AAHRPP
Association for the Accreditation of Human Research Protection Programs, Inc.®

2021 AAHRPP Educational Webinar

Welcome to AAHRPP's November 2021 Webinar:

Health Literacy Resources to Strengthen Your Human Research Protection Program

Sylvia Baedorf Kassis, MPH, Program Manager, MRCT Center
Sarah White, MPH, Executive Director, MRCT Center
Nichelle Cobb, PhD, Senior Advisor for Strategic Initiatives, AAHRPP

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Save the Date!

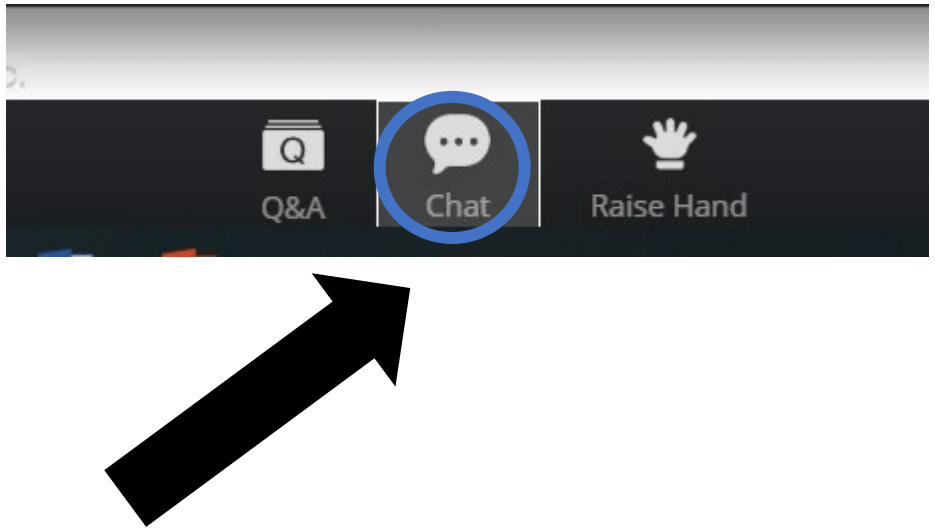
2022 AAHRPP Annual Conference

in Denver, Colorado

May 24-26, 2022

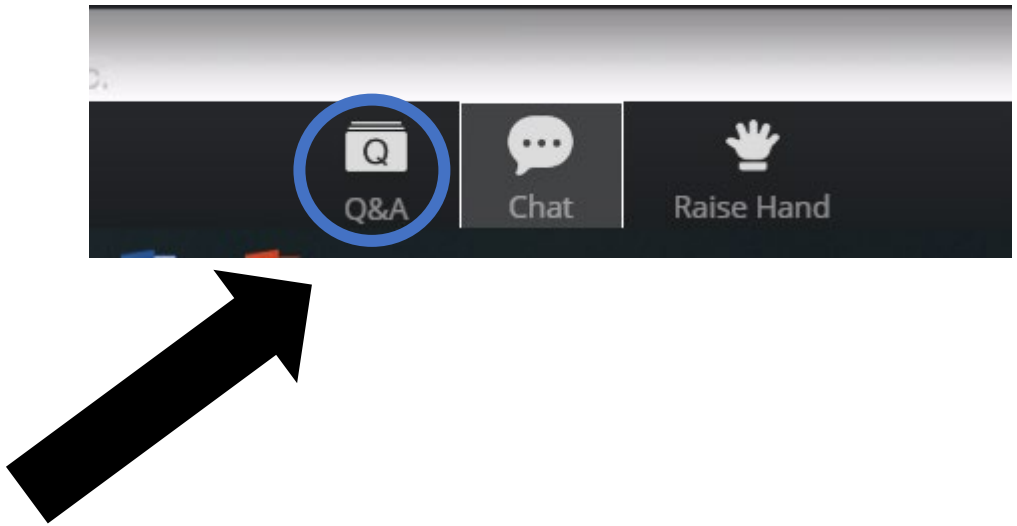
Issues During the Webinar?

To ask Zoom-related questions, use the “Chat” icon:



Questions for the Presenters?

To ask questions about the topic for the presenters, please use the “Q&A” icon:



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Presenter Introductions

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2021 AAHRPP Educational Webinar

Health Literacy Resources to Strengthen Your Human Research Protection Program

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Sylvia Baedorf Kassis, MPH, Program Manager, MRCT Center

Sarah White, MPH, Executive Director, MRCT Center

Disclosure Statement

I have no relevant personal/professional/financial relationship(s) with respect to this educational activity

Sarah White, Executive Director

MRCT Center

Objectives

- Describe why health literacy is an important concept for IRBs to consider in their human research protection activities, and how health literacy is related to AHHRPP accreditation standards.
- Consider ways that IRBs can integrate health literacy into their day to day work through the use of a self-guided health literacy training for IRBs and related IRB checklist.
- Share additional health literacy resources with their research community.

The Multi-Regional Clinical Trials Center (MRCT Center)

OUR VISION

Improve the integrity, safety, and rigor of clinical trials around the world.

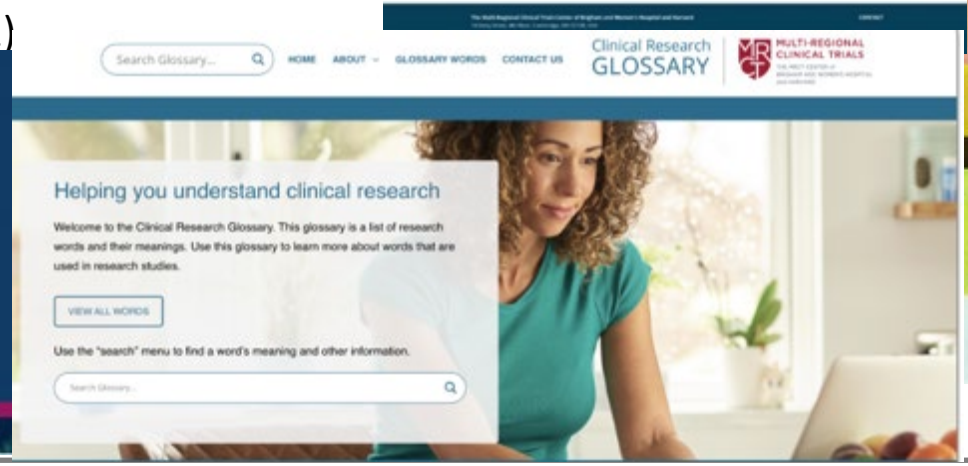
OUR COMMUNITY

We engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

MRCT Center Commitment to Transparency, the Participant, & Health Literacy

- ✓ MRCT Center Return of Results Guidance Document and Toolkit (2015)
- ✓ MRCT Center Return of Individual Results to Participants Recommendations Document and Toolkit released (2017)
- ✓ EMA incorporates of MRCT Center's Aggregate Return of Results Framework into regulation (2017)
- ✓ MRCT Center submits draft guidance on Provision of Plain Language Summary to FDA (2018)
- ✓ MRCT Center launches Health Literacy in Clinical Research website (2019)
- ✓ COVID-19 pamphlets released to support understand of clinical research (English & Spanish) (2020)
- ✓ MRCT Center launches Clinical Research Glossary (2021)



