



# MULTI-REGIONAL CLINICAL TRIALS

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

## Introducing: The MRCT Center Online Health Literacy Training for IRB Members and Staff

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# Agenda

- Welcome and introduction
- Introduction to Health Literacy and the IRB training
- Implementing the Health Literacy Training: One IRB's Experience
- Discussion, Questions, and Answers

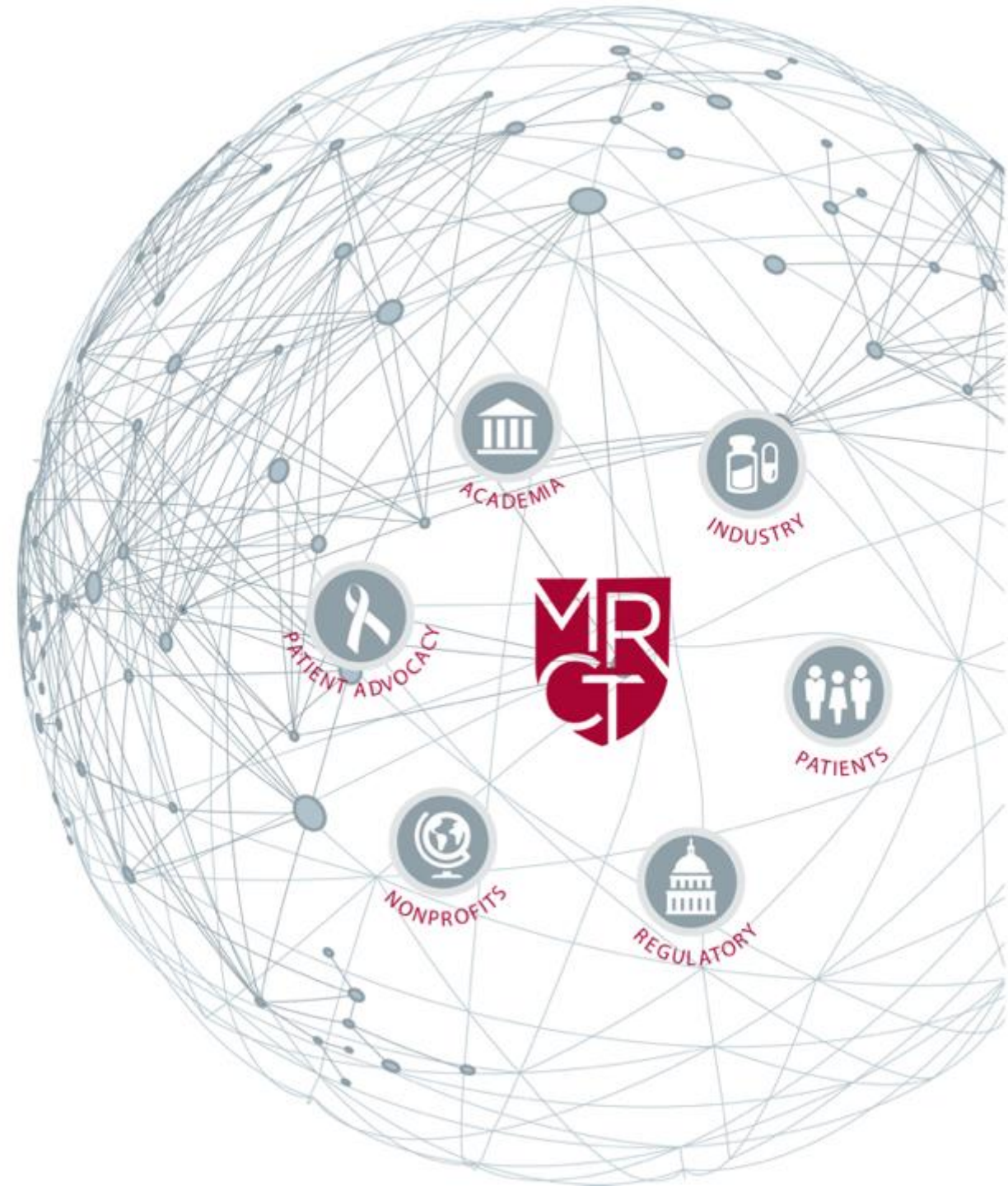
# Introduction to the MRCT Center

## Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

## Our Mission

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



# MRCT Center's Commitment to Health Literacy

- 2013 → Appreciating participant-centricity in research, focused on return of aggregate (plain language) summaries and return of individual results to participants.
- 2019 - Completed a multi-stakeholder initiative and launched a publicly available website on Health Literacy in Clinical Research [www.mrctcenter.org/health-literacy](http://www.mrctcenter.org/health-literacy)
- 2020 – Co-developed COVID-19 pamphlets to support understanding of clinical research (in English & Spanish, for adults and children).  
<https://mrctcenter.org/blog/resources/covid-19-clinical-research-flyers/>
- 2021-2022 – Published a suite of clinical research resources for children.  
<https://mrctcenter.org/blog/resources/pediatric-research-informational-materials/>

