MULTI-REGIONAL CLINICAL TRIALS

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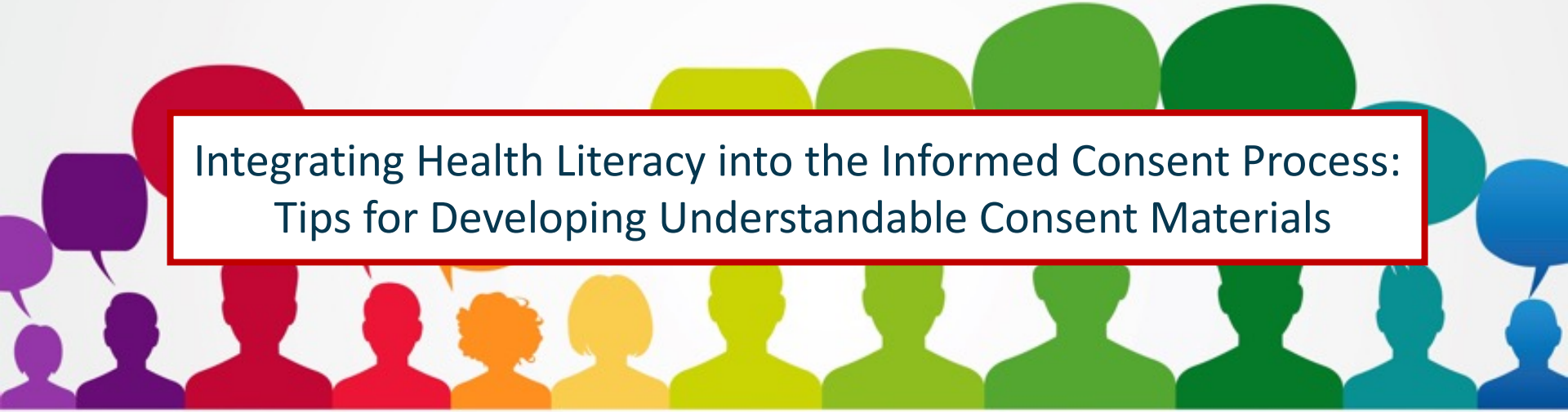

Integrating Health Literacy into the Informed Consent Process: Tips for Developing Understandable Consent Materials

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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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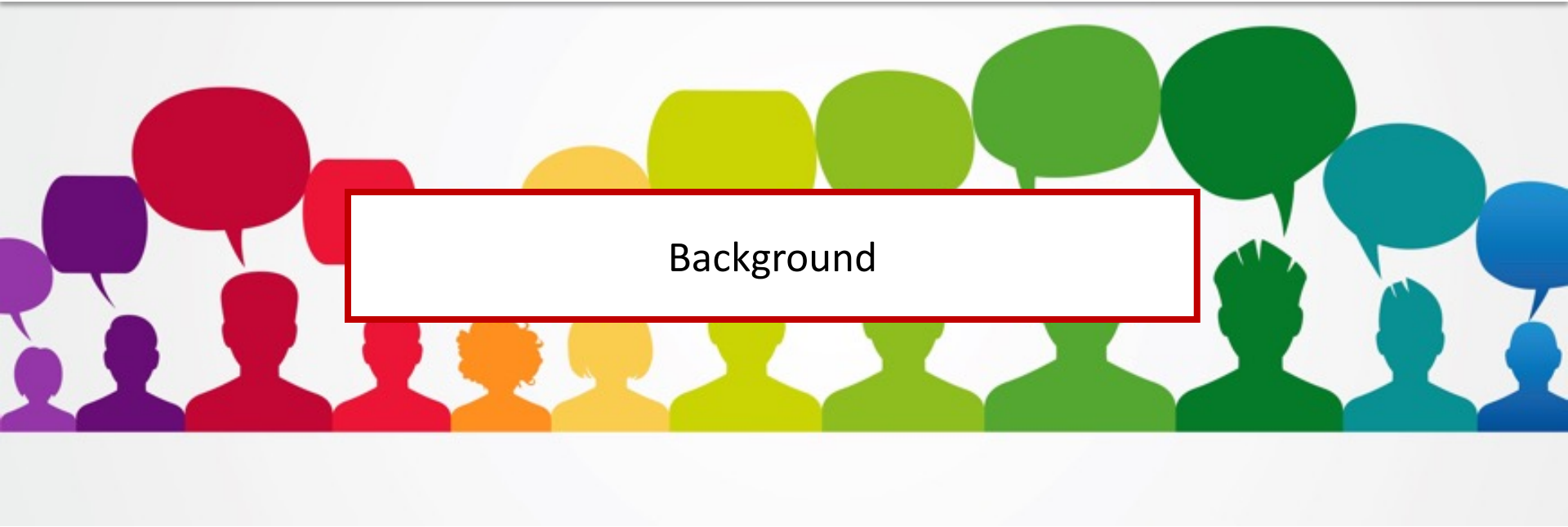
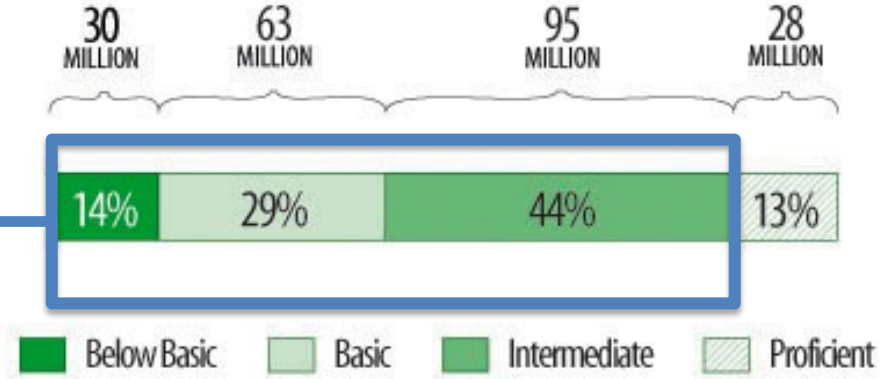


