



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, with various colors including purple, red, orange, yellow, green, and blue. Some silhouettes have speech bubbles above them, suggesting communication or dialogue.

**The MRCT Center Health Literacy in Clinical Research Website:
Supporting Clear Communications Throughout the Clinical Research Life Cycle**

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Program Manager

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- I have no personal conflicts of interests relevant to this presentation.

Objectives

- At the end of the session, attendees will be able to:
 - Describe the application of health literacy principles throughout the clinical research life cycle.
 - Access and use resources on the MRCT Center's *Health Literacy in Clinical Research* website to develop participant-facing materials and processes that support participant understanding.
 - Share best practices with their colleagues and team members to promote greater integration of health literacy best practices into their clinical research processes.

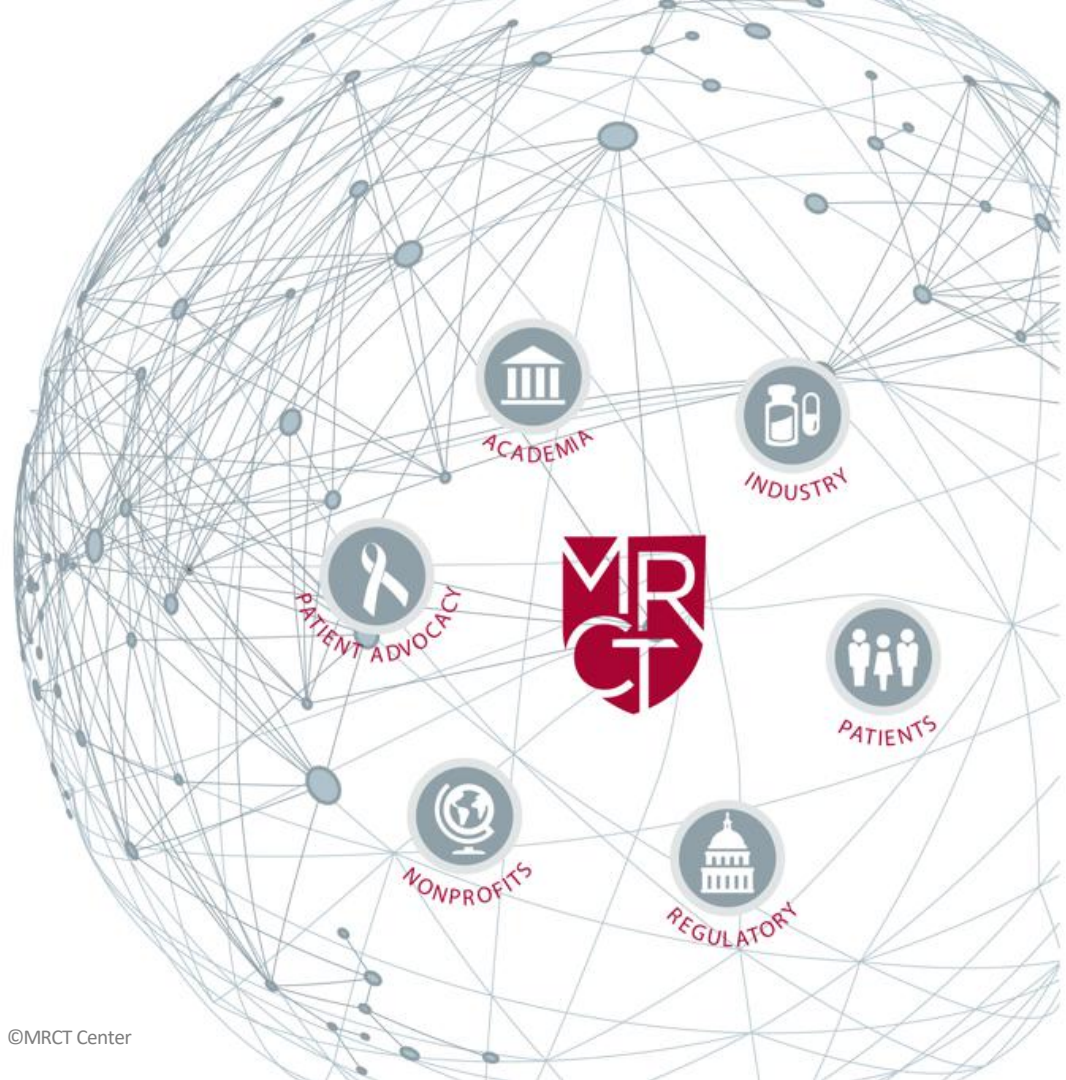
The MRCT Center

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.



