Community-based Participatory Research

Part 5: Informed Consent
May 4, 2021
HRPP (Human Research Protection Program)

**ELEMENT 1.4.C.**

The organization promotes the involvement of community members, when appropriate, in the design and implementation of research and the dissemination of results.

**ELEMENT 1.1.E.**

The organization has an education program that contributes to the improvement of the qualifications and expertise of individuals responsible for protecting the rights and welfare of research participants.
Consent Overview

Nan McMurry, IRB Member
Subjects as Objects: A Troubled History

• Nazi Experiments on Concentration Camp Inmates

• U.S. Public Health Service Study of Untreated Syphilis (1932-1972)

• Willowbrook Studies (1956-1970)

• Jewish Chronic Disease Hospital Study (1963)
Building Protections for Human Subjects

• National Research Act (1974)

• Ethical Principles and Guidelines for the Protection of Human Subjects of Research (Belmont Report, 1979)

• 45 CFR 46: Regulations for the Protection of Human Subjects of Biomedical and Behavioral Research
Belmont Principles and Consent

- Respect for Persons
- Justice
- Beneficence
Consent: From the classroom to candidacy

Miranda Hill, PhD, MPH & Nathan Hansen, PhD
AGENDA

Background ➔ Community Engagement & Consent ➔ Reflection
BACKGROUND

Transgender women’s **social network support for medication adherence (TRANSSFORM)**

- Transgender woman: broad term used to describe women or people of another feminine identity who were assigned male sex at birth
- National online social network study

<table>
<thead>
<tr>
<th></th>
<th>General Population</th>
<th>US Transgender Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poverty</td>
<td>12%</td>
<td>29%</td>
</tr>
<tr>
<td>Unemployment</td>
<td>5%</td>
<td>15%</td>
</tr>
</tbody>
</table>

Source: James et al., 2016

COMMUNITY ENGAGEMENT & CONSENT

Sustained community engagement led to changes in recruitment & consent

- Partnership with local provider
- Observations
- External expert review of materials

**Conclusion:** the consent form was not appropriate for people with lower educational attainment and literacy levels

**Advice:** learn about readability scores & downgrade the reading level from graduate-level to middle school
COMMUNITY ENGAGEMENT & CONSENT

Readability formulas

Measure the ease of reading a certain text or page lay-out
- Number of words
- Sentences (number of letters or syllables)

Score
- Reading ease
- Grade level

Goal: ↑ information accessibility

Limitations
- Comprehension debacle
- Conflicting scores

Rudolph Flesch’s Reading Ease Formula, Flesch’s Grade Level, J. Peter Kinkaid’s Flesch-Kinkaid Index, Robert Gunning’s Fog Index, The SMOG Readability Formula, & New Dale-Chall formula
BEFORE

- Graduate-level vocabulary
- Long statements & text strings
- Passive voice
- College reading level

AFTER

- Plain language
- Succinct bullet points for each section
- Active voice
- 8th grade reading level
Your involvement is voluntary, and you may choose not to participate or to stop at any time without penalty or loss of benefits to which you are otherwise entitled. The decision to take part (or not take part) in the research will not affect your treatment or health care services. If you decide to stop or withdraw from the study, the information that can be identified as yours will be kept as part of the study and may continue to be analyzed, unless you make a written request to remove, return, or destroy the information.

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**About the study**

- This study is voluntary
- You can stop at any time and still get paid for participating
- Taking the survey (or not) won’t affect your health services
- If you want to stop, we will keep your data (unless you tell us that you want it to be deleted)
REFLECTION & RESOURCES

Lessons

- Community engagement & cultural humility are critical to consent
- Change is hard, but necessary
- Ask, Listen, Act, & Advocate

Resources

https://www.plainlanguage.gov/
https://readabilityformulas.com/
THANKS!

Nathan Hansen, PhD  
Professor, Department Head  
Department of Health Promotion  
University of Georgia  
nhansen@uga.edu

Miranda Hill, PhD, MPH  
Postdoctoral Scholar-Fellow  
Department of Medicine  
University of California, San Francisco  
Miranda.Hill@ucsf.edu
Health Literacy and Consent

Lisa Renzi-Hammond, PhD
Vice Chair, Biomedical IRB
Associate Professor
Institute of Gerontology
Health literacy

Understanding, communicating and applying health information to maximize health outcomes and navigate health systems

Pleasant (2014)
Rademakers & Heijmans (2018)
Health autonomy

Willingness to engage in healthcare and recognition of one’s ability to take health-related action.
Shared decision making

Collaborative process where patient and healthcare provider arrive at a treatment decision, together.
An illustration

John Smith        Dr. Red

Take two tablets by mouth twice daily.

Humibid LA       600MG
1 refill

https://www.ahrq.gov/health-literacy/quality-resources/tools/literacy-toolkit/tool3a/index.html
An illustration

![Graph showing literacy levels and understanding rates.](https://www.ahrq.gov/health-literacy/quality-resources/tools/literacy-toolkit/tool3a/index.html)
And consent?

1. Think about the theory of mind problem.
2. Collect data from your participant.
3. Change your process.
4. Test your process.
5. Codify your process.
6. Time, complexity, etc.
Wrap-up