The image displays two digital resources from the MRCT Center. On the left is a screenshot of the 'HEALTH LITERACY IN CLINICAL RESEARCH' website, which features a navigation bar with 'START HERE', 'TRIAL LIFE CYCLE', 'BEST PRACTICES', and 'RESOURCES BY ROLE'. A quote from a research participant is featured: 'Tell me what I need to know and make sure I understand. Tell me again tomorrow.' Below this, there are sections for 'READ THE HEALTH LITERACY' and 'Are you sure your clinical research matters?'. On the right is a COVID-19 research study pamphlet titled 'I AM HEALTHY: Should I Join a COVID-19 Research Study?'. The pamphlet includes sections for 'A research study:', 'COVID-19:', 'What should I ask the research team before joining a COVID-19 research study?', and 'What else should I know about being in a COVID-19 research study?'. It also features logos for 'MULTI-REGIONAL CLINICAL TRIALS' and 'HARVARD CATALYST'.

# Meet the Speakers



- **Sylvia Baedorf Kassis, MPH** is a Program Director who joined the MRCT Center in 2018. She obtained her BS from University of Toronto, Canada, and her Master of Public Health (MPH) from Boston University. She has over twenty years of experience in clinical research, with expertise in health literacy, patient engagement, and research conduct.



- **Jill E. Manning, MPH** obtained her BA from McGill University in Montreal, Quebec, Canada, and her Master of Public Health (MPH) from Boston University. Jill has worked for the Mass General Brigham IRB since 2015 and has served in her current position of IRB Assistant Director of the Full Board since 2018. In 2019, Jill completed a Fellowship in Bioethics at Harvard Medical School.

# Introduction to Health Literacy and the IRB Training

# The Challenge of Limited Literacy in the US

- National Assessment of Adult Literacy (2003)

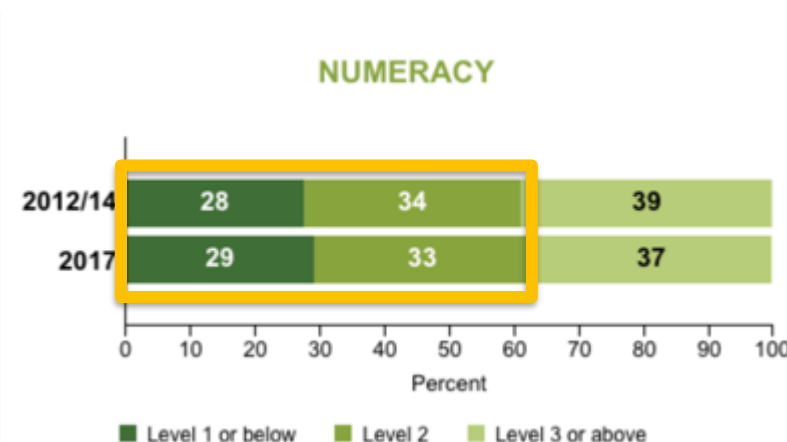
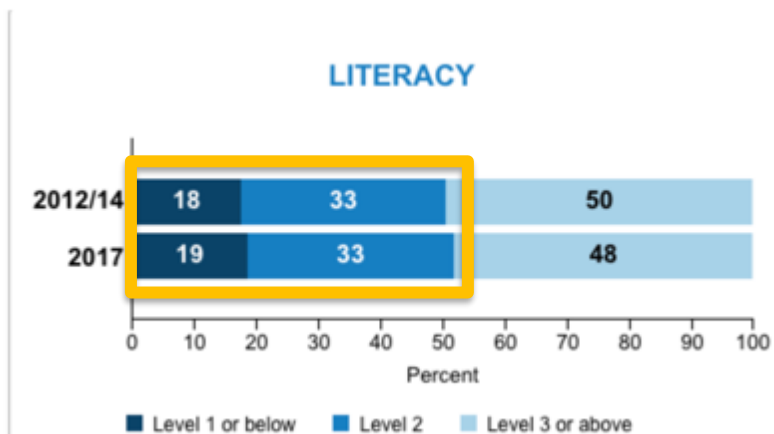
9/10 people in the US need extra help



Below Basic Basic Intermediate Proficient

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

- Program for the International Assessment of Adult Competencies (2012/14, 2017)



From: [https://nces.ed.gov/surveys/piaac/current\\_results.asp](https://nces.ed.gov/surveys/piaac/current_results.asp)

# Evolving Definition of Health Literacy

“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.