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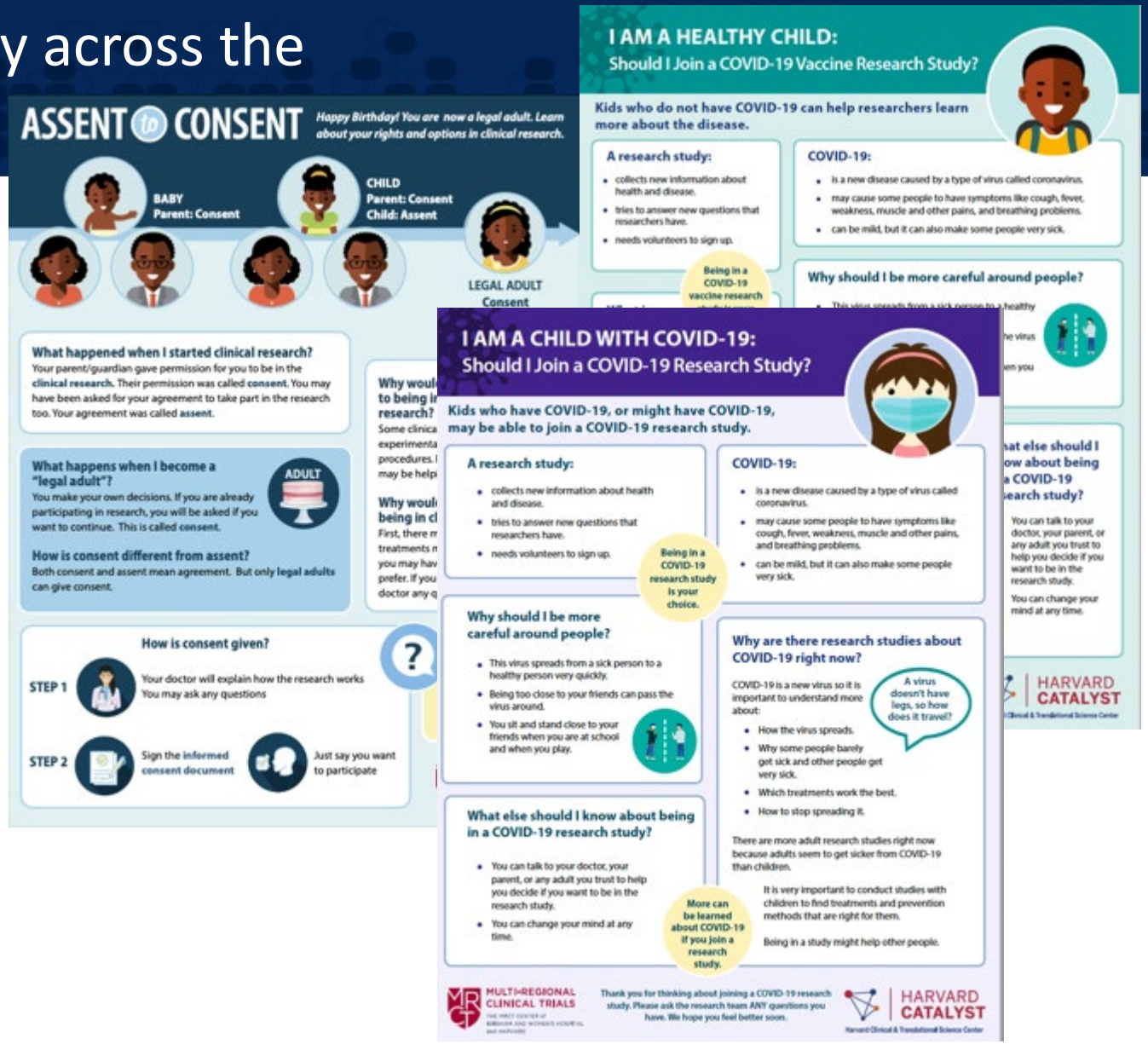
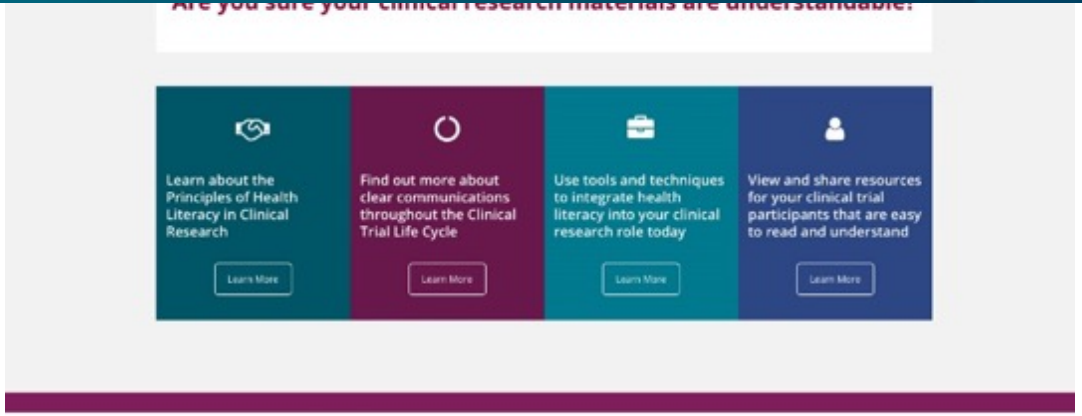
Participant-centricity & health literacy across the age spectrum

- The MRCT Center has also developed a suite of materials for adolescents and young adults
  - Related to COVID-19
  - Introduction to Clinical Research