Prior MRCT Center Work

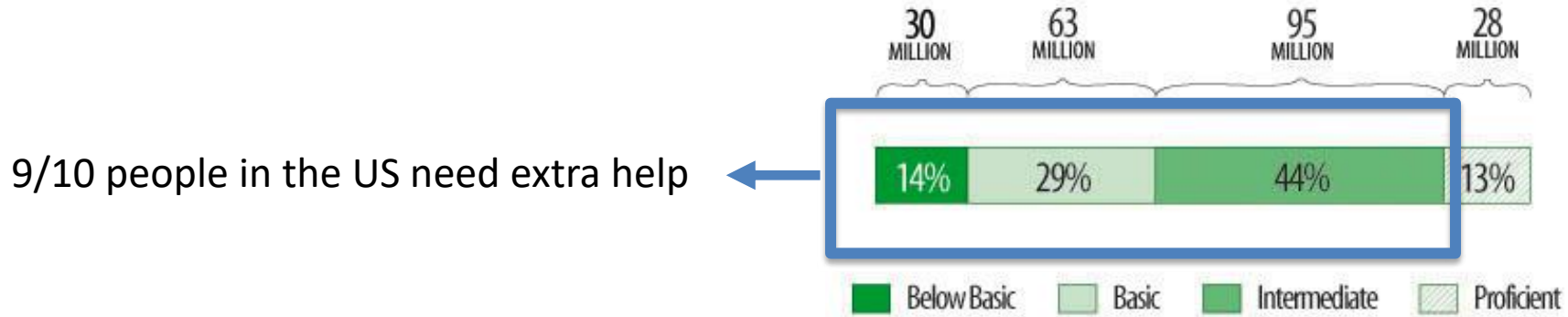


<https://mrctcenter.org/blog/projects/return-of-individual-results/>
<https://mrctcenter.org/blog/projects/return-of-results-to-participants/>



The Health Literacy Opportunity

- Literacy levels are troubling around the world.



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

A Broad View of Health Literacy



...and a shared responsibility.

The Clinical Trial Life Cycle

Clear communication is essential throughout the participant's journey through the clinical trial life cycle



