Integrating Health Literacy into the Informed Consent Process: Tips for Developing Understandable Consent Materials

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• The opinions expressed are those of the author(s) and/or presenter(s) and are not intended to represent the position of Brigham and Women's Hospital, Harvard University, or University of Arkansas Little Rock, Bowen School of Law.

• We have no personal conflicts of interest relevant to this presentation.
Objectives

• By the end of the session, attendees should be able to:
  – Describe what health literacy is and its relevance to clinical research.
  – Explain how health literacy best practices can be integrated into different phases of the clinical research life cycle.
  – Identify strategies for creating clear, understandable informed consent forms that comply with the Revised Common Rule.
Background
The Health Literacy Opportunity

- Literacy levels are concerning around the world.

- A person’s health literacy affects their ability to:
  - Access services and information
  - Understand and follow health-related instructions
  - Make appropriate health-related decisions

9/10 people in the US need extra help

From: https://nces.ed.gov/naal/kf_demographics.asp
The Evolving Health Literacy Definition

Individual Skills

“Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions.”

Societal Responsibility

“Health literacy occurs when a society provides accurate health information and services that people can easily find, understand, and use to inform their decisions and actions.”


A Broad View of Health Literacy
The Potential of Applying Health Literacy Best Practices

- Improved adherence to study procedures
- Higher levels of satisfaction in the research experience (and presumably, a better chance of research being recommended to others)
- Increased participation in studies
- Greater awareness of research
- Reduced participant attrition
Health literacy fulfills key ethical research principles

- Respect for Persons
  - A right to understand
- Beneficence
  - An effort to reduce harm
- Justice
  - Equitable access to research
The Clinical Research Life Cycle
Clear communication is essential throughout the participant’s clinical research journey.
Integrating Health Literacy Principles

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

**DISCOVERY**
Building relationships and sharing general research information with the community

**RECRUITMENT**
Creating thoughtful study-specific recruitment materials and processes

**CONSENT**
Providing detailed study information to support informed decision-making

**END OF STUDY**
Sharing end of study communications and information

**ON STUDY**
Applying tools to support ongoing study participation
<table>
<thead>
<tr>
<th>Stage of Journey through the Life Cycle</th>
<th>Examples of Clear Communication Opportunities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Discovery</strong></td>
<td>- Research awareness campaigns</td>
</tr>
<tr>
<td></td>
<td>- Outreach and engagement efforts to solicit patient input into study design and development</td>
</tr>
<tr>
<td><strong>Recruitment</strong></td>
<td>- Advertisements</td>
</tr>
<tr>
<td></td>
<td>- Recruitment scripts</td>
</tr>
<tr>
<td><strong>Consent</strong></td>
<td>- Consent scripts</td>
</tr>
<tr>
<td></td>
<td>- Consent forms</td>
</tr>
<tr>
<td></td>
<td>- Study schedules/calendars</td>
</tr>
<tr>
<td><strong>On Study</strong></td>
<td>- Study medication/intervention instructions</td>
</tr>
<tr>
<td></td>
<td>- Study commitment contract</td>
</tr>
<tr>
<td></td>
<td>- Adverse event reporting information</td>
</tr>
<tr>
<td></td>
<td>- Participant satisfaction survey</td>
</tr>
<tr>
<td><strong>End of Study</strong></td>
<td>- Instructions for coming off trial</td>
</tr>
<tr>
<td></td>
<td>- Information on maintaining access to treatment options</td>
</tr>
<tr>
<td></td>
<td>- Study results/summaries</td>
</tr>
</tbody>
</table>

October 21, 2021
Applying Health Literacy to the Informed Consent Process
Consent Guide

Applying Health Literacy to Informed Consents for Research:

Quick Tips for Clearly Explaining the Requirements

Adapted from original material created by: Christopher R. Trudeau, JD

Creating consent materials that people can understand involves not only thinking about the content needed, but also how that content will be worded, ordered, and presented. Consent form content is always important, yet due to recent regulatory changes that emphasize clarity, consent forms will be reviewed more closely by Institutional Review Boards/Ethics Committees (IRB/ECs), government regulators, and, sometimes, even in courts.