**Personal health literacy** is the degree to which individuals have the ability to find, understand, and use information and services to inform health-related 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.

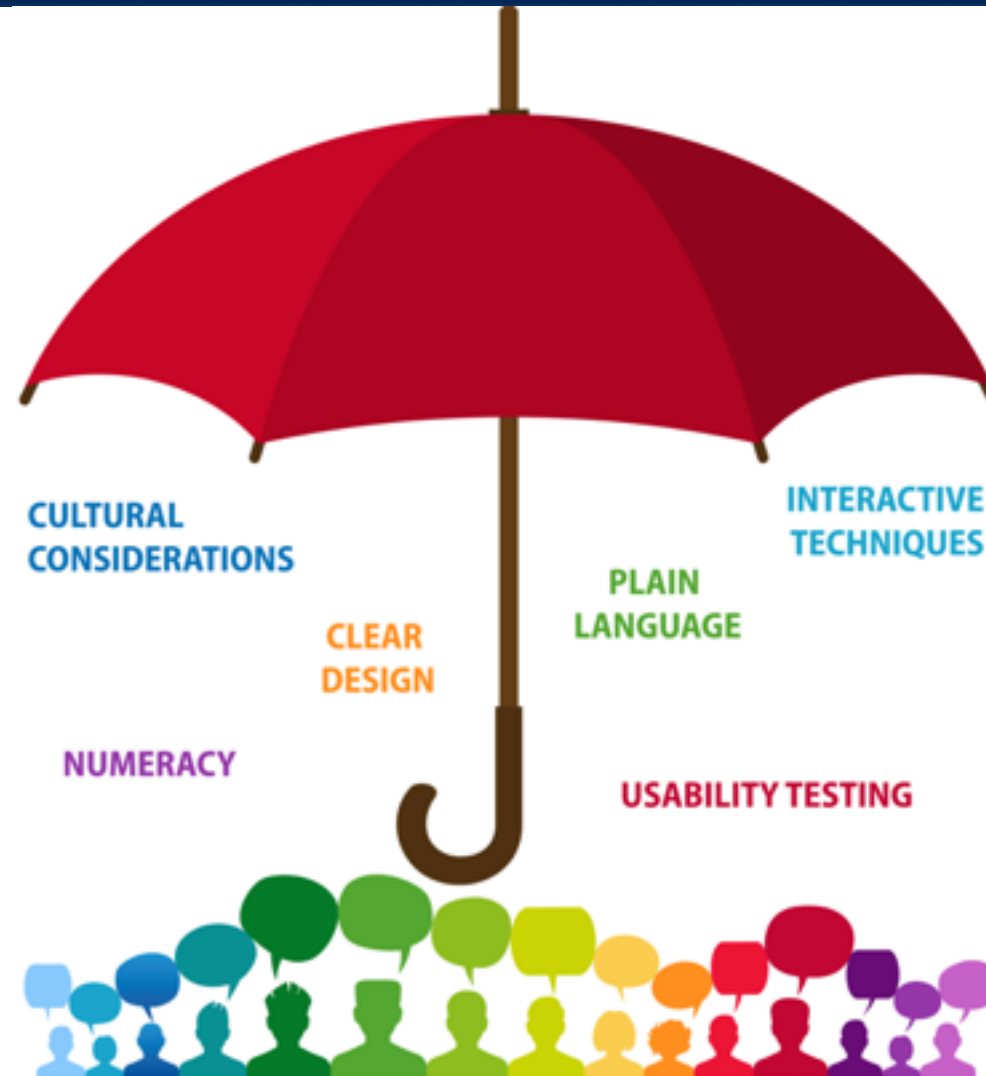
<https://health.gov/our-work/national-health-initiatives/healthy-people/healthy-people-2030/health-literacy-healthy-people-2030>

