Plain language training customized for researchers

[1]Jessica R. Ridpath, BA; [1]Sarah M. Greene, MPH; [2]Cheryl J. Wiese, MA • [1]Group Health Research Institute, [2]University of Michigan Institute for Social Research

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THE REASON

Informed consent is the foundation of ethical research. And an understandable consent form is central to a thoughtful, participant-centered consent process. It serves both as a guide for study staff who administer informed consent and as the study participant's enduring record of procedures and risks.

Federal regulations require that consent forms be "understandable to the subject," and institutional review boards (IRBs) typically recommend a reading level of 6th-8th grade for consent forms—a standard consistent with literacy assessment data that shows an average 8th-grade reading ability among American adults. But a 2003 study found that college-level research consents were common at US medical schools—and that only 8% of forms met institutional readability standards.

Creating complicated consent forms is not intentional—it's a factor of many readability challenges unique to research.

- Researchers are accustomed to writing for the scientific community, so plain language writing may not be intuitive
- Medical jargon PLUS research terminology, like "randomization" and "equipoise"
- Clinical trials often have complex and variable procedures—which hinders template development
- Emerging genomic research involves difficult-to-explain issues of long-term sample storage and future use
- Complicated legal clauses and other language may be mandated by the institution, sponsor, or IRB

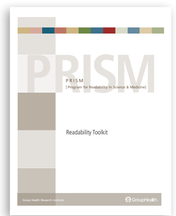
Researchers need flexible, easy-to-use readability tools built around these challenges.

THE RESOURCE

Group Health Research Institute (GHRI) created the Program for Readability In Science & Medicine (PRISM) in 2005 to address health literacy challenges in the research setting. PRISM quickly evolved from a short-term, internal readability training initiative into a suite of customized resources designed to help researchers create easier-to-read participant materials, especially consent forms.

The PRISM Readability Toolkit:

The 81-page toolkit is a public-domain handbook for researchers illustrating how to use plain language in participant materials.



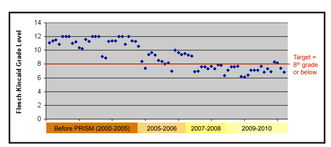
What the PRISM Toolkit provides:

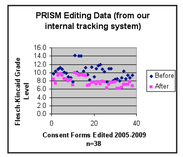
- Plain language principles and strategies
- Quick reference guide and editing checklist
- Alternative wording suggestions
- Before-and-after examples
- Easy-to-read template language for consent forms and HIPAA authorizations
- Links to other helpful resources

The PRISM Toolkit is posted on dozens of websites and included in several health literacy resources guides. It is the #1-downloaded item on GHRI's public website, **www.grouphealthresearch.org.**

PRISM Editing & Consultation

The goal of PRISM editing is to create consent forms and other participant materials that are clear, readable, and well organized. PRISM editing at GHRI has improved consent form readability dramatically.





What PRISM editors do:

- Replace jargon and other complex terms with familiar vocabulary
- Create single-topic paragraphs and concise sentences
- Use reader-friendly formatting
- Achieve a target of 8th grade or below in nearly all cases

PRISM editing is free to GHRI researchers and their collaborators. Fee-for-service editing for external research teams is also available.

PRISM Training Workshops

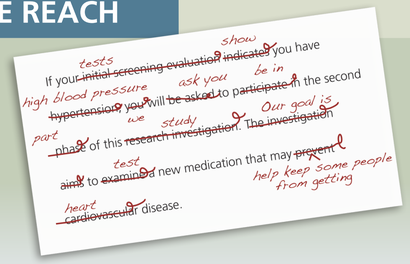
PRISM training takes the skills and knowledge built into the PRISM toolkit and editing service and packages them into a modular, hands-on workshop that can be customized to meet audience needs.

How PRISM training builds skills:

- Explains readability assessment strategies
- Illustrates plain language through before-and-after examples
- Involves participants in hands-on editing exercises
- Provides take-home tools that participants can use right away

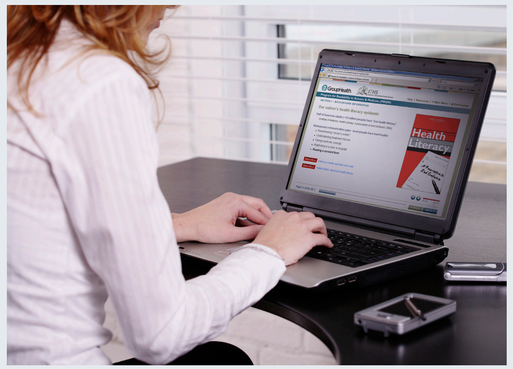
For more information, email us at prism@ghc.org

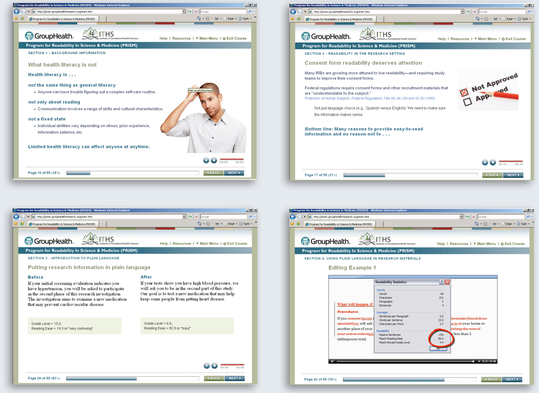
THE REACH



Originally an internal initiative, PRISM gained unexpected traction across the research community—prompting GHRI and the University of Washington's Institute for Translational Health Sciences* to help further its reach by creating an online training module.

Introducing PRISM Online Training—a **FREE** resource that translates PRISM's in-person workshop into a Web-based tutorial accessible to researchers everywhere.





Access PRISM Online Training at
http://prism.grouphealthresearch.org

The course was designed for a wide range of research professionals, including scientists, research staff, IRB administrators, communications staff—or anyone involved in developing print materials for study participants.

The hour-long workshop includes four sections:

1. Background on health literacy and readability
2. Readability challenges in research settings and links to helpful tools
3. Plain language strategies and examples from participant materials
4. Interactive editing examples and exercises

* PRISM Online Training is supported in part by grant UL1 RR025014 from the NIH National Center for Research Resources.

THE ROAD AHEAD

One principle of the U.S. Department of Health and Human Services' 2010 *National Action Plan to Improve Health Literacy* is that everyone has the right to health information that helps them make informed decisions. Informed consent for research is no exception to this ideal—but research consent forms are often plagued by exceedingly high reading levels. Even though online readability resources abound, few address the specific readability challenges posed in the research setting. Without concrete guidance and real-world examples, easy-to-read consent forms have remained the exception rather than the rule. PRISM resources helped change this trend at GHRI, and we hope our new online training module can help change it at other research institutions, as well.

As we continue to proactively disseminate PRISM Online Training and other PRISM tools, we look forward to some important next steps:

- Evaluating traffic to the online course
- Improving the course based on user feedback
- Conducting focus groups and other qualitative research with study participants to better gauge PRISM's overall usefulness