Background

The Health Literacy Opportunity

- Literacy levels are concerning around the world.

9/10 people in the US need extra help



From: https://nces.ed.gov/naal/kf_demographics.asp

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

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-Bohlman 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

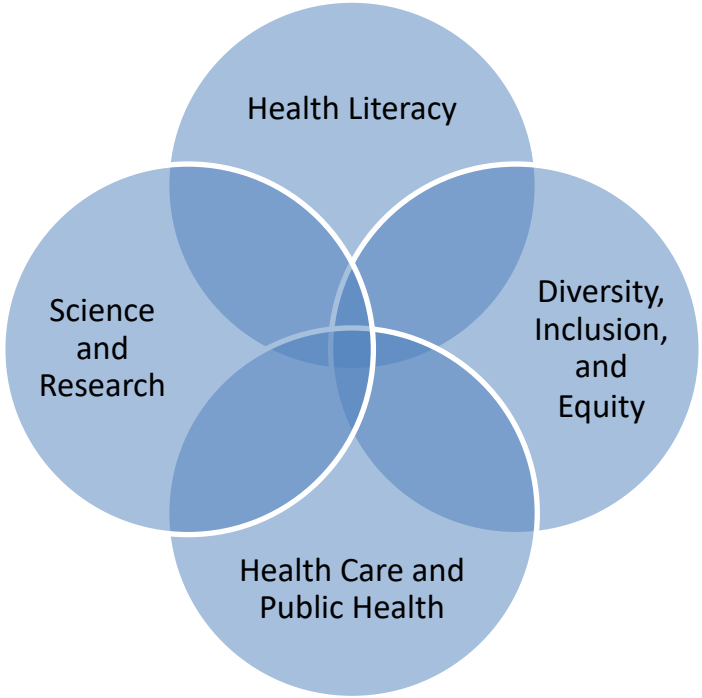
"Health literacy occurs when a society provides accurate health information and services that people can easily find, understand, and use to inform their decisions and actions."

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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The Clinical Research Life Cycle

The Clinical Trial Life Cycle

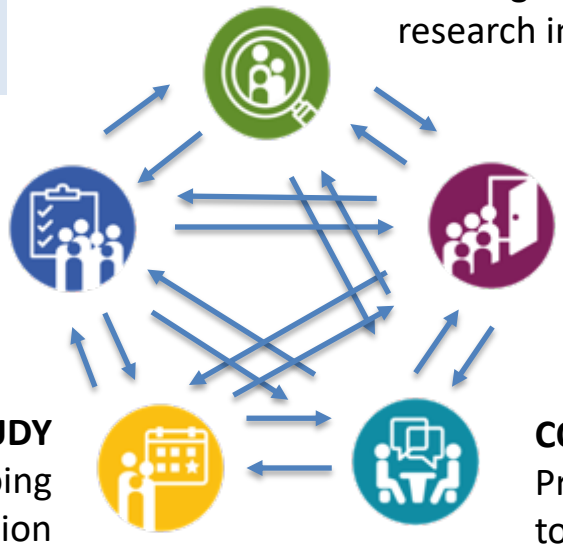
Clear communication is essential throughout the participant's clinical research journey.

DISCOVERY RECRUITMENT CONSENT ON STUDY END OF STUDY

Integrating Health Literacy Principles

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

DISCOVERY
Building relationships and sharing general research information with the community



RECRUITMENT
Creating thoughtful study-specific recruitment materials and processes

CONSENT
Providing detailed study information to support informed decision-making

ON STUDY
Applying tools to support ongoing study participation

END OF STUDY
Sharing end of study communications and information

Stage of Journey through the Life Cycle	Examples of Clear Communication Opportunities
 **Discovery**	- Research awareness campaigns - Outreach and engagement efforts to solicit patient input into study design and development
 **Recruitment**	- Advertisements - Recruitment scripts
 **Consent**	- Consent scripts - Consent forms - Study schedules/calendars
 **On Study**	- Study medication/intervention instructions - Study commitment contract - Adverse event reporting information - Participant satisfaction survey
 **End of Study**	- Instructions for coming off trial - Information on maintaining access to treatment options - Study results/summaries

