Health Literacy in Clinical Research Communications:
Tools and Techniques

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Objectives

- Review the ethical imperative for health literacy (HL) in communications, with particular attention to clinical research
- Highlight the benefits of HL to the quality and conduct of a clinical trial
- Discuss the value of participant feedback from study development through the end of study
- Use the participant’s journey through a clinical trial to introduce tools, technologies, and case examples to support HL communications
The **MRCT Center** is a research and policy center focused on addressing the conduct, oversight, ethics and regulatory environment for clinical trials.

**Vision**

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

- Academic credibility
- Trusted collaborator
- Independent convener
Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.
How we work

Focus Areas

Global Regulatory Engagement

Ethics, Conduct and Oversight

Transparency

Capacity Building

Identify Initiatives

Form Working Groups

Craft Solutions

Pilot Solutions

Implement & Adopt

Disseminate & Communicate

Revise & Improve

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Health Literacy in Clinical Research

Funders

Health literacy in clinical research workgroup

Sponsors, Investigators, and Study Teams

Institutional Review Boards

Health Literate Study Materials

Participants, Caregiver, Families

INCREASED TRUST

Communities

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Clear Communications in Clinical Research
Health literacy is a shared responsibility

- It is not just the responsibility of the person receiving information to try to make sense of it.
- The communicator is responsible for sharing information that is designed to be understood by the target audience.
- The intended audience should be comfortable expressing any lack of understanding.
- And beyond communicators, it is a *systems* problem:
  - Everyone in the clinical trial ecosystem can work to communicate more clearly with potential, enrolled and past research participants.
Health literacy is foundational to the ethical conduct of clinical research.

**Ethics**

- Respect for Persons
  - A right to understand
- Beneficence
- Justice
  - Equitable access to research

- Developing clear participant-facing communications is an ethical imperative
- Helps participants to understand, not just at the recruitment and consent phase, but throughout the study to the return of results.
Health literacy is essential to the scientific integrity and impact of clinical research

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<thead>
<tr>
<th>Science and Business</th>
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<tr>
<td>Generalizability</td>
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<tr>
<td>Proper Adherence and Follow-Up</td>
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<td>Data Validity</td>
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<td>Potential Cost Savings</td>
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<td>Potential Reduction in Liability</td>
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- Communicating clearly supports the inclusion of the population affected by the condition and likely to benefit from the research findings
- Better communication can enhance compliance and thus data validity
- Potential for increased retention and thus completion of the trial
Resistance to adopting clear communications is short-sighted

- In our experience the majority of clinical research stakeholders:
  - have resisted embracing health literacy, or
  - consider the creation of health literate materials to be outside their role and responsibility, or
  - have largely been silent on the issue.

- However, creating clear research communications simply require you to do the work you’ve already been doing in a somewhat different way.
Health literacy is a critical need within the clinical research enterprise.

Clear communication is essential throughout the entire clinical trial life cycle.

Move beyond health literacy → clinical trial literacy.
What does health literate clinical research look like?

Information gathered from participants inform future research studies

Building relationships with, and developing general research information for, the community of interest.

Supporting end of study communications and information sharing

Creating thoughtful (and multi-format) study-specific recruitment materials and procedures

Enhancing and promoting ongoing study participation

Providing detailed study information to support informed decision-making

Bilateral engagement and partnerships are always of benefit
The trajectory of a research study

- New Idea
- Study Design Protocol Development
- Recruitment and Consent
- Collect Data
- Last Patient Last Visit
- Close-out
- IRB & Other Regulatory Requirements
- Collect Data
- Analyze Data Interpret Results
- Communicate Results

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Tools and Techniques for Developing Clear Clinical Research Communications - Plain Language Summaries

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MRCT Center Health Literacy in Clinical Research Website
“Tell me what I need to know and make sure I understand. Tell me again tomorrow.”