Individual Ability

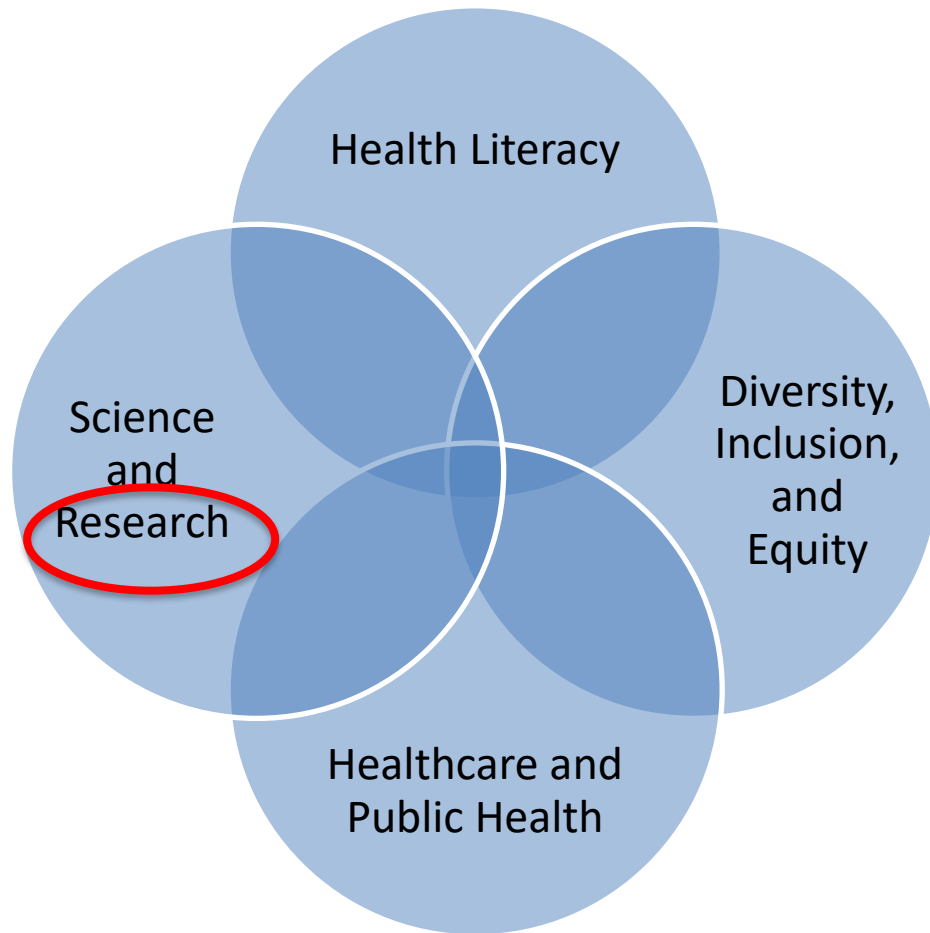
Communicator's Skill and Responsibility



# A Broad View of Health Literacy



# 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 Across the Clinical Trial Life Cycle

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



DISCOVERY



RECRUITMENT








CONSENT



ON STUDY



END OF STUDY

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>

# Health Literacy for HRPP/IRBs: 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.
- **Integrate 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:



## IRB Health Literacy Training

This training can be self-guided or facilitated by someone at your organization.

The purpose of the training is to introduce health literacy and how it applies to the review and approval of clinical research.

FACILITATORS CLICK HERE FOR INSTRUCTIONS

TRAINEES CLICK HERE FOR ONLINE TRAINING



# An online training....

- For IRB members and staff:
  - Full board reviewers
  - Expedited reviewers
  - Administrative personnel
- Co-developed with MRCT Center:
  - Amy Ben-Arieh, JD, MPH (Fenway Institute)
  - Diana Lynnette Fisher, MS, MPH, CPH (Lilly)
  - Margaret Rankovic, MEd, CIP (CITI Program)
  - Christopher Trudeau, JD (University of Arkansas, Bowman School of Law)
- Usability tested at:
  - Large IRB (200+ members): one full board panel, expedited review team, & administrative staff
  - Small IRB (<15 members): one full board panel, expedited reviewers & administrative staff



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



INTRODUCTORY HEALTH LITERACY TRAINING  
FOR HRPP AND IRB MEMBERS AND STAFF



# ... with facilitation guide for in-person discussion

- Features group discussion questions focused on IRB behaviors and potential actions:
  - 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?\*
  - \* Note: If you don't do anything yet, that's ok!
  - Are there ways you could start?
  - How?
  - 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?