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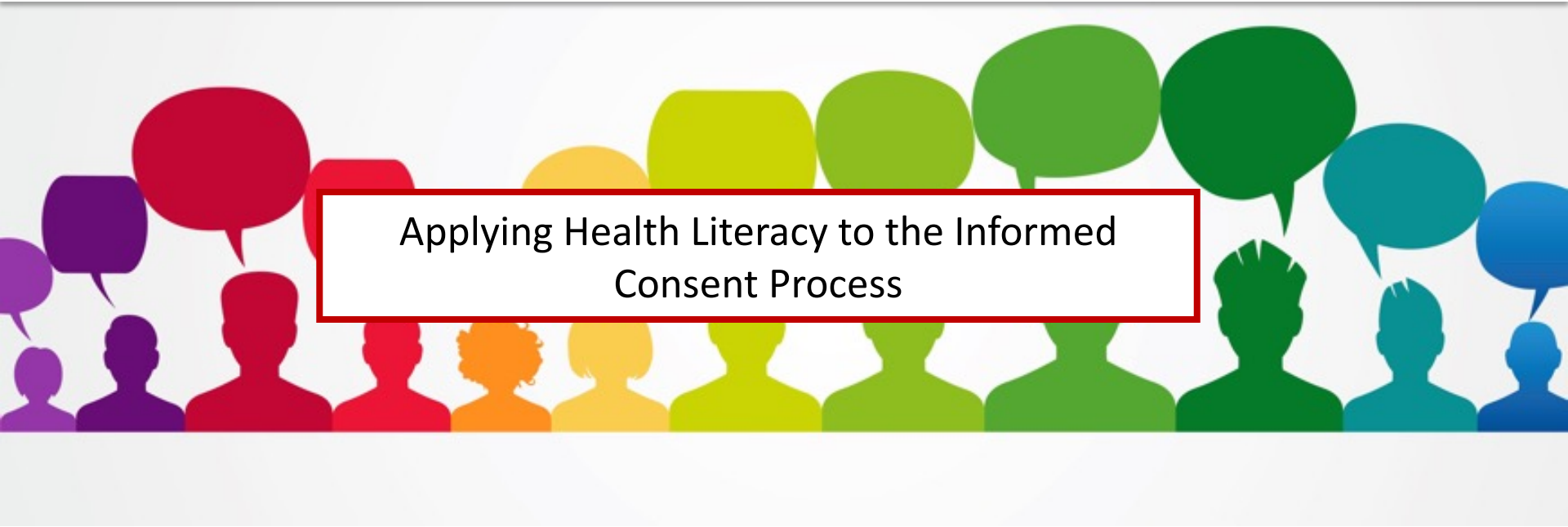

Applying Health Literacy to the Informed Consent Process

HEALTH LITERACY HOME | CONTACT

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HEALTH LITERACY IN CLINICAL RESEARCH

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

Consent Guide

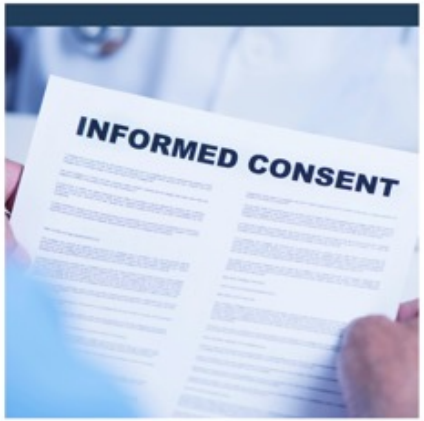
Home > Best Practices > Overview > Consent Guide

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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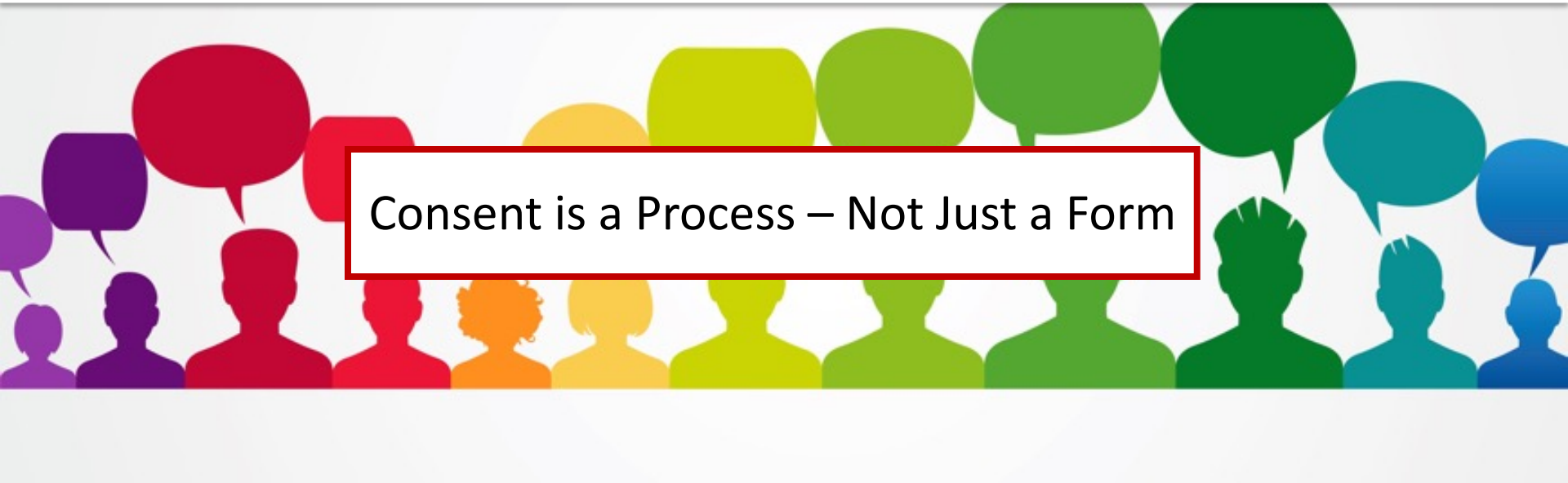
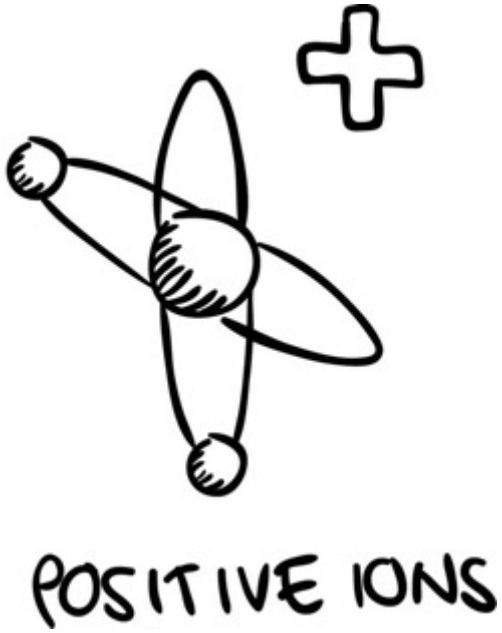