DISCOVERY



RECRUITMENT



CONSENT



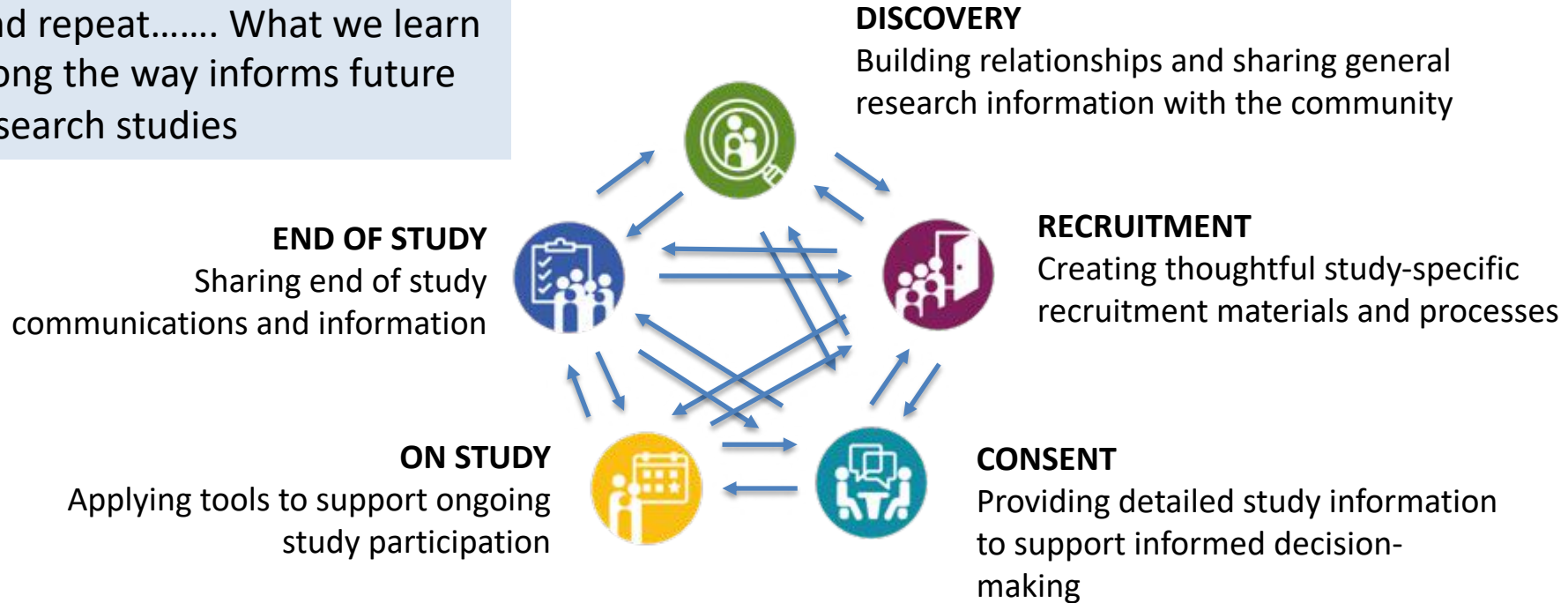
ON STUDY



END OF STUDY

Integrating Health Literacy Principles

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



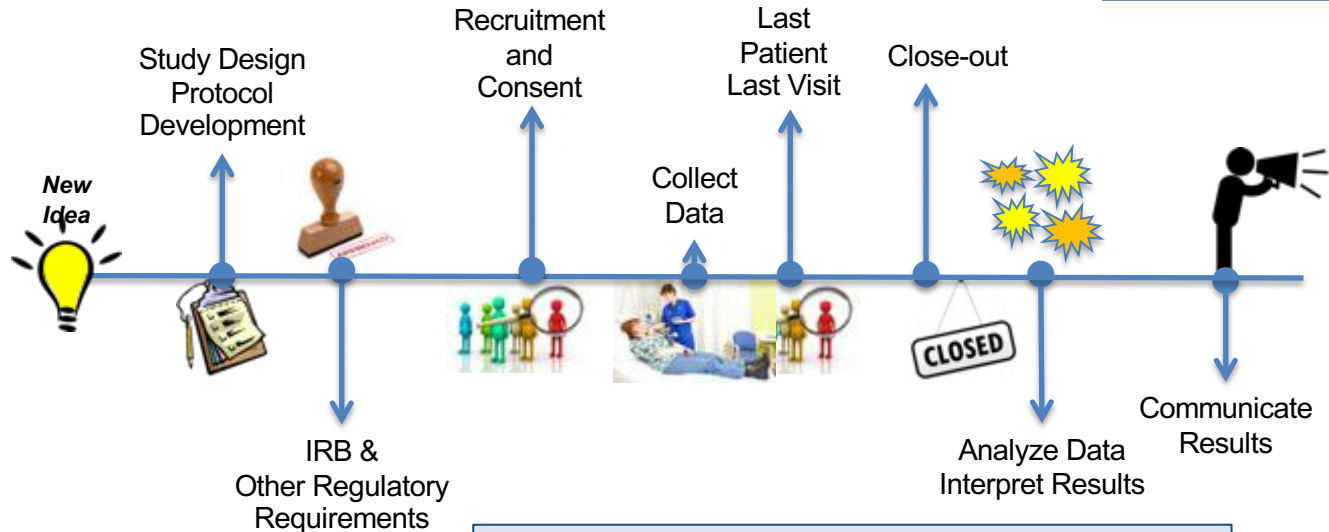
Integrate Health Literacy into the Trajectory of a Research Study