HEALTH LITERACY IN CLINICAL RESEARCH

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



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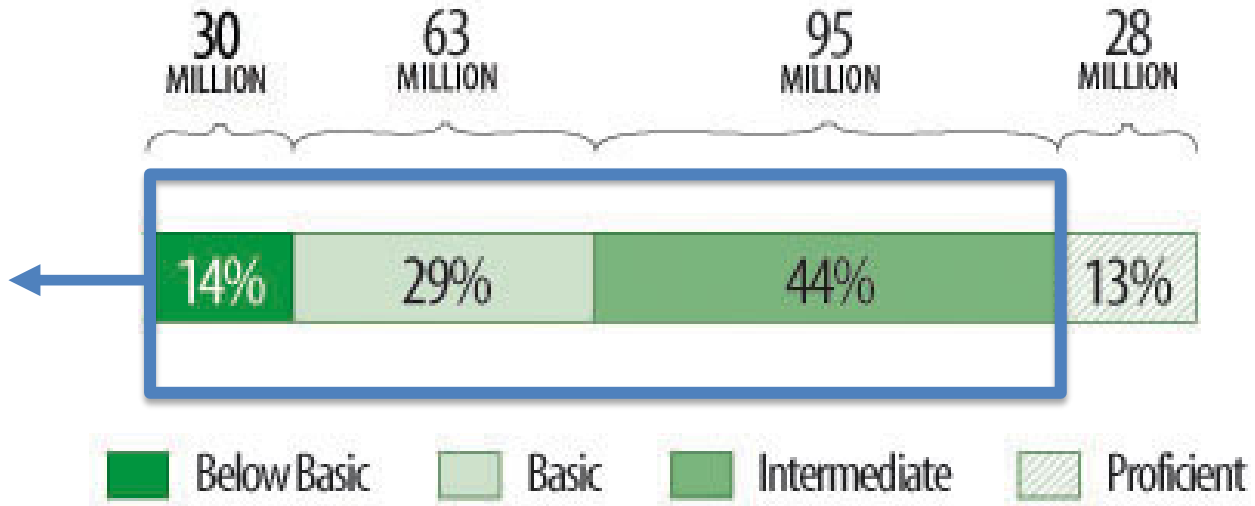
Sylvia Baedorf Kassis, Program Manager

MRCT Center

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.

Health Literacy in Clinical Research Principles

Clear communication with potential, enrolled, and past research participants supports understanding and decision-making that aligns to 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.

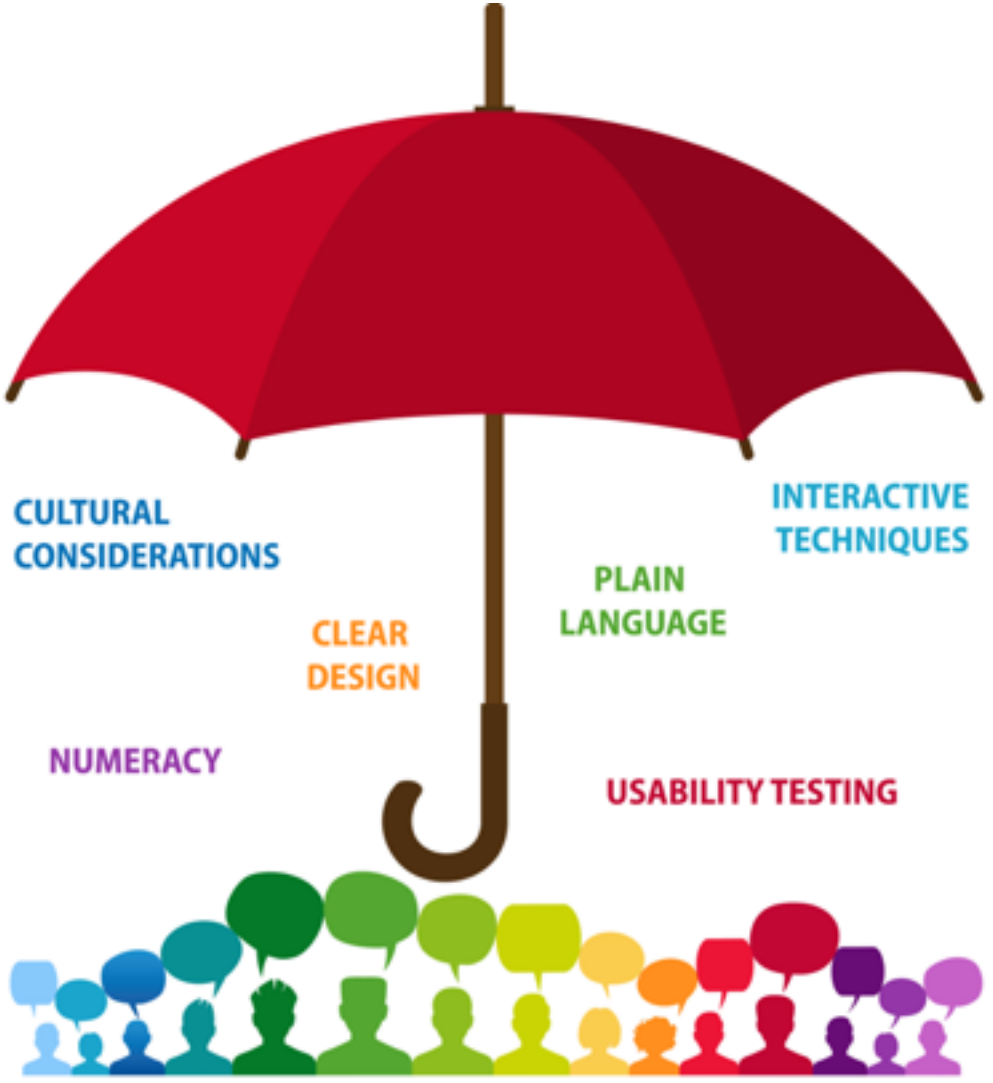
1. All clinical research communications should be clear and easy to understand.
2. Clear communication is necessary throughout the clinical research life cycle.
3. All clinical research stakeholders share an ongoing responsibility for ensuring research communication is clear and easy to understand.
4. 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.

MULTI-REGIONAL CLINICAL TRIALS

For more information about the MRCT Center's work on health literacy in clinical research, visit: https://mrctcenter.org/health-literacy/