Consent is a Process – Not Just a Form

- ✓ 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



☑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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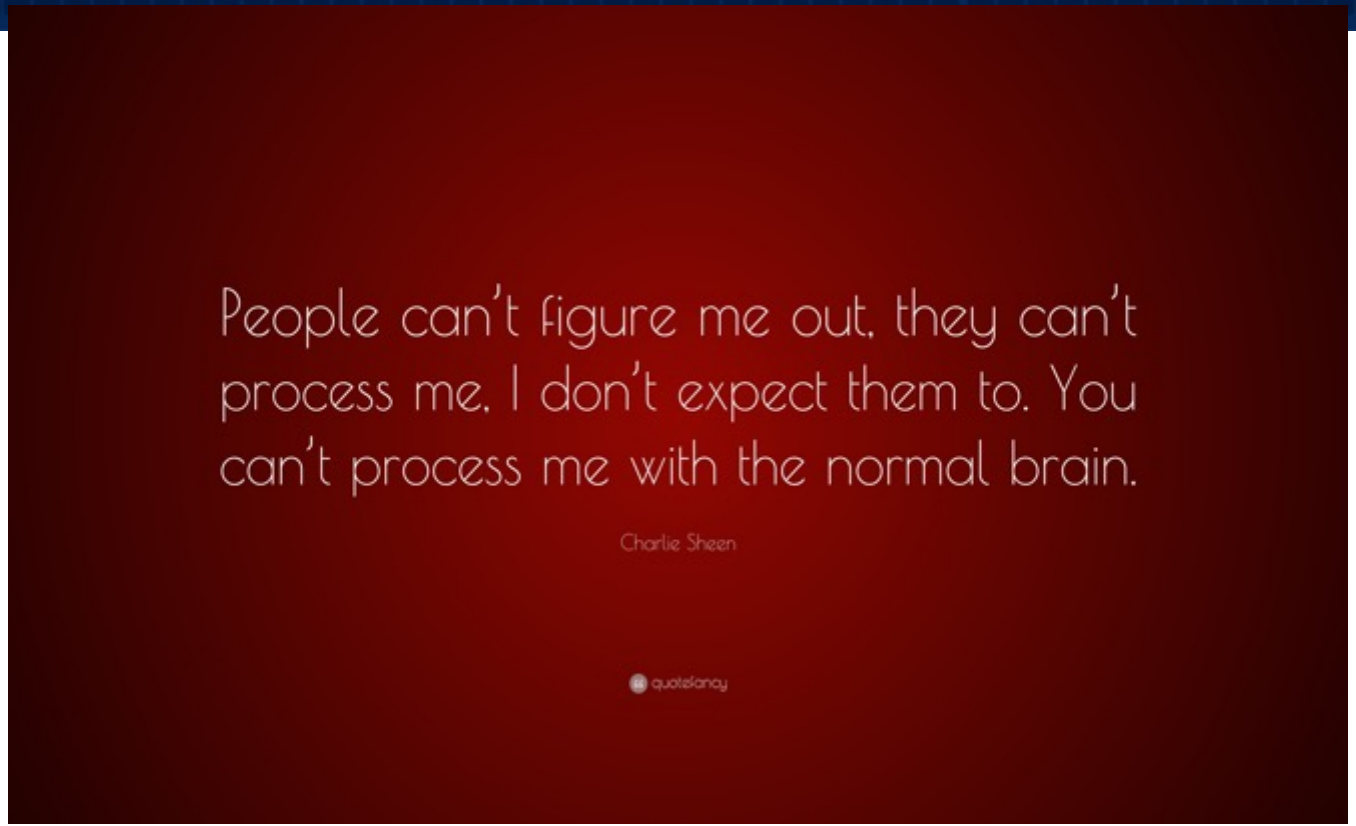
Navigating the Requirements in the Revised Common Rule

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 lost 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.