Get to know about the study population

Ask members of the study population for feedback






Explain end of study processes

Report findings to participants



Provide additional information to support participation

Develop recruitment materials and consent forms using health literacy best practices

Stage of Journey through the Life Cycle	Examples of Clear Communication Opportunities
 <p data-bbox="291 188 455 224">Discovery</p>	<ul data-bbox="759 145 1856 270" style="list-style-type: none"> - Research awareness campaigns - Outreach and engagement efforts to solicit patient input into study design and development
 <p data-bbox="272 347 475 383">Recruitment</p>	<ul data-bbox="759 328 1128 407" style="list-style-type: none"> - Advertisements - Recruitment scripts
 <p data-bbox="305 516 442 552">Consent</p>	<ul data-bbox="759 472 1238 598" style="list-style-type: none"> - Consent scripts - Consent forms - Study schedules/calendars
 <p data-bbox="297 718 450 754">On Study</p>	<ul data-bbox="759 656 1489 827" style="list-style-type: none"> - Study medication/intervention instructions - Study commitment contract - Adverse event reporting information - Participant satisfaction survey
 <p data-bbox="272 936 475 972">End of Study</p>	<ul data-bbox="759 893 1682 1018" style="list-style-type: none"> - Instructions for coming off trial - Information on maintaining access to treatment options - Study results/summaries

The Potential of Applying Health Literacy Best Practices



Clear Communications Benefit Everyone



HEALTH LITERACY IN CLINICAL RESEARCH

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

“
Tell me what I need to know and make sure I understand.
Tell me again tomorrow.”
— A research participant reflecting on their study experience

READ THE HEALTH LITERACY PRINCIPLES >>

Clear communication promotes health literacy and leads to:
• an informed consumer
• a greater transparency
• increased trust

Sponsors and funders, investigators and study teams, and institutional review boards and ethics boards all share a responsibility to create research materials that participants can understand and act upon.

Are you sure your clinical research materials are understandable?

Learn about the Principles of Health Literacy in Clinical Research

Find out more about clear communications throughout the Clinical Trial Life Cycle

Use tools and techniques to integrate health literacy into your clinical research role today

View and share resources for your clinical trial participants that are easy to read and understand

- The MRCT Center led the development of a dynamic web-based resource that highlights:
 - How health literacy applies throughout the clinical trial life cycle
 - Best practices to support clear research communications
 - Case studies and practical examples of how health literacy has already been integrated into research processes
 - Ways to take action in your own clinical research role

www.mrctcenter.org/health-literacy



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1) Advocate at your organization

HEALTH LITERACY IN CLINICAL RESEARCH

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

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Tell me again
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- A research participant
reflecting on their study
experience


[READ THE HEALTH LITERACY PRINCIPLES >>](#)

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Sponsors and funders, investigators and study teams, and institutional review boards and ethics boards all share a responsibility to create research materials that participants can understand and act upon.

Are you sure your clinical research materials are understandable?



Learn about the
Principles of Health
Literacy in Clinical
Research

[Learn More](#)


Find out more about
clear communications
throughout the Clinical
Trial Life Cycle

[Learn More](#)


Use tools and techniques
to integrate health
literacy into your clinical
research role today

[Learn More](#)


View and share resources
for your clinical trial
participants that are easy
to read and understand

[Learn More](#)

HEALTH LITERACY IN CLINICAL RESEARCH

[START HERE](#) | [TRIAL LIFE CYCLE](#)

Health L

[Home](#) > [Start Here](#) > [Health Literacy Overview](#)

What is Health Literacy?

The classic definition of health literacy refers to an individual's capacity to obtain, process, and understand basic health information and services to make appropriate health decisions¹.

Yet, health literacy is in fact a dynamic process – it is a state not a trait. As such health literacy can be affected by various factors, like the stress of a new diagnosis or the setting within which information being shared.

Healthy People 2030 is proposing a new working definition of health literacy that reflects a consensus of health literacy a two-sided construct affected by both:

- an individual's capacities, and
- the abilities of those responsible for c

Health



PLAIN



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 MRCCT 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.



