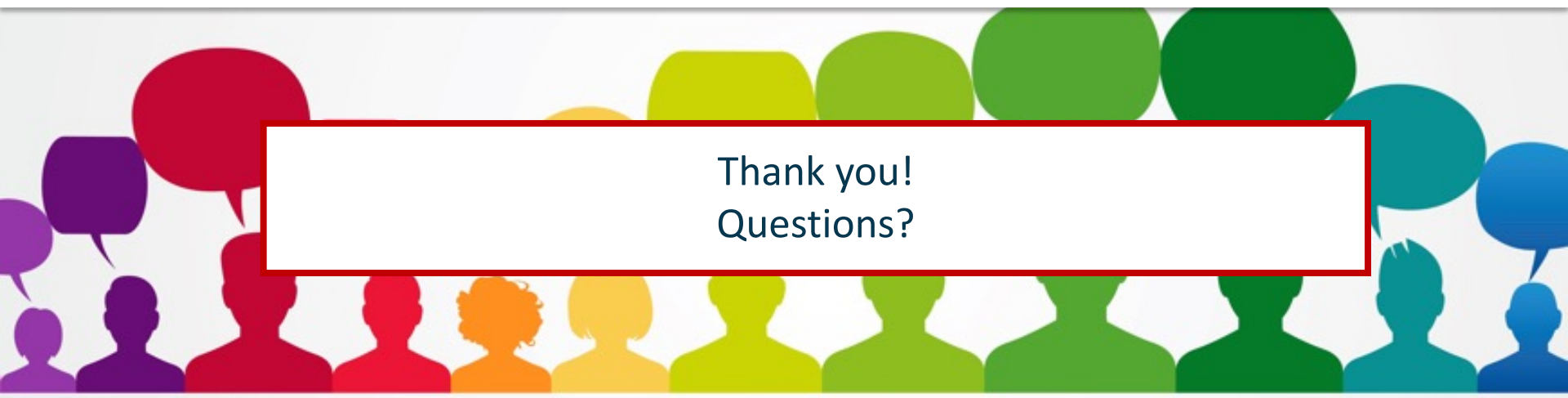
# Key Takeaways

- ✓ **Each of us plays a role in creating more understandable research materials**
  - Clear participant-facing communications are essential throughout the clinical research life cycle.
- ✓ **Consider health literacy best practices in your planning**
  - Preparation and planning for clear research communication starts early in the process.
- ✓ **Practice makes ~~perfect~~ better.**
  - Remember, even small improvements can help you better connect with more research participants.



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Thank you!  
Questions?