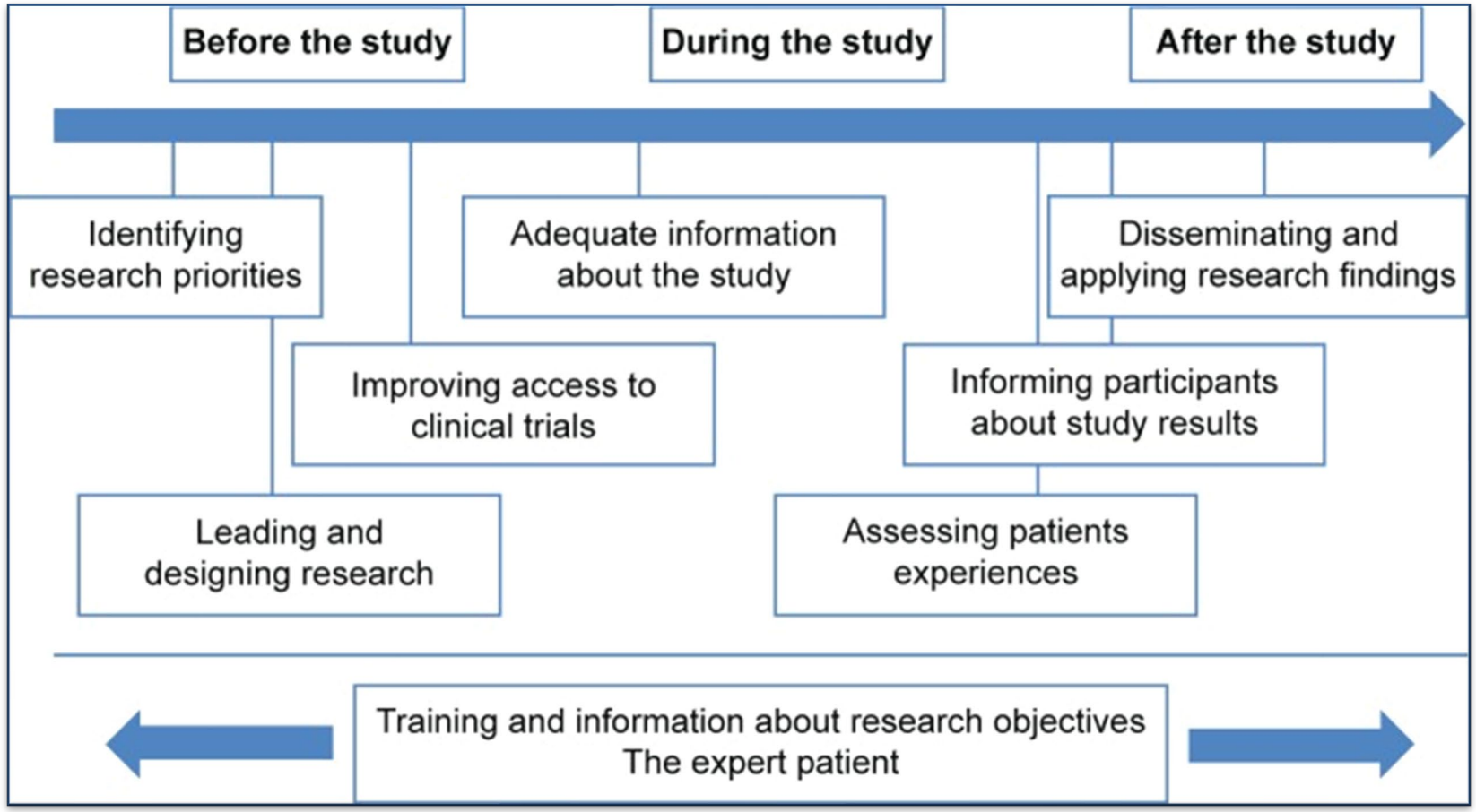
- All clinical research stakeholders share an ongoing responsibility for ensuring research communication is clear and easy to understand.
- Integration of health literacy into clinical research requires proactive planning to develop, test, modify, and confirm understanding of clinical research communications.

A Broad View of Health Literacy



Health Literacy Includes Integrating Input Throughout the Study

Patients and participants can provide input throughout the study….



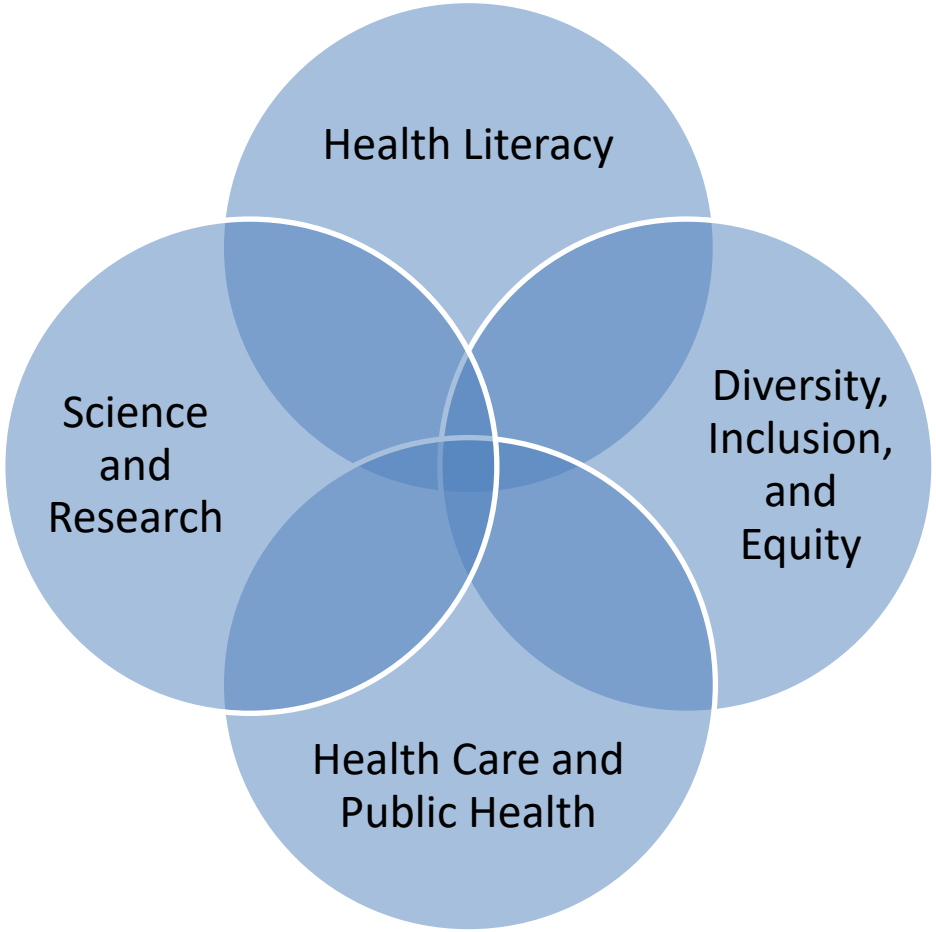
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4854260/

HRPPs and IRBs can also Integrate Patient and Participant Perspectives

- Some examples include:
  - Pilot test consent templates and boilerplate language
  - Collect participant experience data
  - Invite additional/specialized community members to join discussions of particular protocols

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

Health Literacy and AAHRPP Accreditation Standards
Domain I – Organization

- "An Organization has the responsibility not only to protect the rights and welfare of human research participants but also to involve research participants in the research enterprise…"