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2) Start where you are

HEALTH LITERACY IN CLINICAL RESEARCH

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

Clinical Trial Life Cycle Overview

Home > Trial Life Cycle > Overview

Health literacy can support the participant through their 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



5. END OF STUDY

Plain language summaries, results reports, and research publications

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

Home > Trial Life Cycle > Overview > On Study



4. On Study

Clear information about ongoing research procedures, data collection and reporting

"On Study" is the time when the participant is enrolled into the specific research study and undergoes the research procedures outlined in the protocol.

- At this point the focus of the research team is on quality data collection, compliance with the research procedures and retention of enrolled participants.
- Ongoing clear communications about expectations and logistics are important.
- It is advised that any materials and scripts used during the ongoing study should go through **usability testing** with members of the intended audience.
- Through a process of ongoing engagement and active listening, researchers should periodically confirm participants understanding of the research and willingness to continue as the study proceeds

Click through the individual tabs to learn more about how your "On Study" research communications can be improved through plain language, numeracy, clear design and cultural considerations.

Plain Language

Numeracy

Clear Design

Cultural Considerations

Clear Design

During the "On Study" stage clear design techniques can be applied to print materials to support a participant's continued engagement in the study.

All tools and resources (such as health literate study calendars, study medication instructions, and study procedure descriptions), as well as additional materials like a regular study newsletter or results

How to give yourself the study medicine

Panel A (Days 1-5) and Panel B (Days 6-10)

Study medicine

Each bottle holds 1 ml of active drug or placebo.

The study staff will tell you how much medicine to use each time (this is called your dose). Only give yourself the dose the study staff tells you. Do not use all the medicine in the bottle.

The study staff will tell you how much to inject from each bottle.

Important safety information

- Multigrabene is not for... (text obscured)
- Only use each bottle 1 time.
- Use a new syringe and needles each time.
- Only uncap the bottles when you use them.

Steps to give yourself the study medicine

Get ready

1. Gather your supplies:



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



HEALTH LITERACY IN CLINICAL RESEARCH

Return of Results

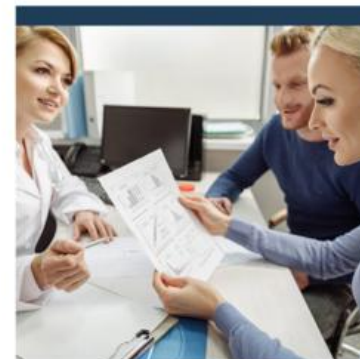
Home > Best Practices > Overview > Return of Results

Create and disseminate general clinical trial result summaries

(also known as Lay Summaries or Plain Language Summaries) so clinical trial participants:

- are informed about the trial results,
- know their participation is respected and appreciated
- understand the value of their contribution to science and public health.

More information about previous MRCT Center work on Return of Results can be [found here](#).



[Download](#) this fillable Return of Results template and adapt it to your study situation.





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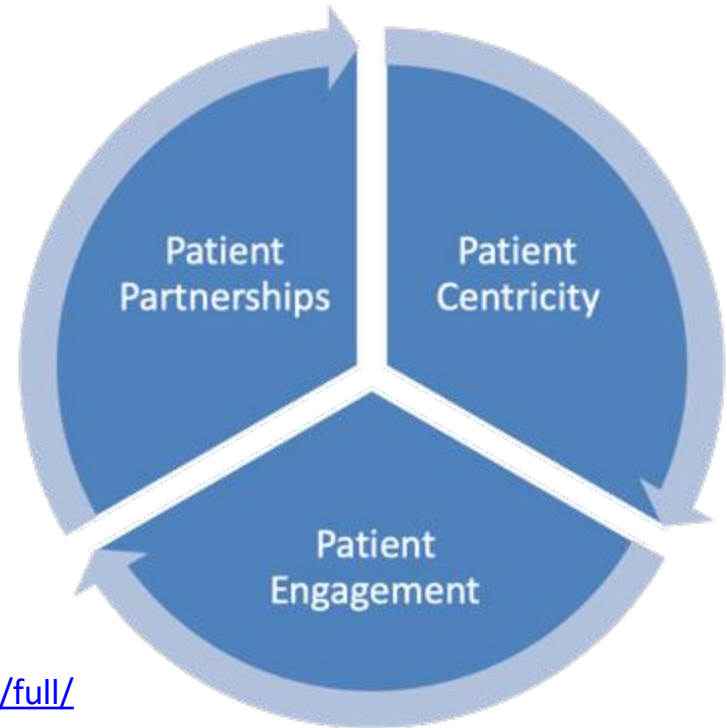
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A horizontal illustration at the bottom of the slide shows a row of colorful silhouettes of people of various ethnicities and ages. Above each silhouette is a speech bubble of a matching color, representing patient input. A white rectangular box with a red border is superimposed over the center of the illustration, containing the text '3) Consider how to get patient input'.