Using health literacy best practices, we can do more with consent forms than simply ensuring regulatory compliance.

Find out how to:

Find it here:

https://mrctcenter.org/health-literacy/tools/overview/consent-guide/
Consent is a Process – Not Just a Form
✓ It is a **conversation** about whether to participate in the trial after learning the risks, benefits, alternatives, etc.

✓ The “informed” portion of the consent does **not** come from the signature indicating “consent.”
The three ions of consent processes

- Conversation
- Education
- Documentation
Think about the audience

What do we know about this specific study population?

Can we involve a subset of them in the creation process on the front end? User test with them after creation?
People in clinical trials may:

- Be worried, stressed, concerned
- Have trouble reading and processing
- Have little to no experience with clinical trials
Navigating the Requirements in the Revised Common Rule
<table>
<thead>
<tr>
<th>Covered? Location?</th>
<th>Basic Requirements</th>
<th>Covered? Location?</th>
<th>If-Applicable Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. Purpose and explanation of the research</td>
<td></td>
<td>10. That there are unknown or unforeseeable risks</td>
</tr>
<tr>
<td></td>
<td>2. Risks &amp; foreseeable discomforts</td>
<td></td>
<td>11. If and when involuntary removal from study is possible</td>
</tr>
<tr>
<td></td>
<td>3. Benefits (to person &amp; others)</td>
<td></td>
<td>12. Additional costs that may be expected by participating</td>
</tr>
<tr>
<td></td>
<td>4. Alternatives that might also help the participant.</td>
<td></td>
<td>13. Consequences of early withdrawal from study</td>
</tr>
<tr>
<td></td>
<td>5. Extent confidentiality will be maintained</td>
<td></td>
<td>14. If significant findings will be provided</td>
</tr>
<tr>
<td></td>
<td>6. Compensation &amp; treatment available if complications</td>
<td></td>
<td>15. Approx. number of people in the study.</td>
</tr>
<tr>
<td></td>
<td>7. Contact info for questions about research</td>
<td></td>
<td>16. [new] whether clinically relevant research results will be disclosed and under what conditions.</td>
</tr>
<tr>
<td></td>
<td>8. Participation is voluntary and there will be no loss of benefits if decline</td>
<td></td>
<td>17. [new] whether biospecimens might be used for commercial profits – even if identifiers are removed.</td>
</tr>
<tr>
<td></td>
<td>9. [new] One of these: (a) The subject's information or biospecimens will not be used or distributed for future research studies even if identifiers are removed. OR (b) That identifiers might be removed and the de-identified information or biospecimens will be used for future research without additional informed consent.</td>
<td></td>
<td>18. [new] If biospecimens research, whether research will or might include whole genome sequencing.</td>
</tr>
</tbody>
</table>
People can’t figure me out, they can’t process me. I don’t expect them to. You can’t process me with the normal brain.

Charlie Sheen
How do you know if something is understandable?

✓ Clarity matters not length.

82 Fed Reg 12 at p. 7265 & SACHRP Commentary

✓ Information should be understandable to a “reasonable person”

✓ “The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.” (emphasis added)

82 Fed Reg 12 at p. 7265
Who is the reasonable person?

• A very common standard in the law – been part of clinical consent for 100+ years.

• SACHRP: “The reasonable person concept recognizes that it is impossible for researchers to determine what information every individual participant would consider helpful in deciding whether or not to participate.”

• “Instead, it asks researchers to include what reasonable people in the same or similar circumstances would want to or need to know.”

Health literacy helps determine what a reasonable person would understand.

Learn from health literacy research & practice – we know a lot more now about what people do and do not understand because of it.

User testing should become a standard practice to determine where your study population may struggle. (Involve study pop from the beginning.)
Consent must BEGIN with “key information”

“Informed consent must begin with 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 the research.

This part of the informed consent must be organized and presented in a way that facilitates comprehension.”