- STANDARD I-4: The Organization responds to the concerns of research participants.
  - ...activities designed to enhance understanding of human research by participants, prospective participants, or their communities (Element I.4.B)
  - ...promotes the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results (Element I.4.C)

Health Literacy and AAHRPP Accreditation Standards
Domain III – Researchers

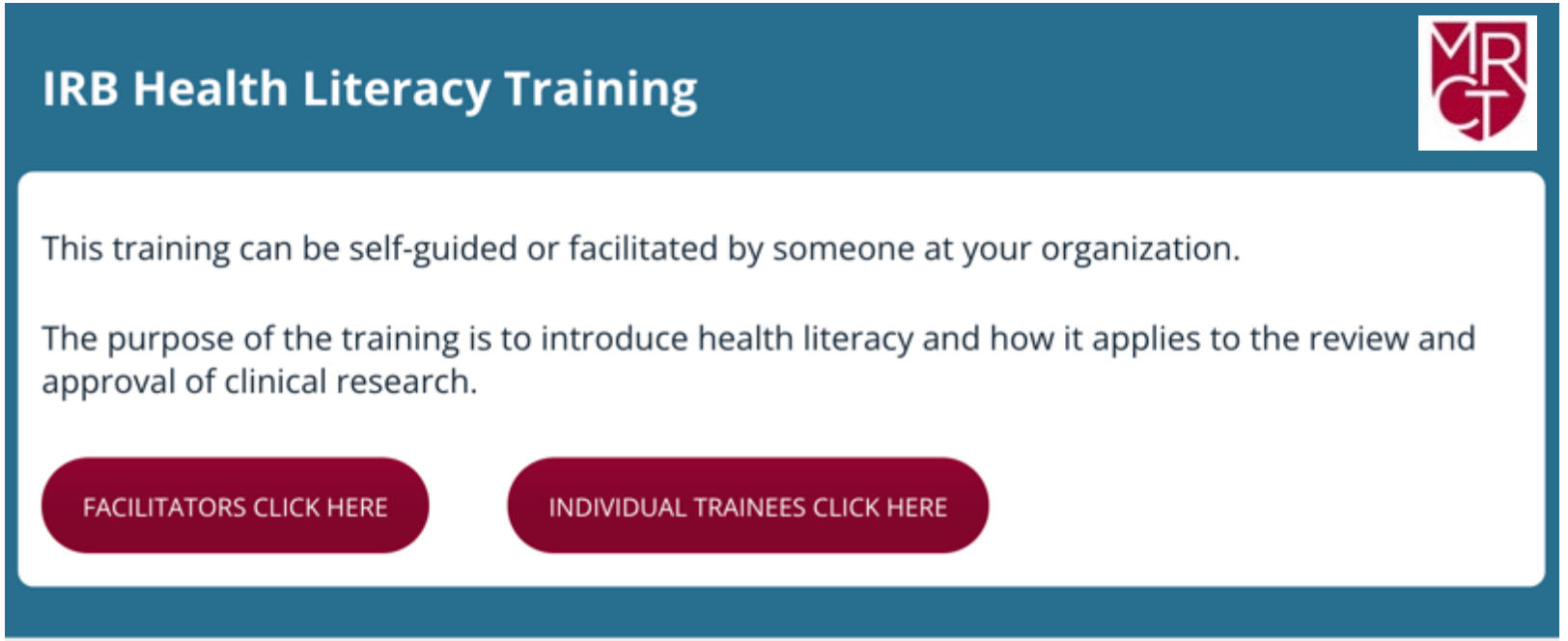
- Competent, informed, conscientious, compassionate, and responsible Researchers and Research Staff provide the best possible protection for human research participants.... As part of its HRPP, an Organization can improve its protection of research participants if it has arrangements for ascertaining and enhancing the competence of Researchers and Research Staff.

  - Element III.1.F. Researchers employ consent processes and methods of documentation appropriate to the type of research and the study population, emphasizing the importance of comprehension and voluntary participation to foster informed decision-making by participants.

Health Literacy for HRPPs: Goals

- Raise awareness amongst HRPPs, and IRB staff and reviewers, about health literacy and its importance in the clinical research.
- Foster internal conversations about health literacy, areas of organizational strength, and areas that could benefit from attention.
- Consider integrating practical resources and tools (training materials and checklist) into the review process and the development of health literate templates and boilerplate.

A Special Health Literacy Resource for IRBs



AAHRPP Accreditation Standard:
Element I.1.E. The Organization has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.

Audience:

- IRB members and staff
  - Full board reviewers
  - Expedited reviewers
  - Administrative personnel

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

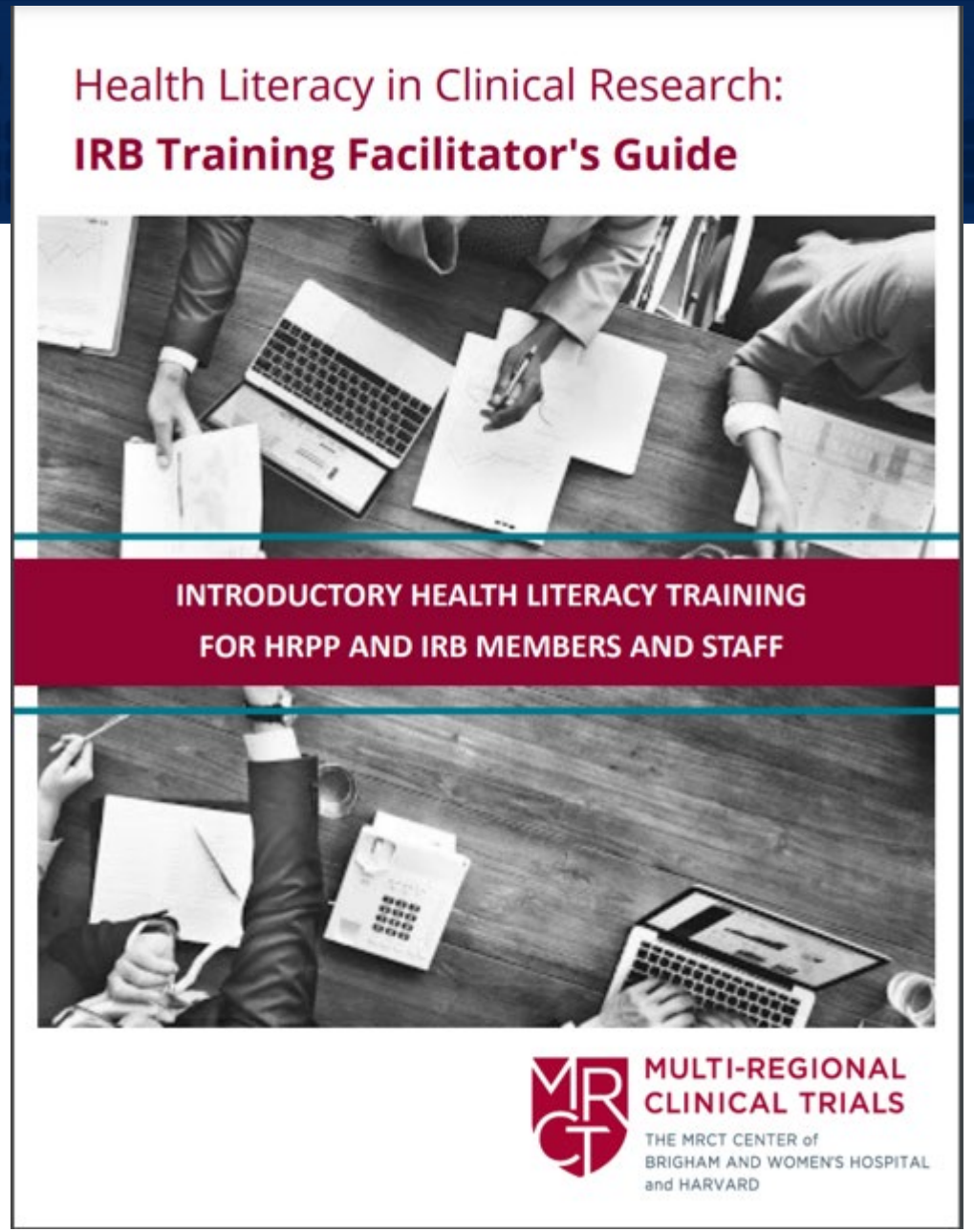
IRB Health Literacy Training Components – two roles