- Patient considering research participation after a new cancer diagnosis

Clear communication promotes health literacy and leads to:

- an informed audience
- greater transparency
- increased trust
These principles of health literacy provide a basis from which to adopt and integrate health literacy practices into clinical research. They are intended to support clinical research stakeholders, including sponsors and funders, investigators and study teams, and Institutional Review Boards in their communications with potential, enrolled, and past participants.

Click here for more information on how you can integrate health literacy into your role.

Principles of Health Literacy in Clinical Research

1. All clinical research communications should be clear and easy to understand.

2. Clear communication is necessary throughout the clinical research
5. End of Study

Plain language summaries, results reports and publication of research findings.

At “End of Study,” all procedures and active follow-up visits are finished for the participant. Using health literate communications at the end of a study reinforces trust in the research establishment and demonstrates transparency and respect. End of study activities apply whenever a participant completes the study, decides to withdraw or is taken off for some other reason.

- At “End of Study,” the focus of the clinical research team is on ensuring:
  - data collection is complete
  - participants end their time in the study in a respectful and orderly manner.

The research study team should plan ahead. Consider what and how to share end of study information with participants early in study development.

- This is a time to express gratitude for the participant’s time and commitment, as well as provide any end of study information that might be interesting and/or useful such as details related to continued access to the study medication, if applicable.
- At “End of Study,” the study team should be prepared to share with participants, as applicable, information such as:
  - their own individual study results, if possible to be shared.
Plain Language

During the “End of Study” individual and overall research activities continue to include the plans earlier in the study process.

- Any information that may be updated after they finish the study medication should be stored.

At “End of Study,” the research team responsible for data collection is ensuring:
- data collection is complete
- participants end their time in the study in a respectful and orderly manner.

Clinical Study Results

Research sponsor:
Drug studied:
Study title: A study to learn the effect in the body and how safe it is in people with cardiovascular disease caused by atherosclerosis

Thank you!
Thank you to the participants who took part in the clinical study for the study drug (high blood pressure). You and all of the participants helped researchers learn more about a medicine to help people with cardiovascular disease caused by atherosclerosis.

In addition, the research team thanks the patients and families who participated in this study. We hope it helps you understand and feel proud of your important role in the medical research.

If you participated in the study and have questions about the results, please speak with the doctor or staff at your site.

What is happening with the study now?
You were in the study for up to 18 weeks. But the entire study took almost 11 months to finish.
The study started in January 2017 and ended in November 2017. The study included 32 patients in the United States.
The sponsor reviewed the data collected when the study ended and created a report of the results. This is a summary of that report.

Why was the research needed?
Researchers are looking for a better way to treat people who have cardiovascular disease caused by atherosclerosis. Before a drug can be approved for patients to take, researchers do clinical studies to find out how it works and how safe it is.

End of Study Visualization and Design Example

- Click the “full screen” icon in the top right corner of the image below to enlarge the example.
- Click the plus signs in the image for more information on what makes this document health literate, and how you can do the same in your own materials.
HEALTH LITERACY IN CLINICAL RESEARCH

INTRO | TRIAL LIFE CYCLE | TOOLS | PARTICIPANTS & PUBLIC | INSTITUTIONAL RESOURCES

Tools & Resources Overview

Home > Tools > Overview

This section provides more information on ways to apply health literacy throughout the clinical trial life cycle.

While the work of health literacy can be simple, this content is intended to raise awareness and boost confidence in your ability to apply health literacy to your role.

Applying health literacy is an iterative process. Whenever possible, work with experts, and keep building your skillset and knowledge by creating content, testing, revising, and learning along the way.

Click on the links to learn about resources for the following topics:

> Foundational Concepts

PUBLIC LIBRARY

Glossary

Case Study Library

Consent Guide

Visualization & Design

Usability Testing

Cultural Considerations

Interactive Techniques

Plain Language

Numeracy

Overview

RETURN OF RESULTS

Iterative process:

- recruitment flyers
- social media outreach
- consent forms and processes
- study procedure descriptions
- participant diaries
- study follow-up letters and reminder emails
- study summaries
- research conversations
Click on the links to learn about resources for the following content.