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?

- 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."

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

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.”

82 Fed Reg 12 at p. 7265

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.

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

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.”

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

How do you determine this for your study?

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

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

Source, CISCRP, 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

HEALTH LITERACY IN CLINICAL RESEARCH

START HERE | TRIAL LIFE CYCLE | BEST PRACTICES | RESOU

Clinical Trial Life Cycle Over

Home > Trial Life Cycle > Overview

Health literacy can support the participant throu clinical trial journey.

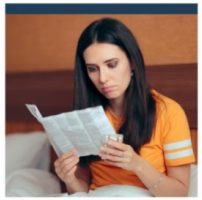
1. DISCOVERY
Public awareness of, education about, and access to clinical research

2. RECRUITMENT
Targeted, relevant, written and verbal invitations to join research

3. CONSENT
Clear written and verbal conversations about informed consent to research participation

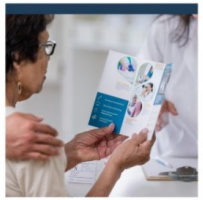
4. ON STUDY
Clear information about ongoing research procedures, data collection and reporting

www.mrctcenter.org/health-literacy

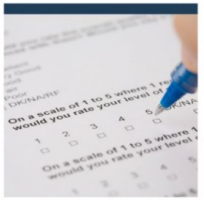


PLAIN LANGUAGE Resources

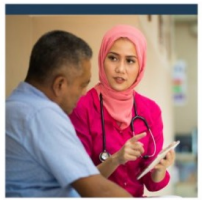
NUMERACY Resources



CLEAR DESIGN Resources

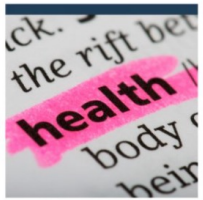


USABILITY TESTING Resources

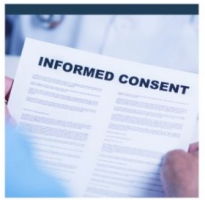


CULTURAL CONSIDERATIONS Resources

INTERACTIVE TECHNIQUES Resources



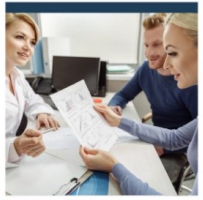
GLOSSARY Resources



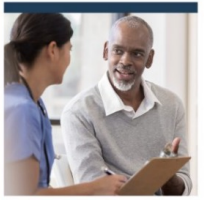
CONSENT GUIDE Resources

CASE STUDY LIBRARY Resources

EDUCATION & TRAINING Resources



RETURN OF RESULTS Resources



RESEARCH PARTICIPANTS' Resources

Search Glossary...

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Clinical Research GLOSSARY

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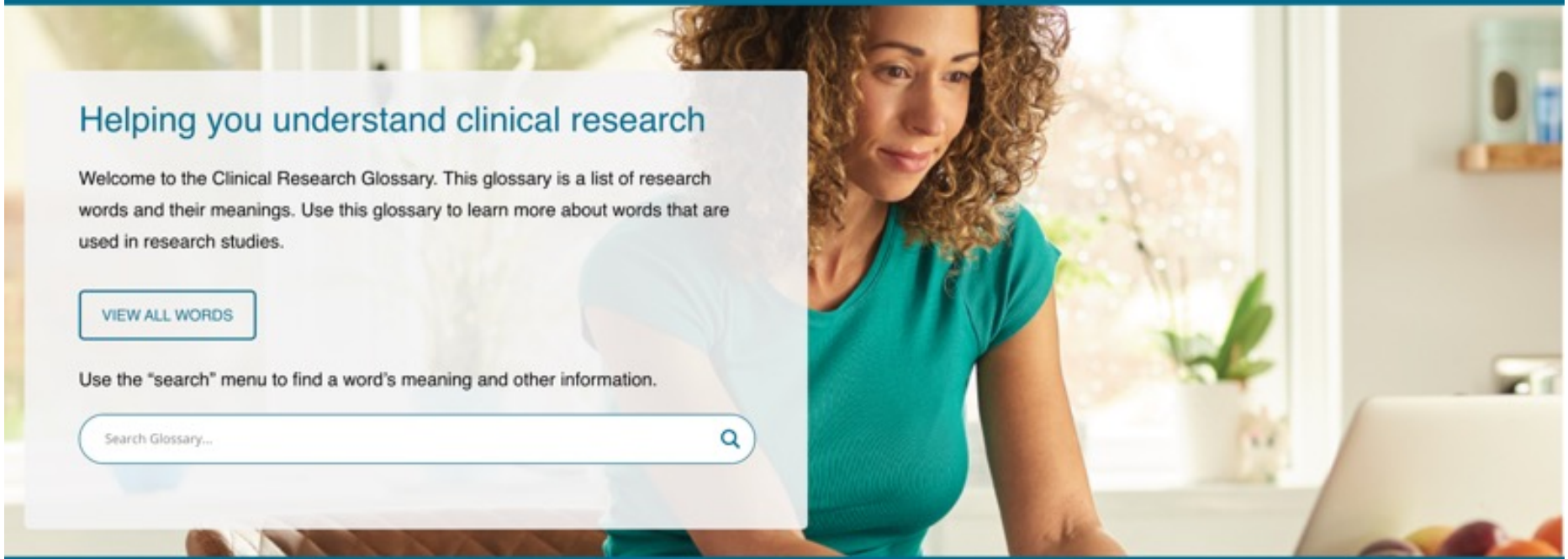


Helping you understand clinical research

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.