<https://mrctcenter.org/health-literacy/wp-content/uploads/sites/2/2022/04/2022-03-28-Facilitators-Guide-Ethos.pdf>



# Online Training Materials

## IRB HEALTH LITERACY IN CLINICAL RESEARCH

Human Research Protection Programs (HRPPs) and Institutional Review Boards (IRBs) can play an important role in supporting research study participants by applying health literacy best practices to their reviews of participant-facing materials.

The purpose of the training is to introduce the concept of health literacy and how it applies to the review and approval of clinical research. Trainees will also have the opportunity to put what they learn into action through the completion of application exercises.

This training is designed to be self-guided. Individuals can take this training and earn a Certificate of Completion. After completing the training, there is also an option for someone at your organization to facilitate a team discussion using the [Facilitator's Guide](#).

Additional information about Health Literacy in Clinical Research can be found here: <https://mrctcenter.org/health-literacy/>.

A health literacy checklist for IRB reviewers can be found here: <https://mrctcenter.org/health-literacy/instructional-resources/overview/irb/#checklist>

To access the modules, please follow these instructions: [Health Literacy Enrollment Instructions.pdf](#)

For any questions, please contact: Sylvia Baedorf Kassis ([sbaedorfkassis@bwh.harvard.edu](mailto:sbaedorfkassis@bwh.harvard.edu)).

## INTRODUCTORY VIDEO

← RETURN TO COURSE HOME

### COURSE PROGRESS

HEALTH LITERACY IN CLINICAL RESEARCH INTRODUCTORY VIDEO

REQUIRED

REVIEW

TEACH BACK QUESTIONS

BEFORE & AFTER: POWERPOINT

BEFORE & AFTER: ACTIVITY

FINAL QUIZ

EVALUATION

CERTIFICATE

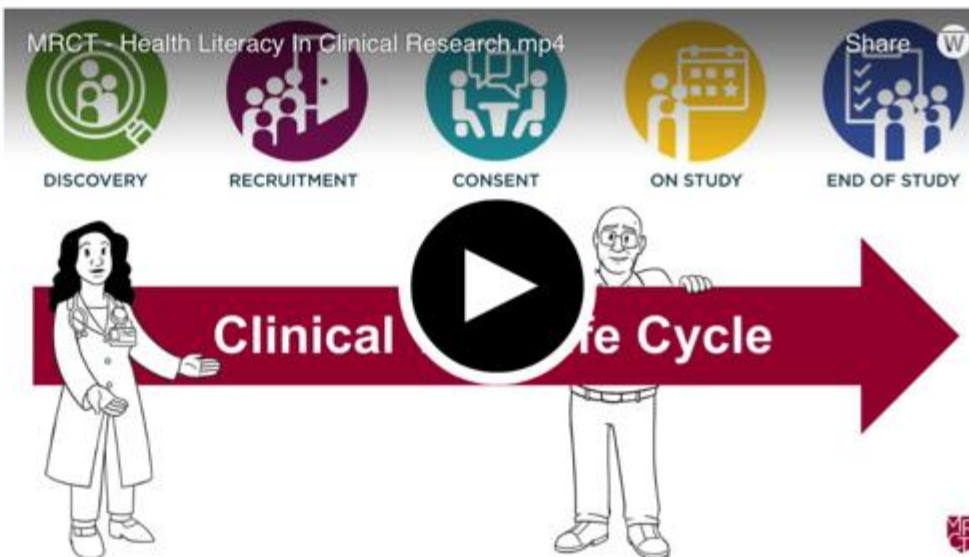
COMPLETE

### HEALTH LITERACY IN CLINICAL RESEARCH INTRODUCTORY VIDEO

Please review the Health Literacy in Clinical Research video, then proceed to complete the Teach Back Questions.

If you are having trouble accessing the embedded video, please use this link to watch the introductory video: [HERE](#)

A transcript of this video is available: [pending]



## Health Literacy in Clinical Research: IRB Checklist



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



- 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.