> **Foundational Concepts**

**Plain Language in Clinical Trials**

Information on techniques that are important for clear and effective communication. Plain language helps participants make informed decisions.

- **Remember**: Even those with higher health literacy levels can find the material understandable, meaningful to them, and easy to understand.

**Try some of these plain language tips:**

- 1. Logical organization and flow of content
- 2. Present only the most necessary information
- 3. Use common, everyday words
- 4. Use simplified terms and definitions
- 5. Use the Active Voice

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**Readability Testing**

Readability tests generally score how easy a piece of written material is to read by checking syllables, words, and sentences in the document. These scores often relate to the grade-level of schooling needed to understand the document.

Readability tests can help frame your revision process and tell you where you might need to make changes. But they are generally not considered to be sufficient on their own and do not necessarily equate to better understanding of the material.

**Testing your materials** with people like your study population, and including people with low literacy, is the best way to know whether your document is understandable.

- **Strengths and weaknesses of readability tests:**
- **Readability resources**

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**Beyond Readability – Use Assessments**

A best practice is to go beyond the readability formulas. Use assessment checklists to review specific criteria as part of the readability assessments.

Here are a few favorites:

- CDC Clear Communication Index
- Patient Education Materials Assessment Tool (PEMAT)
- Health Literacy Checklist

Tailor these to include criteria for assessment that are most relevant to determining whether the content is right for the intended audience.
Click on the links to learn about resources for the following:

> **Foundational Concepts**

> **Interpersonal Aspects**

**Interpersonal Aspects**
Resources to guide the development and testing of clinical research materials, as well as supportive verbal interactions.

**Teach-Back**
Teach-back is an interactive, evidence-based best practice for sharing information and checking understanding. It involves participants demonstrating knowledge by “teaching it back” to the person that explained it.

The spirit of teach-back can be woven into all interactions between participants and clinical research stakeholders.

**Teach-Back Overview**

1. **Share Information**
   Use simple terms to describe information in a way that meets the needs of you target audience

2. **Confirm Understanding**
   Ask the participant to use their own words and repeat/teach back what they just learned

3. **Rephrase or Clarify if necessary, and Reconfirm understanding**
   If the participant does not repeat back the key takeaways as they should have, try to convey the information differently and ask them to teach it back to you again.

4. **Move on and repeat**
   Once the participant has demonstrated adequate understanding, move on to the next topic and continue the teach-back process as necessary

**Teach-back is especially relevant:**
- During the informed consent process
- When reviewing study procedures and instructions
- When scheduling and organizing study visits
- When discussing adverse events and reactions
Click on the links to learn about resources for the following topics:

- **Foundational Concepts**
- **Interpersonal Aspects**
- **Actionable Applications**

**Actionable Applications**
Specific resources to further support putting health literacy into action.

- **Glossary**
  - See Resources
- **Consent Guide**
  - See Resources
- **Case Studies**
  - See Resources
- **Education and Training**
  - See Resources
- **Return of Results**
  - See Resources
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.

Download this fillable Return of Results template and adapt it to your study situation.

More information about previous MRCT Center work on Return of Results can be found here.
Additional Resources to Support Clear Research Communications
For the participant and public

- Participant Bill of Rights
- English video and handout

- MORE TO COME!

Research Participants’ Bill of Rights

The Participants Bill of Rights has been developed especially for people who want to learn more about what to expect when deciding whether to join a clinical research study.

Use this video and the related flyer to raise awareness and educate about clinical research.

Download a PDF of the Bill of Rights

*This material was adapted from pamphlets developed by the New England Research Subject Advocacy Group, with contributions from the affiliated universities and academic healthcare centers of member institutions. For more information see: http://catalyst.harvard.edu/regulatory/language.pdf.
Thousands of health care terms defined in plain, clear language to help you make informed decisions.

SEARCH BY WORD  - or - BROWSE BY LETTER

Search for a health care term...

Top 5 Terms

These words have been getting the most clicks. Do you see any that you need to understand, too?