- Facilitator

+ Training Facilitator's Guide
+ Health Literacy in Clinical Research Introductory Video
+ Teach Back Questions
+ Group Discussion Questions
+ Before & After Example Exercise

- Individual Trainee

+ 1. Health Literacy in Clinical Research Introductory Video
+ 2. Teach Back Questions
+ 3. Before & After Example Exercise



- Step by step instructions, including group discussion questions that focus on IRB behaviors and potential actions
- Self-guided, flexible, and adaptable
- Available online

Training Materials include:

Health Literacy in Clinical Research:

IRB Training Worksheet

INTRODUCTORY HEALTH LITERACY TRAINING

FOR HRPP AND IRB MEMBERS AND STAFF -

TRAINEE WORKSHEET: TEACH BACK QUESTIONS & ANSWERS

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TEACH BACK QUESTIONS

I. What are at least 3 concepts that are included under the umbrella of health literacy?

II. What are at least 2 factors that can lower a person's health literacy level?

III. What are at least 5 reasons why health literacy is important in the context of clinical research?

IV. What are at least 4 ways health literacy can be applied throughout the clinical research life cycle?

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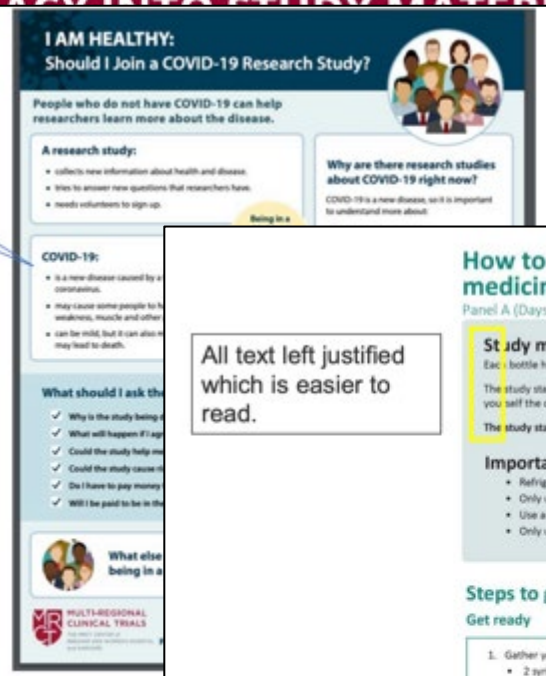
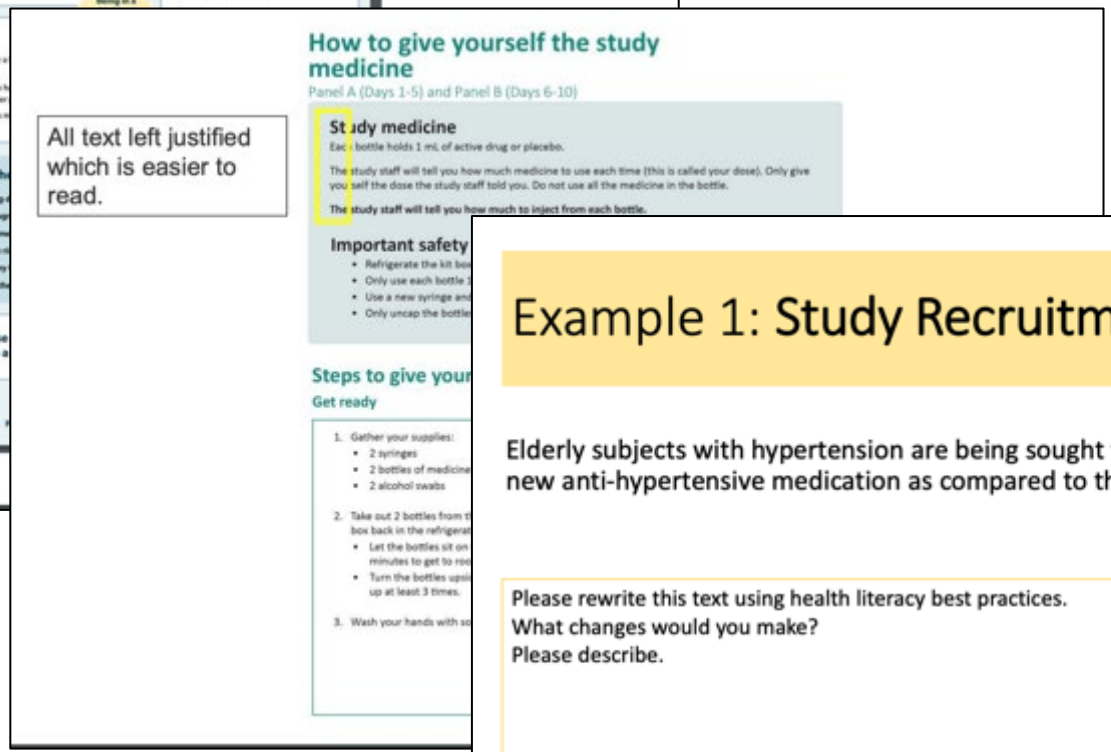
BEFORE AND AFTER:
INTEGRATING HEALTH LITERACY INTO STUDY MATERIALS

Headers are brief and clear.



