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Readability of human subjects training materials for research

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Collaborative Institutional Training Initiative; Community-based Participatory Research; Human Subjects Research Training; Plain Language; Readability

Introduction

The U.S. Department of Health and Human Services (DHHS), Office of Research Protections (ORHP) provides oversight of federal regulations regarding the protection of human subjects in research studies (Office of Human Research Protections, 2010). Institutions are required to ensure that all persons involved in the design and conduct of human subject research receive appropriate training and education on policies regarding human subjects protections (45 CFR 46) (Office of Human Research Protections, 2010). While there are several training programs available, the most widely used human subjects training program is the Collaborative Institutional Training Initiative (CITI) program. The CITI program is a web-based resource that provides online training on nearly two dozen topics in biomedical and social behavioral research along with quizzes at the end of each module (Hansen & Braunschweiger, 2000). The CITI program is currently used by thousands of organizations worldwide to fulfill the federal requirement of training faculty, staff, and students involved in conducting human subjects research (Hansen & Braunschweiger, 2000). The average time to complete all modules required to receive human subjects research certification is about two to four hours depending the organization's requirements (Hansen & Braunschweiger, 2000), and a refresher course may be required approximately every three years or as required by each institution. Most researchers find the CITI training program too complex for those with limited research experience and recommend tailoring human subjects training to meet the needs of non-researchers or community partners (Anderson, 2015; Hawley, Wieland, Weis, & Sia, 2014; Kue, Szalacha, Happ, Crisp, & Menon, 2017; Merritt et al., 2010; Solomon & Piechowski, 2011; Terpstra, Coleman, Simon, & Nebeker, 2011).

Community members often serve as stakeholders in Community-based Participatory Research (CBPR) and are increasingly collaborating with institutional researchers in the

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planning, data collection, and dissemination of research results (Israel et al., 2010; Leung, Yen, & Minkler, 2004; Tamariz et al., 2015). Since all persons involved in the conduct of human subject research must obtain documented training on the protection of human subjects, community members are often expected to obtain the same human subjects training certification as faculty, staff, or student researchers. Community members collaborating with institutional researchers share the responsibility of understanding and ensuring compliance with policies regarding the protection of human subjects. Community members may struggle to obtain the required human subjects training if course content is written at a high grade level and is difficult to understand.

Readability is used to describe the average grade and level of difficulty of written material. The average reading level in the U.S. is eighth grade (Nielsen-Bohlman, Parker, Kindig, & Institute of Medicine, 2004) and materials written above this level are often too difficult for most persons to read and understand (Badarudeen & Sabharwal, 2010; Brega et al., 2015; Egbert & Nanna, 2009; Mayer & Villaire, 2009; Nielsen-Bohlman et al., 2004; Wilson, 2009). For this reason, experts recommend that written materials developed for public use are written at a sixth to eighth grade level or below for ease of reading and comprehension (Centers for Disease Control and Prevention, 2009; Nielsen-Bohlman et al., 2004). This study aimed to determine the readability of CITI modules that are most frequently used in community-based participatory research. Readability evaluation of CITI alternative trainings that were developed for community use was also conducted. With a baseline objective measure, modifications can be made to improve the plain language quality and understandability of essential content for community members who participate in human subject research.

Methods

Training Materials

Human subjects' trainings were identified by translational research experts and through Internet searches by reference librarians and research associates. These training materials varied in length and depth of content, the extent to which they covered the Common Rule, and mode of delivery (slides, online module, written materials).

Analysis

The 18 CITI modules required by the authors' Institutional Review Board for community researchers were selected for assessment. CITI modules and alternative trainings were assessed using three readability formulas: the Fry Graph (Fry, 1977), which assesses average number of syllables and words per 100 words; the Flesch-Kincaid Grade Level formula (Flesch, 1948), which assesses the average number of syllables and words in a sentence; and the Simple Measure of Gobbledygook (SMOG) Index (McLaughlin, 1969), which assesses the number of sentences that have words with more than two syllables. These formulas report results as U.S. grade-level equivalents, and require sample text sizes of up to 600 words. Text sections of less than 600 words were analyzed as one sample; those more than 600 words were analyzed as two to three samples with the means calculated for all three formulas. The text samples were prepared for Fry, Flesch-Kincaid, and SMOG analysis by

the following University of Arkansas for Medical Sciences, Center for Health Literacy protocol for “cleaning” documents for readability assessment. These methods are based on the readability formulae guidelines for use to ensure reliable, accurate results.