1. EOB
2. deductible
3. HMO
4. Medicaid
5. out-of-pocket cost

Term of the Week

registered nurse

Also known as: RN

A person who has graduated from an accredited registered nursing program and has passed a state licensing exam.

Learn more about this term

Uniform Glossary

The Just Plain Clear® Glossary includes all the words in the Uniform Glossary established by the federal government.

View the Uniform Glossary

Also known as the Glossary of Health Coverage and Medical Terms. This was jointly developed by the Department of Labor and the Department of Health and Human Services.
Available in
- English
- Albanian
- Portuguese
- Arabic
- Italian
- Russian
- Cape Verdean
- Khmer/Cambodian
- Spanish
- French
- Korean
- Chinese
- Greek
- Polish
- Vietnamese
- Japanese

https://catalyst.harvard.edu/services/rsa/
Projects advancing health literate translation

Research Subject Bill of Rights
As a research subject, you have the following rights:
• To be treated in a caring and polite way.
• To be told what the study is trying to find out.
• To be informed what will happen, and whether any of the procedures, drugs, or devices are different from what we would use in standard medical care.
• To be told about possible side effects or discomforts that happen during the study.
• To be told if you can expect any benefit from being in the study.
• To receive a copy of a signed consent form.

Why Volunteer in Clinical Research?
• The development of new medical treatments and cures would be impossible without the active participation of research volunteers.
• By volunteering in a study, you will help others by contributing to medical research.
• You could also help researchers to learn about a disease or condition.
• In some cases, you can try a new treatment before it is available outside of research studies; however, these new drugs, procedures, or devices may or may not be more effective than the ones that are already available.

10 Questions to Ask Before Enrolling in a Study:
• Why is the research being done?
• What is expected of me if I agree to participate in the research?
• How will I benefit from the research?
• Could the research hurt me?
• What will the researcher do with my information?
• Will the research cost me anything?
• Who pays if I’m unexpectedly injured in the study?
• How long will the study last?
• What happens if I decide to leave the study early?
• Who should I call if I have a question about the research?

Informational Materials for Prospective Participants:
• 25 brochures developed
• 16 languages available

Questions? Call us at [phone number]
https://mrctcenter.org/blog/resources/2017-11-22-template-mrct-return-aggregate-results-participants-toolkit-version3-1/
Applying health literacy practices throughout the clinical trial process
The trajectory of a research study – where to integrate health literacy

Get to know about the study population

Ask members of the study population for feedback

Study Design Protocol Development

Recruitment and Consent

Last Patient Last Visit

Collect Data

Close-out

Analyze Data Interpret Results

Communicate Results

Provide additional information to support participation

Develop recruitment materials and consent forms using health literacy best practices

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Phasing of return of results

Pre-Study preparation
- New Idea
- Study Design
  Protocol Development
- IRB &
  Other Regulatory
  Requirements

Protocol Development
- Identify and Recruit

During the study
- Last Patient
  Last Visit
- Collect Data
- Analyze Data
  Interpret Results

When the study ends
- Close-out
- Communicate
  Results

- Organizational Preparation
- Level, timing, methodologies
- Address whether, what, when and how to return results
- IRB review and approval

- Introduce PLS
- Manage expectations
- Engage and communicate

- Prepare summary
- Website or outreach through PIs/sites
- Follow up
Clinical Research Communications Can Be Improved

Start here:

- Build health literacy into early study material development and involve other role groups, such as protocol drafters, consent form writers
- Engage members of the intended audience early and often
- Apply health literacy techniques, strategies and methods to the research communications you create for participants
- Re-engineer existing resources for your purposes
- Check out other summaries
- Test clinical research materials out before you finalize
- Continue to learn and improve your processes
- Bookmark the MRCT Center Health Literacy in Clinical Research website!
Takeaways

• Clear participant-facing communications are essential throughout the clinical research

• Preparation and planning for clear research communications, including plain language summaries, starts early in the clinical research process.

• Including the participant’s input is a critical part of creating understandable study-related materials, including plain language summaries

• Email me if you want an invitation to join the webinar launch of our website on October 21st at noon

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Thank you!!

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