

# Advancing Health Literacy in Clinical Research: Clear Communications for Every Participant

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## Introduction

One-third of the US population has health literacy levels that are basic or below basic [1]. This statistic, while surprising, is not unique to the United States: limited health literacy impacts access to appropriate health-related services around the world. The European Health Literacy Survey, for example, found that 12 percent of all respondents have inadequate general health literacy and 35 percent have problematic health literacy [2]. These numbers are likely higher in the clinical research context, given the complexity of clinical research information and the types of environments in which research conversations typically occur.

Clinical trials are an integral part of the practice of medicine and the delivery of health care. Clinical trials, and other clinical research, form the evidence base for many available treatment options and help determine whether the benefits of a new investigational treatment outweigh the potential risks. Further, comparative effectiveness research studies refine which existing clinical and public health interventions work best for improving health. The ethical design and conduct of all research involving human participants and their data rests on the premise that the participant understands and gives informed consent. Since consent and clinical trial participation are processes during which participants must be actively engaged, the development of clear and understandable materials to share with participants throughout their clinical research experience is crucial to successful study participation.

Supporting participant engagement in, and comprehension of, the clinical research process has become

a central focus both within the United States and beyond. The US Food and Drug Administration (FDA) draft guidance assembled in response to the 21st Century Cures Act, entitled "Patient-Focused Drug Development: Collecting Comprehensive and Representative Input," provides information on how stakeholders can collect and submit relevant experience and other data from patients and caregivers for medical product development and regulatory decision making [3]. In addition, the Revised Common Rule of the US Department of Health and Human Services requires that the informed consent form include 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 research" [4].

Further, recent regulations in Europe have mandated that reports containing end-of-study results be provided to research participants (after the regulatory effective date) [5]. Similar considerations within the United States are underway, as a draft guidance on the provision of plain language summaries of clinical trial results was submitted to the FDA in 2017 [6]. Some resources to support informed consent or other stages of clinical research already exist (for example, the US Agency for Healthcare Research and Quality's Informed Consent and Authorization Toolkit) [7]. Nevertheless, there was a need for an integrated and systems-based approach for providing clear and understandable clinical research information to research participants throughout the clinical trial.

**Figure 1 |** The Participant’s Journey through the Clinical Trial Life Cycle



**SOURCE:** Baedorf Kassis, S., S. A. White, L. Myers, C. Trudeau, and B. Bierer. 2019. Advancing health literacy in clinical research: Clear Communications for Every Participant. *NAM Perspectives*. Commentary, National Academy of Medicine, Washington, DC. <https://doi.org/10.31478/201910c>

**NOTE:** In general, a participant’s journey through the clinical research process involves the following phases: Discovery (learning about research as a concept and opportunities to contribute input on study design), Recruitment (considering invitations to join specific research studies), Consent (receiving written materials and engaging in verbal conversations with study team members to determine whether to participate in a research study), On Study (ongoing communications to support successful study follow-through), and End of Study (receiving instructions to support coming off the study, as well as reports of results when the study is complete).

**Figure 2 |** Screenshot of Health Literacy in Clinical Research Website - Discovery Phase Resources

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

- Ideally, many of these activities would occur prior to finalizing a study protocol
- Any materials and scripts used to introduce research concepts should ideally be subject to usability testing with the population of interest.

Click through the individual tabs below to learn more about how your “Discovery” research communications can be improved through plain language, numeracy, clear design and cultural considerations.

Plain Language | Numeracy | Clear Design | Cultural Considerations

**Plain Language**

- During the “Discovery” stage, use clear and simple language to explain general research concepts, like
  - What is research?
  - How is research different from medical care?
  - Should I be a research participant?
  - What are my rights if I participate in research?
- Use resources to support plain language explanations of clinical research:
  - Participant’s Bill of Rights to make potential participants aware of their rights
  - Research Pamphlets to describe research concepts and procedures
  - Glossaries for words that are more likely to be understood by the intended audience.

FIND OUT MORE ABOUT PLAIN LANGUAGE

**SOURCE:** <https://mrctcenter.org/health-literacy/trial-life-cycle/overview/discovery/>

**Table 1 |** A Description of the Stages of the Participant’s Journey through the Clinical Trial Life Cycle

Stage of Participant’s Journey through the Life Cycle	Brief Description	Clear Communication Opportunities
Discovery	Public awareness of, education about, and access to clinical research Study design that is relevant to the population being researched	<ul style="list-style-type: none"> <li>• Awareness campaigns</li> <li>• Outreach and engagement efforts to solicit patient input into study design and development</li> </ul>
Recruitment	Targeted, relevant, written, and verbal invitations to join research	<ul style="list-style-type: none"> <li>• Advertisements</li> <li>• Recruitment scripts</li> </ul>
Consent	Clear, written documents and verbal conversations about informed consent to participate in research	<ul style="list-style-type: none"> <li>• Consent scripts</li> <li>• Consent forms</li> <li>• Study schedules</li> </ul>
On Study	Clear information about ongoing research procedures, data collection, and reporting	<ul style="list-style-type: none"> <li>• Medication instructions</li> <li>• Study commitment contract</li> <li>• Adverse event reporting information</li> <li>• Participant satisfaction survey</li> </ul>
End of Study	Plain-language summaries, results reports, and research publications	<ul style="list-style-type: none"> <li>• Instructions for coming off trial</li> <li>• Instructions for maintaining access to treatment</li> <li>• Study results and summaries</li> </ul>