3) Consider how to get patient input

Partnering with Patients

- Lessons learned from healthcare
 - People actively involved in their health and health care tend to have better outcomes.*
 - Patient decision making is *enhanced* by personal experience and *complemented* by scientific knowledge of healthcare professionals.**
 - Recognition of patients as experts fosters collaboration.**

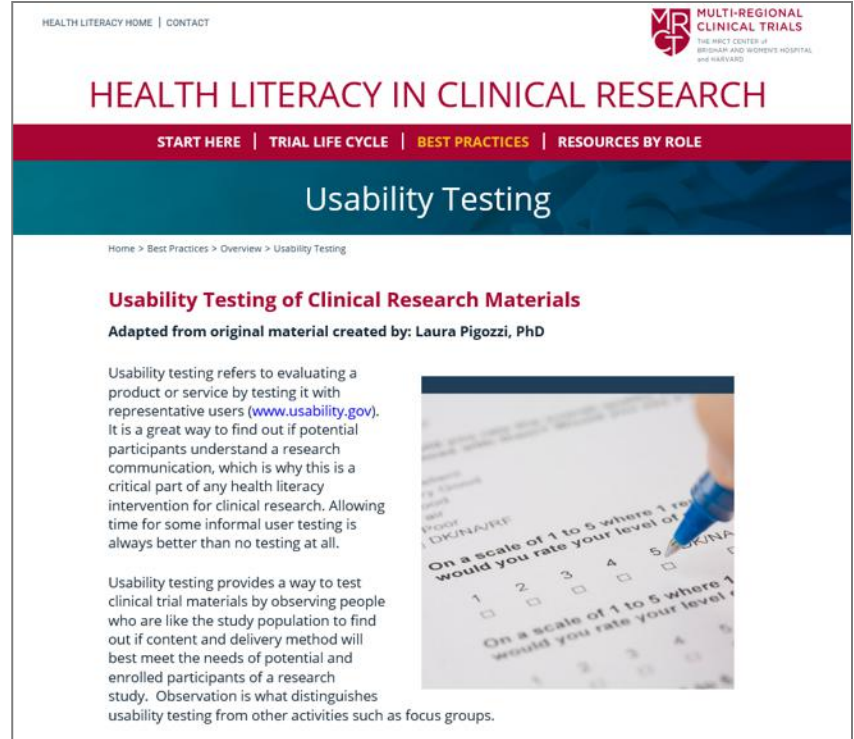


*<https://www.healthaffairs.org/doi/10.1377/hpb20130214.898775/full/>

**<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4391791/>

Usability Testing of Clinical Research Materials

- Get input on whether research materials, documents and/or processes work as intended.
 - Can the user complete a specific task or set of tasks?
 - Can the user answer questions about what the information actually means?



HEALTH LITERACY HOME | CONTACT

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HEALTH LITERACY IN CLINICAL RESEARCH

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Usability Testing

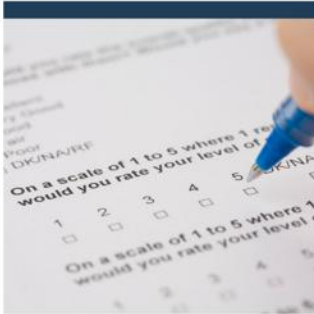
Home > Best Practices > Overview > Usability Testing

Usability Testing of Clinical Research Materials

Adapted from original material created by: Laura Pigozzi, PhD

Usability testing refers to evaluating a product or service by testing it with representative users (www.usability.gov). It is a great way to find out if potential participants understand a research communication, which is why this is a critical part of any health literacy intervention for clinical research. Allowing time for some informal user testing is always better than no testing at all.