82 Fed Reg 12 at p. 7265
The preamble to the new Common Rule lists the following elements to begin with:

– Consent is for research and participation is voluntary.
– Purpose, duration, and procedures to be followed.
– Reasonably foreseeable risks or discomforts.
– Alternatives to the research that might be advantageous to the subject.
– Benefits to subject or others.
Flexibility & creativity are encouraged

Because there is great variability across clinical trials, there may be great variability in the choice and presentation of key information. Concern about variability should be balanced with recognition of the importance of flexibility. The existing system of drafting consent forms and obtaining consent has become stagnant, and it needs to improve.

Because the key information requirement will apply to a broad range of research studies being conducted with many diverse populations of research subjects, SACHRP does not believe that there are any elements of consent that would never be appropriate as an item of key information.

Don’t ignore how being in this study will impact participants’ daily lives

SACHRP further notes that existing elements of consent, and traditional approaches to consent, have emphasized benefit and risk, but have not given similar attention to burdens or to the impact of participation in research on an individual’s normal life activities.... In many cases, impact is certain, but benefits and harms are not.

In many studies discomforts and inconveniences, rather than risks, might be key information. Examples include, “you will have to avoid exposure to sunlight for four months,” “all of your hair will fall out,” “you will not be able to drink alcohol for six months,” “you should avoid sexual contact” or “you will have 20 study visits.”

1. **What are your study population’s needs?**
   - Think of health literacy needs, life & health circumstances, etc.
   - Don’t think about what you think is important or where you are concerned about liability – be participant-centered.

2. **How can you involve your study population in the creation or vetting process?**
<table>
<thead>
<tr>
<th>Most Important Information Influencing Decision to Participate</th>
<th>Percent Rate “Very Important”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential risks and benefits</td>
<td>83%</td>
</tr>
<tr>
<td>Purpose of the clinical research study</td>
<td>75%</td>
</tr>
<tr>
<td>Types of medical procedures required</td>
<td>73%</td>
</tr>
<tr>
<td>If my confidentiality would be protected</td>
<td>63%</td>
</tr>
<tr>
<td>Physical location of the research study center</td>
<td>60%</td>
</tr>
<tr>
<td>Potential costs and reimbursements</td>
<td>57%</td>
</tr>
<tr>
<td>Length of participation</td>
<td>56%</td>
</tr>
<tr>
<td>If I would receive a summary of the study results after my participation ended</td>
<td>56%</td>
</tr>
<tr>
<td>Being provided with supporting information on managing my health condition in general</td>
<td>53%</td>
</tr>
<tr>
<td>Being provided with supporting information on the clinical research study</td>
<td>54%</td>
</tr>
<tr>
<td>Duration of each study visit</td>
<td>50%</td>
</tr>
<tr>
<td>Number of study visits</td>
<td>48%</td>
</tr>
<tr>
<td>If I would have access to the study drug after my participation ended</td>
<td>47%</td>
</tr>
</tbody>
</table>

Source, CISCRP, All Respondents, Study N=12,427, 2017
<table>
<thead>
<tr>
<th>MOST LIKED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Helping advance science and the treatment of my disease/condition</td>
</tr>
<tr>
<td>Helping others who may have my disease/condition</td>
</tr>
<tr>
<td>The compensation (money) I received</td>
</tr>
<tr>
<td>The amount of care and attention that I received from the study doctors and staff</td>
</tr>
<tr>
<td>My relationship with the study staff</td>
</tr>
<tr>
<td>Access to new, cutting-edge treatment:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LEAST LIKED</th>
</tr>
</thead>
<tbody>
<tr>
<td>There was nothing I didn't like about my clinical study experience</td>
</tr>
<tr>
<td>The possibility of getting a placebo</td>
</tr>
<tr>
<td>The location of the study center was too far or not convenient</td>
</tr>
<tr>
<td>The study visits were too time-consuming</td>
</tr>
<tr>
<td>The side effects of the study drug</td>
</tr>
<tr>
<td>The compensation (money) I received was not enough</td>
</tr>
</tbody>
</table>

Source: CISCRP, Those Participated in Clinical Research Study, N=2,194, 2017
The MRCT Center’s Commitment to Health Literacy

In 2019 the MRCT Center launched a publicly available website on Health Literacy in Clinical Research.