**SOURCE:** Baedorf Kassis, S., S. A. White, L. Myers, C. Trudeau, and B. Bierer. 2019. Advancing health literacy in clinical research: Clear Communications for Every Participant. *NAM Perspectives*. Commentary, National Academy of Medicine, Washington, DC. <https://doi.org/10.31478/201910c>

**Taking Action - Creating Resources for Clear Communications**

In April 2018, the Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard (MRCT Center) convened a workgroup of diverse stakeholders—including patients and representatives from industry, academia, foundations, patient advocacy groups, nonprofit organizations, and government entities—to examine the issue of health literacy in clinical research. Over 18 months, the workgroup identified the challenges that low health literacy presents within the clinical research environment. In response, the workgroup developed and curated content to harness the opportunities that two-way communication can have when integrated throughout the entire clinical research life cycle.

This content took the form of a suite of web-based resources that focus on five discrete stages of a partici-

part’s clinical trial journey (i.e., Discovery, Recruitment, Consent, On Study, and End of Study, see *Figure 1*). The content includes resources to help identify the potential health literacy opportunities in each stage. For example, at the research “Discovery” stage, broad and early outreach to communities using health literacy best practices can increase their awareness of clinical research and how their population may benefit from these studies (see *Figure 2*). Further, at the “Discovery” stage, researchers can integrate the patient voice into the design and development of a study question. During the “On Study” stage, participants can also be provided with carefully designed study medication instructions to facilitate compliance with the study procedures and minimize attrition. All such efforts help build trust in the clinical research enterprise and can support future study-specific recruitment.

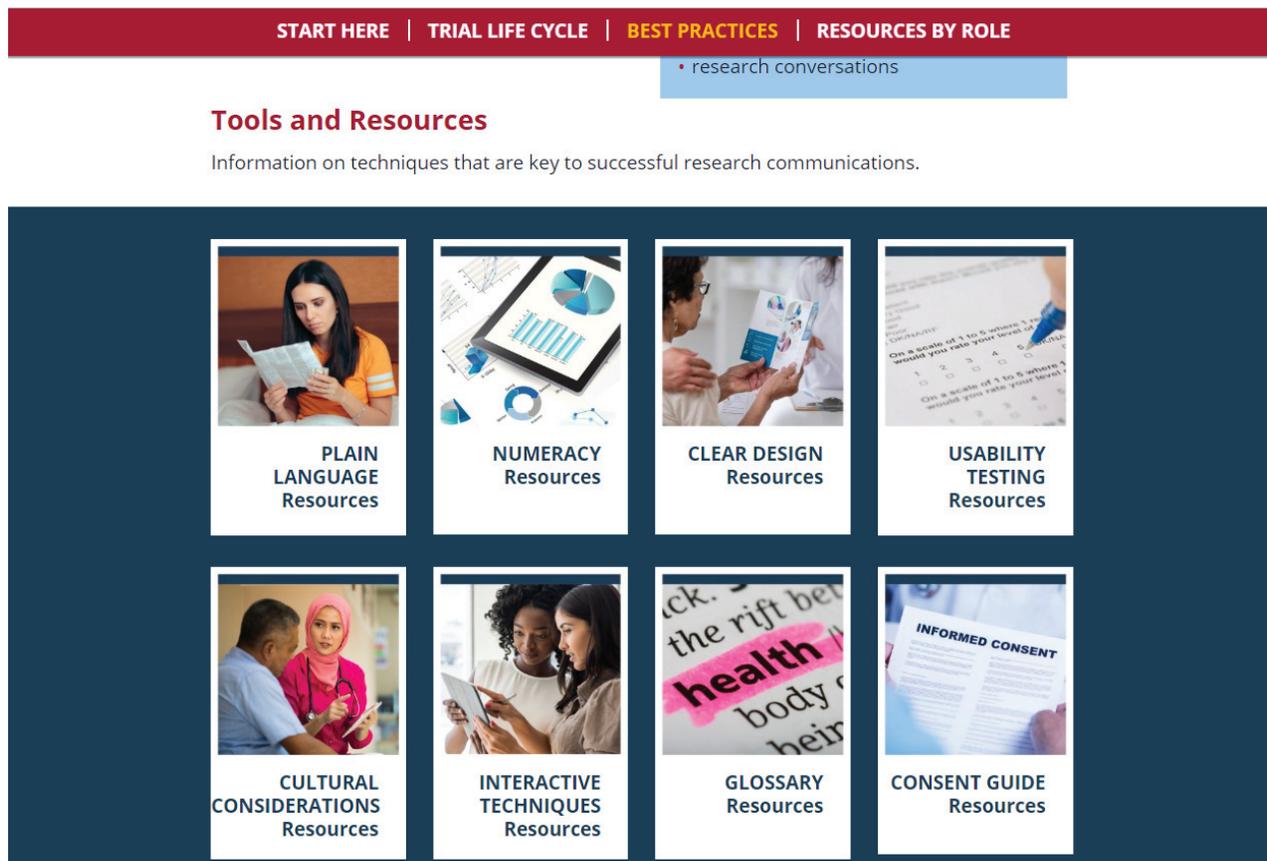
The workgroup designed targeted resources to help primary writers and reviewers of participant-facing materials, including funders, sponsors, investigators and their study teams, institutional review board members, and ethics committees. See *Table 1* for additional examples.