1. Remove bullets, numbers, and other symbols from the beginning of lists;
2. Insert periods at the end of bullet list items that are four or more words in length;
3. Insert periods at the end of all headings that are four or more words in length;
4. Remove all punctuation that does not denote end of sentence (i.e., Dr., etc.);
5. Exclude email addresses and hyperlinks from the readability sample;
6. Exclude bullet items and headings that are less than four words from readability sample.

Results were displayed numerically for the Flesch-Kincaid Grade Level, and SMOG Index. Results for the Fry readability formula were displayed as a point on the Fry Graph. If the readability score was on the line between two grade levels, it was identified as both grade levels. If results from the Fry formula did not fall on the Fry Graph, the readability results were verified manually with the extended Fry Graph (Fry, 1977). This was performed by manually plotting the average number of syllables per 100 words against the average number of sentences per 100 words that was given in the assessment results. All results were verified by two plain language experts at the UAMS Center for Health Literacy; full-time writers who have completed and provide extensive training in readability assessment, plain language writing and editing, and field testing.

Results

Demographics

Table 1 details the study sample and includes the title and source of the human subjects training evaluated, the number of modules, the length in pages, and the estimated time it takes to complete the training as published from the source. The human subjects’ trainings ranged from three to eighteen modules with an average of approximately three hours to complete.

Readability

Table 2 includes the readability results for the CITI human subjects trainings evaluated, as well as the means and ranges derived from the three readability formulas for each sample. The readability results for the modules ranged from eleventh grade to college, with an overall mean of grade 14.5 (college).

Table 3 includes the readability results for the alternative human subjects trainings evaluated, as well as the means and ranges derived from the three readability formulas for each sample. The readability results for the modules ranged from seventh grade to college, with an overall mean of grade 12.

Discussion

Readability assessment of current CITI training modules revealed that the overall mean reading level for all online modules was 14.8 (college) grade level. This is way too high for the majority of community members to understand because people generally have reading skills that are about five grades lower than the highest educational level attained (Badarudeen & Sabharwal, 2010). Based on these readability results, there is a pressing need for standardized human subjects training that is written in a way that makes it easier for community members to read and understand.

While many organizations have aimed to provide alternative human subjects trainings that are easier for non-research-trained stakeholders, our readability assessment of these alternatives demonstrated that the materials may still be difficult for some community-based research stakeholders to understand. The level of difficulty is undoubtedly due to the complex nature of research. However, best practices for plain language and user-centered design can likely improve the ease of understanding of these and other research training materials.

There are limitations to this study that should be noted. First, while the readability assessments were conducted by experts with oversight from the first author, readability assessment is, by nature, variable according to sample text selection. It is reasonable to expect that some variation in results could be found by selecting different text samples. However, best practices for cleaning and preparing the samples, and application of appropriate formulas were employed throughout the study. Second, it is also possible that there are human subjects' trainings that are easier to understand that are available, but not discovered by the authors in our searching. Furthermore, since the focus of this project was on readability, the content of these modules was not assessed in terms of adequacy of information or compliance in meeting Common Rule requirements. Finally, the best way to test whether this information is understood is through direct input from the intended audiences for these trainings. As a result, further evaluation is needed to confirm this readability data and to measure the usability of such modules to ensure preferences that can drive optimal understanding. Furthermore, other assessments including the Centers for Disease Control and Prevention's "Simply Put" resource provides a checklist for easy-to-understand print materials (https://www.cdc.gov/healthliteracy/pdf/simply_put.pdf).

Best Practices

Plain language experts recommend the following best practices to promote ease of understanding (Centers for Disease Control and Prevention, 2015; Centers for Medicare and Medicaid Services, 2016; National Institutes of Health, 2013):

- Using active voice
- Making sentences direct, simple, and short
- Deleting unnecessary information
- Using personal pronouns

- Using common, everyday words and not jargon
- Placing the main message at the beginning; most important info first
- Defining technical terms if they must be used and providing explanations and examples when needed
- Using headings to guide readers and “chunking” information
- Using bullets or numbered lists or tables
- Using simple, readable fonts
- Including white space

As these best health communication practices suggest, clearly communicating human subjects research to community participants will require course developers to consider both how the content is written and the usability of how the content is organized and presented.