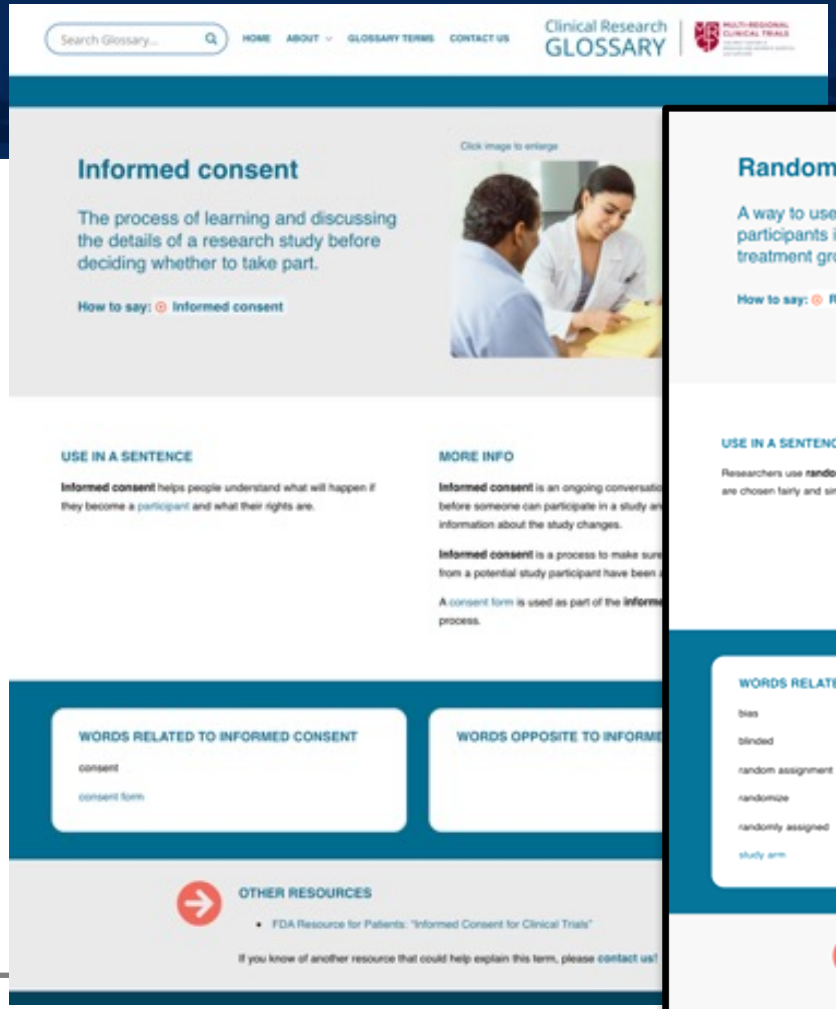
VIEW ALL WORDS

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

Search Glossary...

Search Glossary...

HOME ABOUT GLOSSARY WORDS CONTACT US



www.mrctcenter.org/glossary

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?

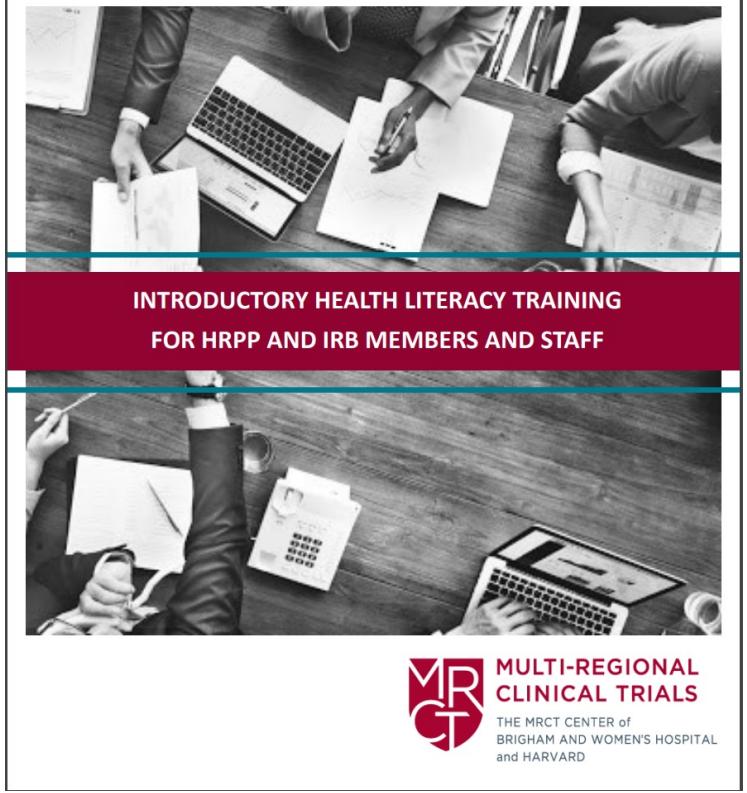
The MRCT Center has developed two health literacy resources specifically for Human Research Protection Programs (HRPPs) and Institutional Review Boards (IRBs).