- Developed by a multi-stakeholder workgroup
- Designed for research professionals
- Provides ways to take action in your own clinical research role

www.mrctcenter.org/health-literacy
Health literacy can support the participant through the 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

- **PLAIN LANGUAGE** Resources
- **NUMERACY** Resources
- **CLEAR DESIGN** Resources
- **USABILITY TESTING** Resources
- **CULTURAL CONSIDERATIONS** Resources
- **INTERACTIVE TECHNIQUES** Resources
- **GLOSSARY** Resources
- **INFORMED CONSENT** Resources
- **CASE STUDY LIBRARY** Resources
- **EDUCATION & TRAINING** Resources
- **RETURN OF RESULTS** Resources
- **RESEARCH PARTICIPANTS’** Resources

[www.mrctcenter.org/health-literacy](http://www.mrctcenter.org/health-literacy)
Helping you understand clinical research

Welcome to the Clinical Research Glossary. This glossary is a list of research words and their meanings. Use this glossary to learn more about words that are used in research studies.

VIEW ALL WORDS

Use the "search" menu to find a word’s meaning and other information.

Search Glossary...
**Informed consent**

The process of learning and discussing the details of a research study before deciding whether to take part.

*How to say:* Informed consent

**Randomization**

A way to use chance to place study participants into different study treatment groups.

*How to say:* Randomization

**USE IN A SENTENCE**

Informed consent helps people understand what will happen if they become a participant and what their rights are.

**MORE INFO**

Informed consent is an ongoing conversation before someone can participate in a study and learn all the information about the study changes.

Informed consent is a process to make sure that each participant is selected fairly and similarly. A consent form is used as part of the informed consent process.

**USE IN A SENTENCE**

Researchers use randomization to make sure that study groups are chosen fairly and similar.

**MORE INFO**

Every participant has a chance to be put into one of the study groups. No one can choose which group a participant is placed in, because it is done by a computer program.

Randomization helps make sure the study groups can be compared against each other at the end of the study. This is a way to avoid bias.

**WORDS RELATED TO INFORMED CONSENT**

- consent
- consent form

**WORDS OPPOSITE TO INFORMED CONSENT**

- bias
- blinded
- random assignment
- randomize
- randomly assigned
- study arm

**OTHER RESOURCES**

- FDA Resource for Patients: "Informed Consent for Clinical Trials"
- Exploring Randomization in Clinical Trials
Are you sure that the participant-facing materials you review and approve are clear to participants?

The MRCT Center has developed two health literacy resources specifically for Human Research Protection Programs (HRPPs) and Institutional Review Boards (IRBs).

- Health Literacy Training for IRBs
- Health Literacy Checklist for IRBs

IRBs can play an important role in supporting research study participants by applying health literacy best practices to their reviews of participant-facing materials.

NOTE: These materials are currently being piloted. If you have feedback please email mrct@bwh.harvard.edu, and check back soon for updated versions!
Consent Example
An example of making something more understandable

**Before:**

We are conducting a research study in order to determine the current status of the psychosocial and health problems due to SARS-CoV-2 (COVID-19) faced within our patient community and to implement a brief online intervention based on Cognitive Behavior Therapy techniques and measure its effect. Study subjects will be assessed by completing a battery of psychological tests at various timepoints throughout the study.

**After:**

In this research study we want to learn more about what kinds of health and wellness problems people are having due to COVID-19.

We also want to know whether a few short mental health lessons offered on the internet could help with any of these problems.

We will use some surveys during the study to find out if people in the study start to feel better after viewing the lessons.
Key Takeaways

✓ Each of us plays 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 planning
  • Preparation and planning for clear research communication starts early in the process.

✓ Practice makes perfect better.
  • Remember, even small improvements can help you better connect with more research participants.

October 21, 2021
Thank you!
Questions?