[https://mrctcenter.org/health-literacy/wp-content/uploads/sites/2/2021/08/For-Pilot\\_IRB-Checklist-fillable.pdf](https://mrctcenter.org/health-literacy/wp-content/uploads/sites/2/2021/08/For-Pilot_IRB-Checklist-fillable.pdf)

# 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	<input type="checkbox"/>	
Participant population is described with sensitivity and care	<input type="checkbox"/>	
Text is at a 6 <sup>th</sup> grade reading level or lower	<input type="checkbox"/>	
Key messages are clear and succinct	<input type="checkbox"/>	
Font size is at least 12 point	<input type="checkbox"/>	
White space is used generously throughout the document	<input type="checkbox"/>	
Content is chunked into sections that are easy to discern	<input type="checkbox"/>	
Section headings are clear and simple	<input type="checkbox"/>	
Images, icons and/or graphics are used to engage and help explain concepts	<input type="checkbox"/>	
Numeric info is explained using additional images or simple graphs	<input type="checkbox"/>	
Study steps are clearly explained and easy for participants to follow	<input type="checkbox"/>	

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

# Implementing the Health Literacy Training: One IRB's Experience



# Introducing the IRB

## Mass General Brigham IRB

- one of the largest hospital system-based research enterprises in the U.S.
- annual research budget of nearly \$2 billion
- 2,700 + ongoing clinical trials
- 9 network sites
- ~40 IRB Staff Members
- 7 Physician Chairs
- ~200 Full Board Members

# IRB Experience: Regulatory Requirements (excerpts)

HHS Regulations: [§ 46.116 General Requirements for Informed Consent](#)

FDA Regulations: [§ 50.20 General Requirements for Informed Consent](#)

- “...An investigator shall seek informed consent **only under circumstances** that provide the prospective subject ...**sufficient opportunity to discuss and consider whether or not to participate...**”
- “The **information** that is given to the subject... **shall be in language understandable to the subject...**”
- “The subject 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.”**”

# MGB IRB Full Board: Pilot of Health Literacy Training

- Pilot Exercise took place in September 2021
- Objective: pilot test two resources: **Health Literacy Training and Checklist for IRBs** and generate feedback for the MRCT Center for their finalization of materials
- Process:
  - Staff logged into the **Health Literacy Training Materials** and viewed the 7-minute Health Literacy **Training Video**
  - Met together as a team to work through **“Teach Back Questions”**
  - After the group exercise, staff were asked to independently utilize the **Health Literacy Checklist** for review of at least one **participant-facing study document** (recruitment letter or flyer, consent form, study schedule, study instructions, etc)
  - Staff completed the online Health Literacy Training **Feedback Survey**

# IRB Health Literacy Training: Lessons Learned

- Ethics: Health Literacy is about **JUSTICE, BENEFICENCE, RESPECT**
  - IRB is required to assess submissions based on the federal regulatory criteria for approval, which flow directly from these core ethical principles!
- Increased awareness of the **prevalence of low health literacy**, and that it can be **situational and affect everyone**.
- **High-quality IRB review** includes promoting health literacy across ALL participant-facing materials used **across the “life” of the study**
- Checklist as a Valuable Tool: IRB Staff found identifying specific elements of **health literacy** facilitated more robust and **thorough review of materials**



## IRB Health Literacy Training: Lessons Learned (cont'd)

- Consistent with **fulfilling our IRB mission** to protect the **rights and welfare of human subjects** in clinical research, ensure **federal and institutional requirements** are met, and to **work collaboratively** with the research community
- NOT implementing these “checks and balances” → lower trust in health care, lower enrollment, and increased risk of Adverse Events

**Formalizing the assessment of health literacy as a component of IRB review promotes equitable selection of subjects, compliant participation from subjects, and ultimately yields higher quality data that is generalizable to the affected patient population!**

# IRB Experience: Takeaways

- **Easy to implement** – not a heavy admin burden!
- Foundational to the **ethical review** of human research
- Health Literacy Checklist is a valuable supplement to existing IRB review resources - incorporating into **IRB Onboarding** moving forward
- Ability to **share these resources** promotes a more **collaborative relationship** b/t the IRB and the MGB **Research Community** (Investigators, Study Staff, etc.)
- Small changes (i.e., specific review directives) can make a **BIG impact** when implemented **consistently** across staff **over time**

# Recap of the IRB HL Training Steps

- **Step 1:** Complete the online health literacy training yourself  
<https://cpd.partners.org/content/irb-health-literacy-clinical-research#group-tabs-node-course-default1>
- **Step 2:** Have team members also complete the online health literacy training
- **Step 3:** Engage in a team discussion using the Group Discussion Guide
- **Step 4:** Start integrating health literacy considerations into research review and approval activities.

## In conclusion...

- HRPPs, and IRBs in particular, can champion health literacy best practices.
- A focus on health literacy:
  - Supports the regulatory (OHRP, FDA) requirements
  - Establishes an educational program as an AAHRPP requirement
  - 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/>

Thank you!!

Questions  
And  
Discussion