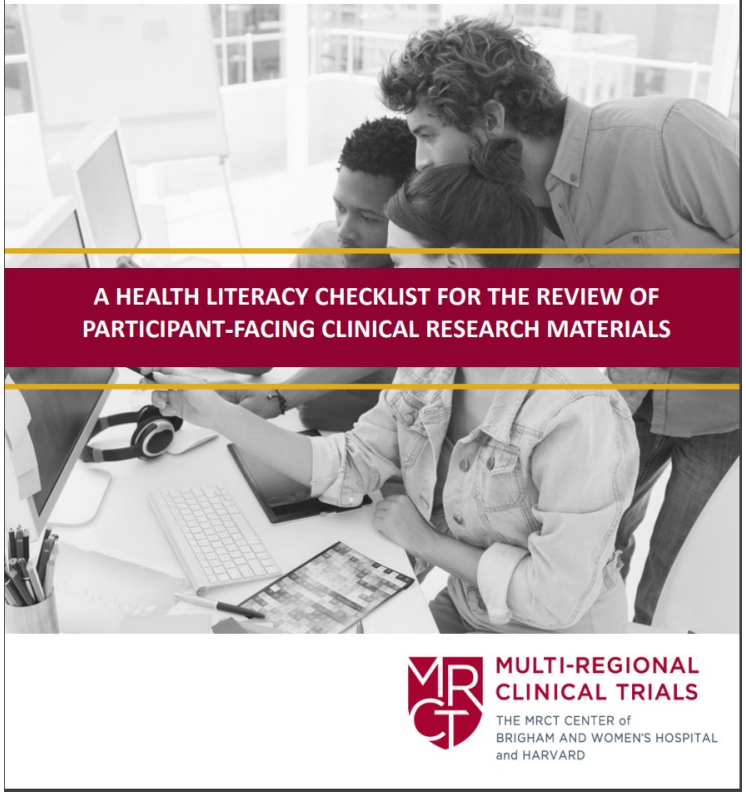
- Health Literacy **Training** for IRBs
- Health Literacy **Checklist** for IRBs

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, and check back soon for updated versions!

https://mrctcenter.org/health-literacy/instructional-resources/overview/irb/





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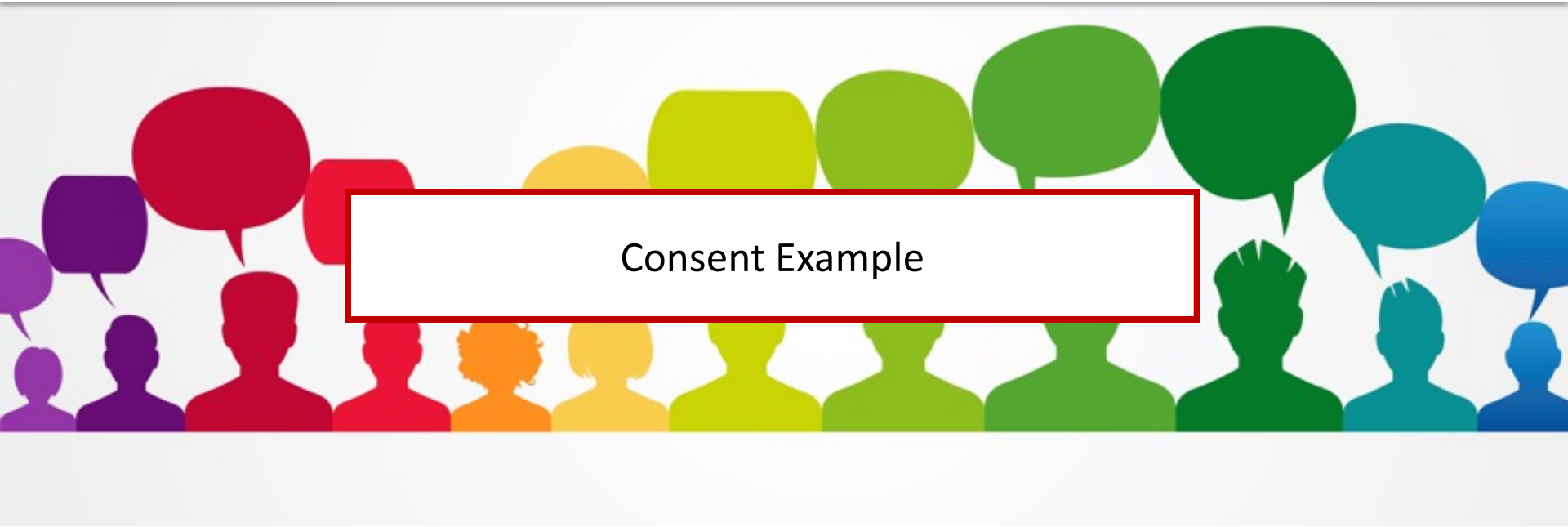