Usability testing provides a way to test clinical trial materials by observing people who are like the study population to find out if content and delivery method will best meet the needs of potential and enrolled participants of a research study. Observation is what distinguishes usability testing from other activities such as focus groups.



Learn more at <https://mrccenter.org/health-literacy/tools/overview/usability-testing/>



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4) Learn from others

Research Teams are Applying Health Literacy Best Practice

HEALTH LITERACY HOME | CONTACT



HEALTH LITERACY IN CLINICAL RESEARCH

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

Case Study Library

Home » Best Practices » Overview » Case Study Library

Welcome to the Health Literacy Case Study Library

The MRCT Center has worked with stakeholders around the country to develop case studies and examples showing how health literacy has been integrated into various clinical research settings. Click on the presentations below to learn more about each case and key takeaways that could be applicable to your clinical research activities.

The MRCT Center is continuing to work with our stakeholders to create additional case studies. Check back soon to discover more examples of how health literacy has already been put into action. If you have a case to share, we invite you to [contact us](#).

List of cases on this page:



- Case Studies are a great way to learn more about what others are doing.
- Cases include:
 - Creating pediatric assent forms
 - Supporting participant retention
 - Developing informed consent templates
 - Implementing implicit bias exercises into staff training
- Do you have a case to share?

Learn more at <https://mrctcenter.org/health-literacy/tools/overview/casestudies/>

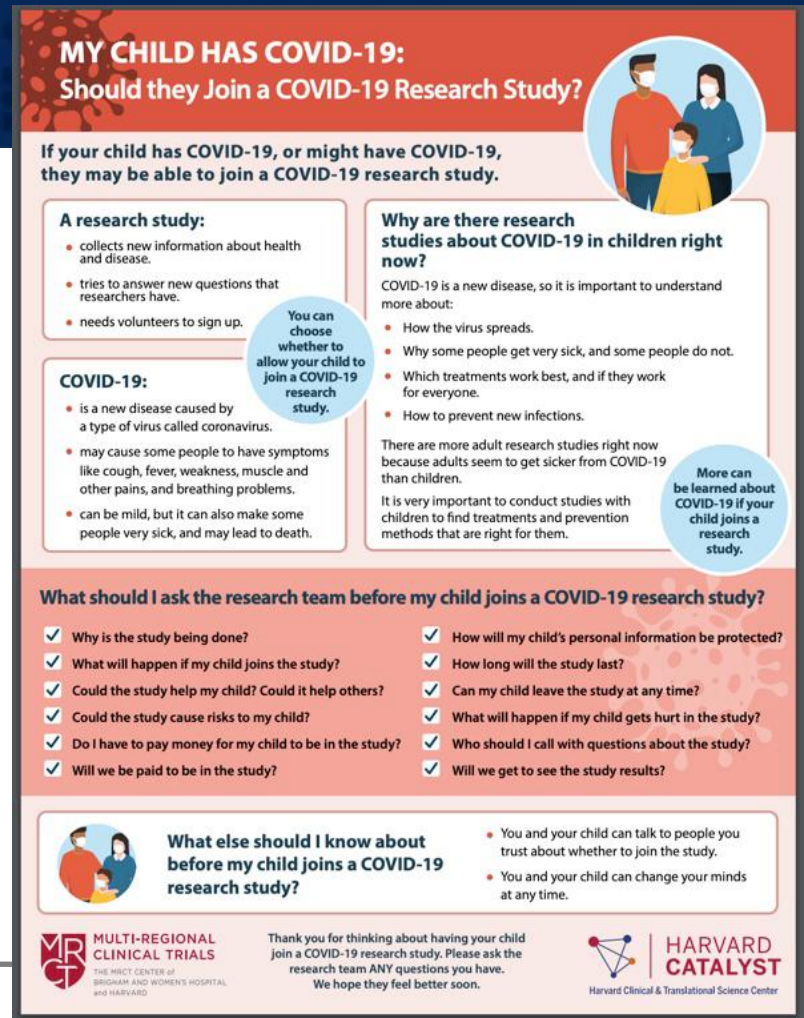


Example Recruitment Flyer

- Introductory research information can help people be better able to understand the details of your study
- Health literacy best practices were applied to develop introductory information like in this one on joining COVID-19 trials

<https://mrctcenter.org/blog/resources/covid-19-clinical-research-flyers/>

October 20, 2020



MY CHILD HAS COVID-19:
Should they Join a COVID-19 Research Study?

