Health Literate Consent Form Templates: Collaborating with the IRB

A Case Study from the University of Arkansas for Medical Sciences, developed with the MRCT Center
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The Opportunity:

The University of Arkansas for Medical Sciences (UAMS) noticed that its research consent forms could be improved.

“They were at too high of a reading level and there was little chance that potential participants could understand them.”

-Dr. Kristie Hadden, Executive Director
UAMS Center for Health Literacy (CHL)
UAMS started working:

1. Raise Awareness
2. Perform Readability Assessments
3. Provide Education
4. Develop a Health-Literate Consent Template
5. Get Participant Feedback Through User Testing
1. Raise Awareness

UAMS’s Center for Health Literacy (CHL) knew that no one was working on health literacy in informed consent documents.

There was an opportunity for the Institutional Review Board (IRB), UAMS’s Translational Research Institute*, and others to understand the impact of low health literacy on participant understanding and research studies overall.

* The UAMS Translational Research Institute is supported through a Clinical and Translational Science Award from the National Center for Advancing Translational Sciences of the National Institutes of Health, grant #UL1TR000039.
2. Perform Readability Assessments

A key to success was data: existing investigator-initiated consent forms were run through a detailed readability assessment.

The average reading level of U.S. adults is 6-7th grade.
Most consents were written at a 10th grade mean readability level, too high for the average person.
CHL raised awareness about integrating health literacy into the research consent process by:

- Presenting at Grand Rounds
- Holding lectures and presentations for UAMS’s Translational Research Institute, its Biomedical Science Division, the College of Public Health, and the Arkansas Department of Health.
- Requiring health literacy education for all students starting any degree program at UAMS through its Interprofessional Education (IPE) program.

These helped **build the foundation** for embracing health literacy on the clinical and research sides of UAMS.
To ease adoption of health literacy, the CHL developed a health-literate research consent template, focused on investigator-initiated studies.

This template includes all the requirements of the Federal research regulations, and the template’s common language is written at about the 5th grade reading-level.
5. Get Participant Feedback Through User Testing

Experts at CHL conducted focus-group testing of the template with people having low and average health literacy using a method called **stoplight coding**:

Focus group participants circle in **red** what is too hard, highlight in **green** things that are easy, and highlight in **yellow** the content that made them pause.

Who helped make this happen?

Institutional Review Board
- Helped develop the health literate consent template and co-authored research about the topic.
- Strongly encouraged use of the template, increasing adoption.

UAMS’ Translational Research Institute
- Helped create the health-literate consent template.
- Increased adoption through educational sessions and e-newsletters/announcements.
- Provided funding for a validation study that demonstrated the effectiveness of the template.

Center for Health Literacy
- The Executive Director personally educated stakeholders and encouraged implementation
- Helped develop the consent template and conduct focus-group testing.
- Health-literacy lawyer further developed and updated the form for Common Rule compliance.
Successes

• The average reading level of research consent forms using the template is now below the 8th grade level.

• The current adoption rate of the new consent template is increasing thanks to the promotional efforts of TRI and the IRB.

• Much greater awareness of the importance of health literacy in consent for all researchers.

Challenges

• Increasing the use of the health-literate form.
  • Although the adoption rate is increasing thanks to increased researcher awareness

• The people who are using the consent form templates for their studies may not really understand or know how to implement health literacy.
  • The study specific language that investigators write often makes the consent form harder to read and understand.

Solution: UAMS CHL started offering review & editing services for consent forms to increase understandability and lower the grade level
Lessons Learned

✓ It was vital to work with IRB as a **true partner:**
  - Engaging them in every step
  - Making them co-investigators and co-authors in the investigation of consent form reading levels.

✓ **Review & editing services** for consent forms helped to increase understandability and reduce readability levels.

✓ The health literacy process is **iterative.**
  - Seemingly small steps can help motivate the adoption of health literacy principles in clinical research.

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Recommendations

Engage the IRB as a partner from the beginning. After all, IRB shares the common goal of creating consents that all participants can understand.

- Engage IRB members in research projects related to consent and human subjects research to help build collaborative relationships.
- These relationships are important to initiating and sustaining health literacy changes at the oversight level.

Increase Awareness

- Engage with research groups (for example, CTSAs) or departments to increase awareness of the importance of health literacy across the research continuum.
- Give examples of how to incorporate health literacy measures into research projects.

Provide Education

- Provide lectures/grand rounds for researchers, practitioners, and students in all health professions. Keep health literacy at the top of their minds.
Resources

Stoplight Coding:

UAMS consent form template*:
http://irb.uams.edu/new-study-tools/

MRCT Center Health Literacy in Clinical Research consent information:
https://mrctcenter.org/health-literacy/trial-life-cycle/overview/consent/

*This template is frequently updated based on what we learn from user testing and researcher experience. So please check back often to get the most up-to-date version.

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