Research Agenda

To this end, further research on human subjects’ training for community members should integrate research-stakeholder engagement and feedback using qualitative methods. Training modules should be field-tested with participants who may struggle the most. When this is done, and research training material is written using plain language best practices, the material will be well within the sixth to eighth grade readability levels. As a result, community members will be better able to understand what they have learned and be better able to apply that knowledge in research settings. Additionally, future research should focus on evaluating the content of the modules to assess the extent to which they meet criteria for covering the Common Rule and other human subjects’ protection standards.

Educational Implications

Institutional Review Boards and investigators should be educated on readability and plain language guidelines, as well as best practices to ensure that trainings are appropriate for all research staff, especially those who are community members.

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Table 1

Selected human subjects training programs

Training Program	Modules Assessed	Length of training in pages/screens	Average Time to Complete
Collaborative Institutional Training Initiative (CITI) https://www.citiprogram.org/index.cfm?pageID=154	18	157	4.5 Hours (Basic) 2 Hours (Refresher)
JHSPH Human Subjects Research Ethics Field Training Guide, Johns Hopkins School of Public Health http://www.jhsph.edu/offices-and-services/institutional-review-board/_pdfs-and-docs/field-guide-2010-02-25.pdf	11	6	Not reported
Protecting Human Research Participants, National Institutes of Health (NIH) https://phrp.nihtraining.com/users/login.php	7	23	3 Hours
CIRTification, University of Illinois at Chicago Human Subjects Protection Training https://www.ccts.uic.edu/sites/default/files/uploads/Facilitator%20Manual.pdf	3	28	3 Hours
Community Partnered Research Ethics Training (CPRET), University of Pittsburgh http://www.ctsi.pitt.edu/research-community-cpret.html	5	39	Not reported

Table 2

Readability of CITI documents

Training Resource	Samples* n	Mean FK	Mean SMOG	Mean Fry	Overall Mean (SD)
Informed Consent IDE 504	2	12.7	11.4	17	13.7 (2.9)
Privacy and Confidentiality ADE 505	2	15.3	13.4	16.5	15.1 (1.6)
Ethical and Practical Considerations in Community-Engaged Research	2	16.3	14.3	17	15.9 (1.4)
Intro to Community-Based Participatory research	3	14.2	12.4	17 ⁺	14.5 (2.3)
Intro to Community-Engaged Research	2	15	13.2	17 ⁺	15.1 (2.3)
Assessing Risk 503	2	14.2	13	16.5	14.6 (1.9)
Belmont Report/CITI Course Intro	2	14.3	13.1	17 ⁺	14.8 (1.8)
Conflicts of Interest in Research Involving Human Subjects	2	16.7	15.4	17 ⁺	16.4 (2.0)
Historical and Ethical Principles 490	2	14.5	12.9	16.5	14.6 (0.9)
International Research	2	14.5	12.5	17 ⁺	14.7 (2.3)
Research and HIPAA Privacy Protections	2	15.8	13.6	17 ⁺	15.5 (1.7)
Research with Children 507	2	12.9	11.8	16.5	13.7 (2.5)
Research with Prisoners 506	2	13.3	12.3	17 ⁺	14.2 (2.5)
Research in Public Elementary and Secondary Schools - SBE	3	13.6	16.0	15.7	13.8 (1.3)
Defining Research with Human Subjects 491	2	14.9	12.9	17 ⁺	14.9 (2.1)
Students in Research 1321	3	15.5	13.3	17 ⁺	15.3 (1.9)
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research	2	13.6	12.3	16.5	14.1 (2.2)
Vulnerable Subjects - Research Involving Workers/Employees	2	15.1	13	17 ⁺	15.0 (2.0)
Overall Mean					14.8 (1.8)

* If original document was too long to assess the readability in its entirety, multiple samples were taken and assessed individually.

** Most documents included in-text parenthetical citation. These were removed for readability assessment protocol.

⁺ Document scored beyond grade 17 (college graduate).

Table 3

Readability for CBPR training courses

CBPR Alternative Training Source	Flesch-Kincaid	SMOG	FRY	Overall Mean (SD)	Overall Range
JHSPH Human Subjects Research Ethics Field Training Guide, Johns Hopkins School of Public Health	11.7	10.5	12.7	11.6 (1.1)	9–15
Protecting Human Research Participants, National Institutes of Health (NIH)	15.2	13.3	16.7	15.1 (1.7)	12–17+
CIRTIification, University of Illinois at Chicago Human Subjects Protection Training	12.1	10.3	15.0	12.5 (2.4)	9–16
Community Partnered Research Ethics Training (CPRET), University of Pittsburgh	10.5	8.9	16.7	12.0 (4.1)	7–17+