All text left justified which is easier to read.



Example 1: Study Recruitment Flyer Text

Elderly subjects with hypertension are being sought to enroll in a randomized double-blind trial of a new anti-hypertensive medication as compared to the standard of care.

Please rewrite this text using health literacy best practices.
What changes would you make?
Please describe.

GROUP DISCUSSION QUESTIONS

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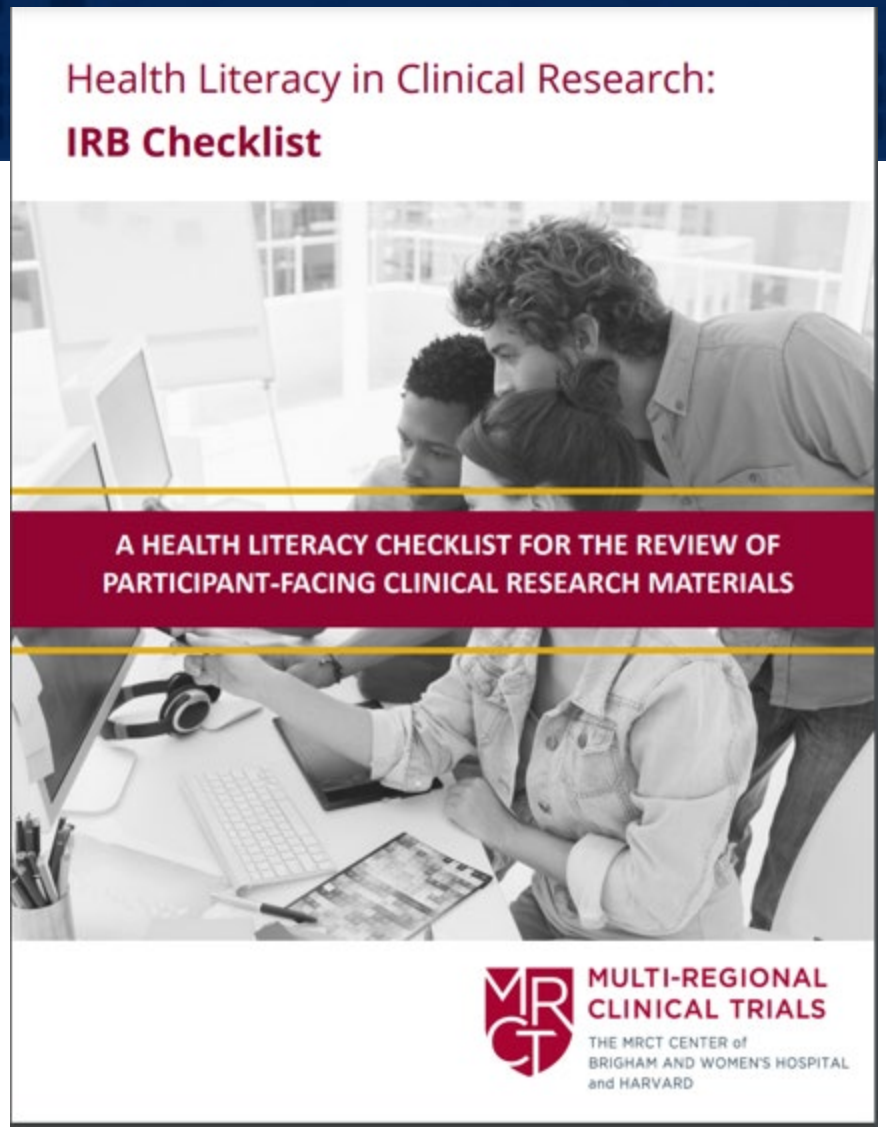
9

- What are some ways that IRBs can help promote health literacy in clinical research more generally?
- What does your IRB already do to help make participant facing materials clear and understandable?
- If you already integrate health literacy best practices, what more could you do to include it in your work and reviews? What would that look like in practice?



- Designed for IRB reviewers and staff to consider how well study information is being communicated to research participants.

- These questions can also be included in the protocol template or in your institution's informed consent template to promote the adoption of health literacy best practices by researchers and study teams in advance of submission.

Health Literacy Checklist Components

- Review of participant-facing materials for health literacy best practices

- Assent/consent considerations
  - Plain language use
  - Supportive aids
  - Specific risk descriptions
  - Use of teach-back/consent scripts

	Participant-facing Document*:	Recommendations/Comments
Research terms and concepts are explained in plain language	☐	
Participant population is described with sensitivity and care	☐	
Text is at a 6th grade reading level or lower	☐	
Key messages are clear and succinct	☐	
Font size is at least 12 point	☐	
White space is used generously throughout the document	☐	
Content is chunked into sections that are easy to discern	☐	
Section headings are clear and simple	☐	
Images, icons and/or graphics are used to engage and help explain concepts	☐	
Numeric info is explained using additional images or simple graphs	☐	
Study steps are clearly explained and easy for participants to follow	☐	

*Participant-facing documents include recruitment materials, consent/assent forms, study instructions, letters/postcards, etc.

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Quality Improvement (QI) User Testing for IRB Health Literacy Training