Consent Example

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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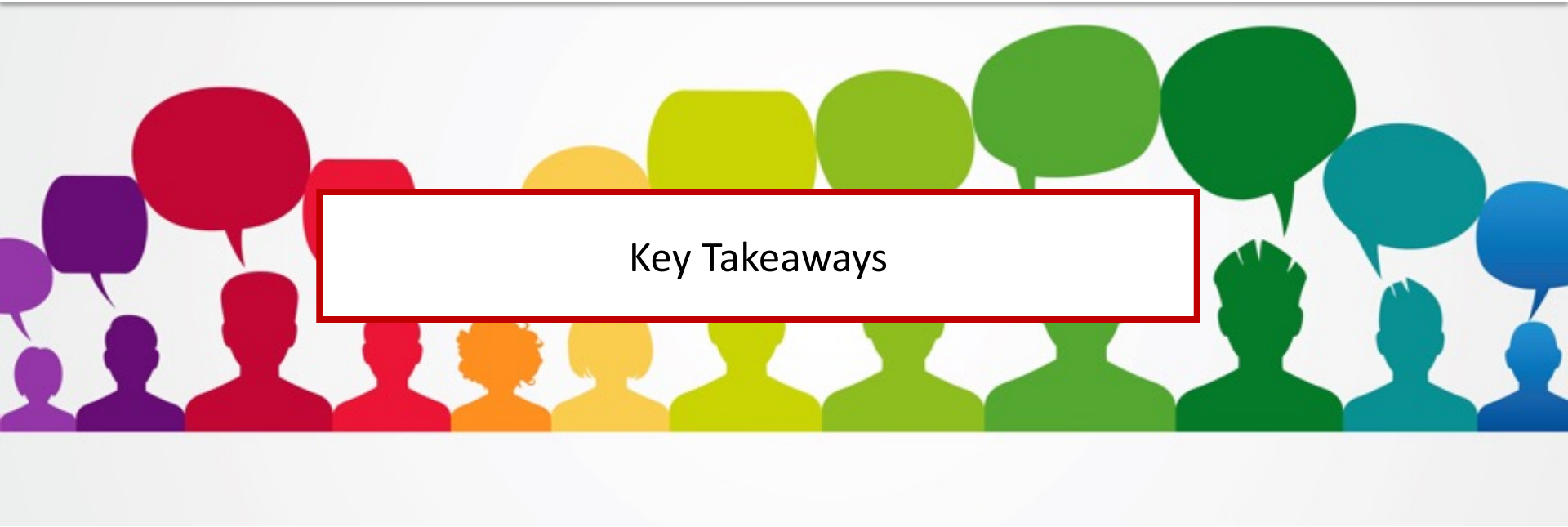

Key Takeaways

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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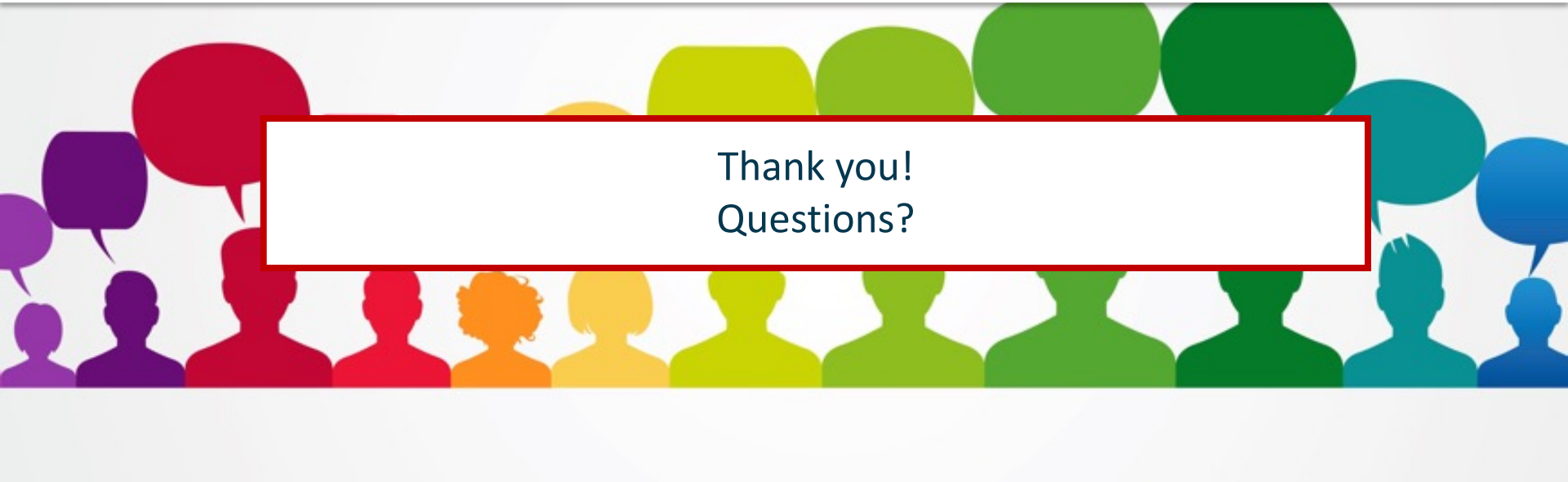

Thank you!
Questions?