If your child has COVID-19, or might have COVID-19, they may be able to join a COVID-19 research study.

A research study:

- collects new information about health and disease.
- tries to answer new questions that researchers have.
- needs volunteers to sign up.

COVID-19:

- is a new disease caused by a type of virus called coronavirus.
- may cause some people to have symptoms like cough, fever, weakness, muscle and other pains, and breathing problems.
- can be mild, but it can also make some people very sick, and may lead to death.

Why are there research studies about COVID-19 in children right now?

COVID-19 is a new disease, so it is important to understand more about:

- How the virus spreads.
- Why some people get very sick, and some people do not.
- Which treatments work best, and if they work for everyone.
- How to prevent new infections.

There are more adult research studies right now because adults seem to get sicker from COVID-19 than children.

It is very important to conduct studies with children to find treatments and prevention methods that are right for them.

What should I ask the research team before my child joins a COVID-19 research study?

- ✓ Why is the study being done?
- ✓ What will happen if my child joins the study?
- ✓ Could the study help my child? Could it help others?
- ✓ Could the study cause risks to my child?
- ✓ Do I have to pay money for my child to be in the study?
- ✓ Will we be paid to be in the study?
- ✓ How will my child's personal information be protected?
- ✓ How long will the study last?
- ✓ Can my child leave the study at any time?
- ✓ What will happen if my child gets hurt in the study?
- ✓ Who should I call with questions about the study?
- ✓ Will we get to see the study results?

What else should I know about before my child joins a COVID-19 research study?

- You and your child can talk to people you trust about whether to join the study.
- You and your child can change your minds at any time.

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Thank you for thinking about having your child join a COVID-19 research study. Please ask the research team ANY questions you have.
We hope they feel better soon.

HARVARD
CATALYST
Harvard Clinical & Translational Science Center



Study Medication Instructions

- Study-specific instructions can help participants follow the requirements of the study
- Use health literacy best practices to develop instructions like this one on how to give yourself the study medicine

Merck & Co., Inc. example with input from Health Literacy Media

How to give yourself the study medicine

Panel A (Days 1-5) and Panel B (Days 6-10)

Study medicine

Each bottle holds 1 mL of active drug or placebo.

The study staff will tell you how much medicine to use each time (this is called your dose). Only give yourself the dose the study staff told you. Do not use all the medicine in the bottle.

The study staff will tell you how much to inject from each bottle.

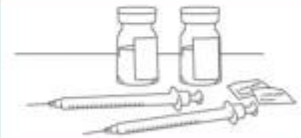
Important safety information

- Refrigerate the kit box – Do not freeze.
- Only use each bottle 1 time.
- Use a new syringe and needle each time.
- Only uncap the bottles when you use them.

Steps to give yourself the study medicine

Get ready

1. Gather your supplies:
 - 2 syringes
 - 2 bottles of medicine
 - 2 alcohol swabs
2. Take out 2 bottles from the kit box and put the kit box back in the refrigerator.
 - Let the bottles sit on the counter for at least 15 minutes to get to room temperature.
 - Turn the bottles upside down and then right side up at least 3 times.
3. Wash your hands with soap and water.





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5) Make a plan

What is one thing you learned that you plan to share with your colleagues?



Key Takeaways

- Each of us can play 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 research study planning
 - Preparation and planning for clear research communications starts early in the process.
- Engage patients and participants with the lived experience to co-create
 - Including the participant's input is an essential part of developing understandable study-related materials.
- There is no need to re-invent the wheel
 - Resources exist on the MRCT Center website!

Join us:



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Contact me at: sbaedorfkassis@bwh.harvard.edu



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Thank you!!