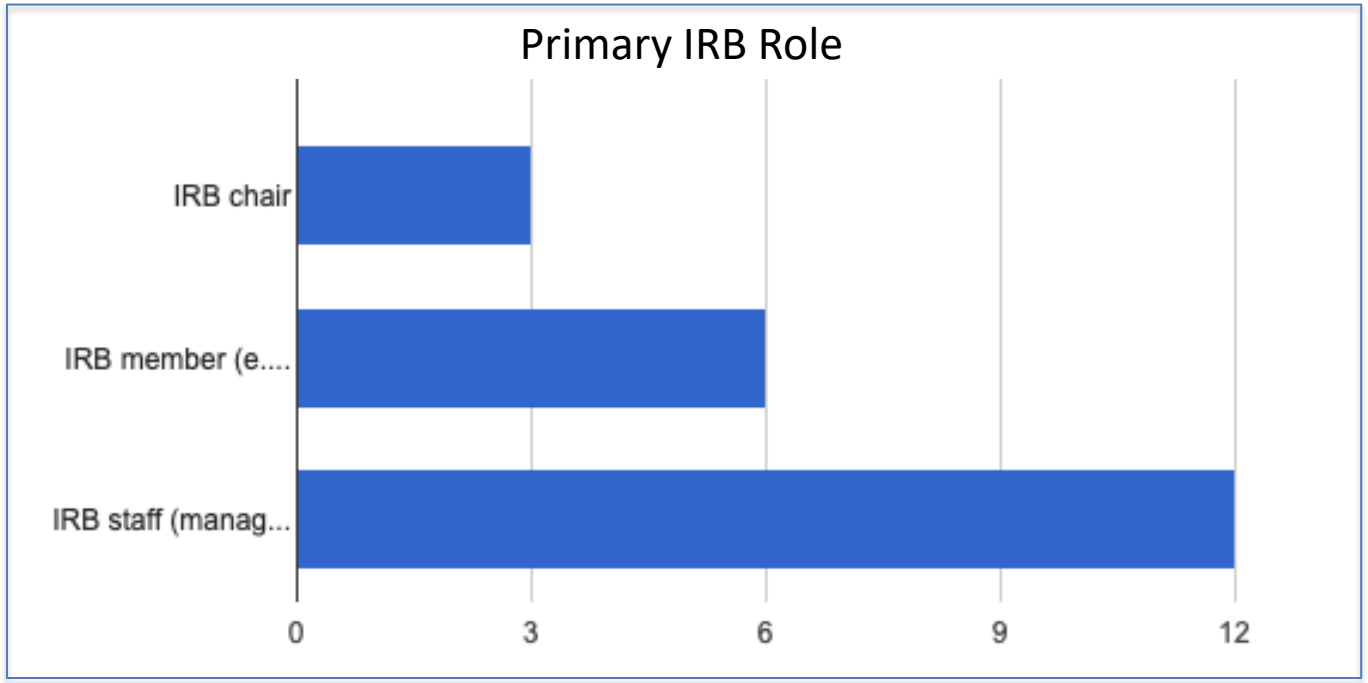
- Goal:
  - Conduct user testing at two separate USA-based IRBs to determine:
    - Ease of use
    - Acceptability of materials

- QI User Testing Process in August-October 2021 :
  - Sites provided with link to resources
  - Sites followed the process as described on the website and in the facilitation guide
    - Engaged in training activities/process
    - Tested checklist
  - Users (facilitators and trainees) completed voluntary, anonymous feedback survey

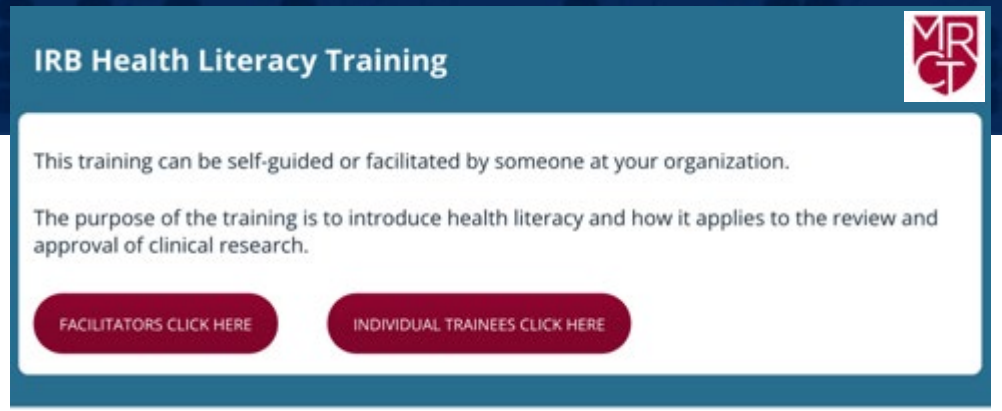
User Characteristics

- QI User Testing Sites:
  - Large IRB (200+ members): participants included one full board panel, the expedited review team, and administrative staff
  - Small IRB (<15 members): participants one full board panel, expedited reviewers and administrative staff

- QI survey completed by 21 people
  - 2 Facilitators
  - 19 Trainees



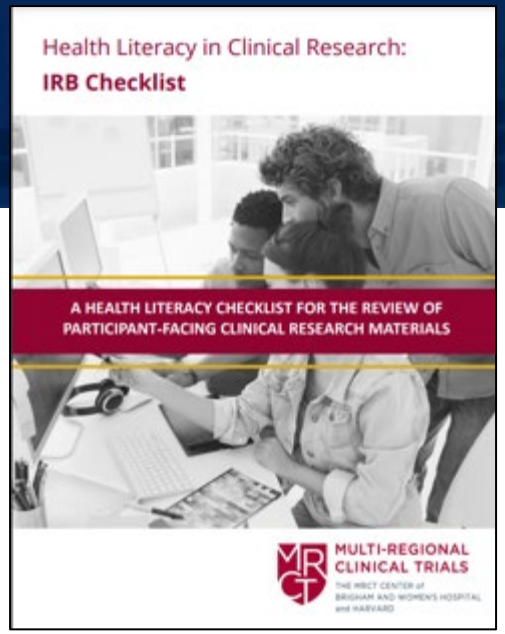
Feedback on the Training Materials



- **100%**
  - found the training clear and easy to follow.
  - reported having enough information at the end of the training to apply health literacy concepts to participant-facing materials.

- **Most!** [17/19 trainees (89.5%)] would recommend the training to others in the field of human research protections.

Feedback on the IRB Health Literacy Checklist



- 14/21 individuals used the checklist in one of their reviews.
  - 13/14 found it clear and understandable
  - 11/14 found it easy to integrate into the review process
  - 11/14 reported that the checklist helped them make some health literacy recommendations to the study team

- **Most!** [13/14 (92.8%)] would recommend using the checklist during the IRB review process

Findings from User Testing

- Accolades

This was really insightful! I think this is quite valuable and can be applied to our reviews of patient drug diaries etc. The discussion at the IRB meeting about this was excellent I thought

These materials sparked truly great discussion. The IRB panel as a whole felt that this is a vital topic.

- Constructive Feedback

Update the checklist to allow for multiple participant-facing materials

Ensure universality of concepts across studies

The checklist seems like a duplication of work.

Next steps for these IRB health literacy resources

1. Refinement of the training/checklist based on the feedback received

2. Availability of the updated materials on our website:
   https://mrctcenter.org/health-literacy/instructional-resources/overview/irb/

3. Adaptation to an online Learning Management System in 2022 for more formal tracking, a quiz and a certificate of completion.

Key Takeaways

- HRPPs, and IRBs in particular, can champion health literacy best practices.

- A focus on health literacy:
  - Is supported by AAHRPP accreditation standards
  - Makes research more understandable (for everyone!)
  - Builds trustworthiness of the research enterprise.

- Resources exist to enhance your human research protection efforts.

https://mrctcenter.org/health-literacy/

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Questions?

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