Underpinning all of the workgroup’s efforts is a broad definition of “health literacy” that extends beyond the widely cited individualistic definition (“a person’s ability to obtain, process, and understand basic health information and services needed to make appropriate health decisions”)[8]. Instead, the workgroup’s definition of “health literacy”, around which the Health Literacy in Clinical Research website ([www.mrctcenter.org/health-literacy](http://www.mrctcenter.org/health-literacy)) was designed, reflects the philosophy of a two-sided approach to health literacy and the need to expand the focus from participant understanding alone to the ability of communicators to present research information that is clear and understandable to

the intended audience of potential, enrolled, and past trial participants. This broad definition encompasses principles of plain language, numeracy, and clear design, as well as other components deemed essential to effective communications, including cultural considerations, usability testing of materials, and supportive verbal interactions (see *Figure 3*). Creating clear communications that integrate health literacy best practices involves more than simply writing at a sixth- to eighth- grade reading level; it involves integrating the feedback of the intended audience, considering their information and usability needs, and meeting those needs through tailored messaging.

Health Literacy in Clinical Research principles were developed by the workgroup to form the foundation upon which all website content was built, and they encourage individual and organizational change. Additional highlights from the workgroup’s suite of digital materials include a background information on health

**Figure 3 |** Screenshot of Health Literacy in Clinical Research Website - Health Literacy General Resources



**SOURCE:** <https://mrctcenter.org/health-literacy/tools/overview/>

**Figure 4 |** Screenshot of Health Literacy in Clinical Research Website - 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:

- > [Health Literate Consent Forms: Collaborating with the IRB](#)
- > [Environmental Health Literacy](#)
- > [A Health Literacy Approach to Developing Assent Templates for Pediatric Studies](#)
- > [Using Health Literacy to Improve Follow-Up Data Collection](#)
- > [Implementing implicit bias exercises for study staff working with African American caregivers of children with autism](#)



**SOURCE:** <https://mrctcenter.org/health-literacy/tools/overview/casestudies/>

literacy, practical ways to integrate health literacy best practices into written and oral communications throughout the clinical trial life cycle, and overarching considerations for implementation. Further, the workgroup developed a case study library containing proof of concept scenarios that include informative examples of health literacy implementation such as an academic center’s development of health literate consent templates, the process by which one pharmaceutical company created health literate pediatric assent forms, a study team’s effort to address implicit bias, improvement of follow-up data collection, and sharing study findings with participants (see *Figure 4*).

The workgroup focused on the inclusion of the patient and participant voice throughout the clinical trial life cycle, conducting usability testing of participant materials, and adapting communications to the needs of the community. Of note, the entire website underwent

a health literacy review, as well as tailored usability sessions with individuals representing industry, academia, institutional review boards and ethics committees, and patients who tested the website.

### Conclusion

Clinical research stakeholders who develop, review, and approve participant-facing study materials should integrate health literacy best practices throughout the clinical trial life cycle and across different professional roles. By raising awareness, supporting advocacy, and bringing together clinical research-focused health literacy information in one place, the website resources highlighted above can help all stakeholders create clear, understandable communications that support research participants throughout their clinical trial journey.

The work does not stop here. Additional tailored resources to support health literacy in clinical research will be added over time. In the near future, additional stakeholder-specific resources, including those tailored for participants will be developed. Sections of the Health Literacy in Clinical Research website will be further enhanced, including considerations of health literacy needs in other countries and materials for language translation. Working together, clinical research stakeholders can advance the systematic integration of health literacy best practices into all phases of clinical research.

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### Conflict-of-Interest Disclosures

**Laurie Myers** is an employee and stock holder of Merck Sharp & Dohme Corporation, a subsidiary of Merck & Co. **Christopher Trudeau** reports grants and personal fees from UAMS Translational Research Institute. **Trudeau** also has various independent consulting relationships with IRBs from Tufts University and the University of North Texas Health Science Center. **Trudeau** also does consulting work with CISCRP (the Center for Information and Study on Clinical Research Participation). Finally, **Trudeau** is a special government consultant for the FDA's Risk Communication Advisory Committee.

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