PRISM

PRISM

[Program for Readability In Science & Medicine]

Readability Toolkit

Group Health Research Institute

GroupHealth®

Notes for users

This Toolkit is a copyrighted, public-domain resource that you may feel free to use and share as you see fit. Downloadable copies in PDF format are available at: www.tinyurl.com/prismtoolkit.

Navigation links and links to dozens of outside resources are indicated in standard hyperlink format (blue underlined text). The external links in this edition were last accessed on June 29, 2009.

We welcome your feedback about the Toolkit's usefulness, as well as suggestions for improvements or updates. Please share your comments through our online survey at http://www.surveymonkey.com/s.aspx?sm=_2b4zMSskDsOeFHLEqUW9EzQ_3d_3d. You may also send your comments by email to the PRISM team at PRISM@ghc.org.

We plan to update the Toolkit periodically. To receive updated versions, please register your email address via our online tracking system available at http://www.surveymonkey.com/s.aspx?sm=k_2fC41IyMGw3Ug3MKv4avMg_3d_3d.

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Resources for HIPAA Authorization Documents – Links to helpful HIPAA templates and guidelines, along with a brief selection of easy-to-read HIPAA language

Alternative wording suggestions – A list of plain language alternatives for hundreds of words typically used in medical and research settings and links to online resources that define medical and research jargon

Examples of improved readability – Before and after "snapshots" of plain language revisions to original text taken from actual participant materials

Examples of improved formatting – Techniques for improving readability through formatting changes are illustrated with three before and after examples: an advance letter, a consent form, and a study information sheet. While the focus is on improved formatting, all three examples also illustrate other plain language techniques.

Repository of readability resources and references – A clearinghouse of web-based resources focused on health literacy, readability, plain language, and informed consent, plus a short bibliography of articles related to literacy and readability in health research

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One strategy that can aid the development of study materials is to use a participant-centered approach. Ask yourself what it would be like to participate in a given study. What thoughts, feelings, and questions would be on the participant's mind? For instance, participants who are invited into a study because they have diabetes will likely want to know how the research team came to know about their condition.

Other common questions might include: Will my doctor find out I am in the study? Should I talk to my doctor first? What's in it for me? Do I have a choice about what happens to me? Will there be bad side effects? If so, what are they and what can I do about them? How do I find out more information? Try to anticipate a participant's concerns and questions and address them thoughtfully. This will help you develop materials that are inviting and meaningful and may increase the chance that your readers will understand what you've written.

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The Principles of Plain Language

This section explains four major principles of plain language, describes several strategies that support those principles, and provides links to additional plain language resources.

Plain language: more than just simple words

Stated simply, using plain language means communicating clearly. No one technique describes plain language, rather it consists of a range of strategies that lead to a common end: clear, readable information. While it may be obvious that plain language is based on using understandable language and avoiding jargon or other unfamiliar terms, there is much more to it than that.

Plain language is written in a conversational style, with ideas organized into short, succinct sentences and paragraphs. Using plain language also involves using reader-friendly formatting so that the document looks easy to read. Finally, using plain language means keeping your readers' needs in the forefront of your mind as you organize and filter your content. Doing so helps you organize the content in a way that will make sense to the reader and omit unnecessary details.

The most important thing to bear in mind when using plain language is that it is a continual process of improvement. Achieving clear communication is more of an art than a science, and your skills will improve dramatically with practice. The clearest communication—and the best examples of plain language—usually result after multiple rounds of editing, so be prepared for an iterative process.

Strategies to support plain language principles

The principles and strategies described below are summarized in the Quick Reference Guide on page 13.

Use language your audience can easily understand.

In most cases, this means **using common, everyday words**, which may mean adjusting your writing style significantly if you're used to writing in an academic or scientific environment. The key is to edit rigorously and search for multi-syllable words that you can replace with simpler alternatives. It's also imloo outh for shote words with

mplxc ormu(ltile(m)8

To gauge the complexity of the language you're using, it can be helpful to **check the reading level using a readability formula**. Most readability formulas are based on the US high school grading system and will give you an approximation of the education level required to understand what you've written. However, all readability formulas have limitations that must be considered. For more about using readability formulas, see How to Determine Reading Level on page 11.

Write in a conversational style, as if you were speaking

Use active voice, where the subject acts instead of being acted upon. It is more readable and more powerful than passive voice. "We will ask you questions about your health" is active, while "You will be asked questions about your health" is passive.

Write in the first person using pronouns, such as "I," "we," and "you." It is more engaging and more personal. People will often read comfortably at a higher grade level than normal if they are interested in and can relate to the subject matter. The more words about people and the more sentences addressed to an audience, the more interesting a document is to read.

Although it may seem awkward, **reading your document aloud** is probably the best way to ensure that you're using a conversational style. Also, taking a break if you get stuck can be helpful. Try stepping away from the keyboard (or the paper and pen) and just speaking your thoughts.

Organize and filter content with your readers' needs in mind

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Organize your document in a way that will make sense to your readers. Put the most important information first. When relevant, ensure that stepwise information is in chronological order. Be clear about what your participants need to do and when they need to do it.

Take time to **consider what you know about your audience**—their literacy level, age, culture, ethnicity, or potential chronic health conditions. Does your writing include

Helpful plain language resources

There are many other excellent resources that describe techniques for improving readability and include information about plain language principles and strategies. Among the most comprehensive are:

The Health Literacy Style Manual – A detailed guide that includes tips on project planning, writing, formatting, field testing, and translating into languages other than English. Unlike many plain language resources, it addresses the readability of applications and other forms and is based on a variety of real-world examples. Developed by The MAXIMUS Center for Health Literacy as part of a national program funded by the Robert Wood Johnson Foundation.

Teaching Patients with Low Literacy Skills, 2nd Edition – A classic health literacy

How to Determine Reading Level

There are many formulas available to help determine the approximate reading level of a document, and you can find a wealth of information about each of them on the Internet. Most readability formulas provide a grade level score and are based on the average number of syllables per word and words per sentence. In general, the more syllables there are in a word and the more words there are in a sentences, the harder it is to read and understand the text.

Among the most commonly used methods to determine readability are the Fry formula and the Flesch-Kincaid formula. Most health literacy experts recommend using the Fry formula, however, the analysis can take 20 minutes or more since computations are traditionally done by hand. The Flesch-Kincaid formula has been criticized for being less accurate than the Fry, however, results can be obtained quickly and automatically using the readability analysis tool in Microsoft Word . Assessing the reading level via multiple formulas is probably the best way to get a reasonably accurate estimate of reading level. Many software packages provide multiple readability scores, and this may be the best option for those who can afford the investment.

Despite the fact that the Flesch-Kincaid method may be less accurate than the Fry, it still has considerable value as a rough estimate and is especially useful when time or resources are limited. The readability tool in Microsoft Word also provides the Flesch Reading Ease score and the percent of passive sentences (see table below). For instructions on how to use the readability analysis tool in Microsoft Word , please see Appendix A on page 36. Pfizer's Principles for Health Communication provides a detailed description of how to use the Fry formula (see page 62).

For other resources and information related to readability, see Appendix E: Repository of Readability References and Resources on page 71.

Readability statistics available in Microsoft Word

Formula	Description	PRISM Goal
Flesch-Kincaid Reading Level	provides a grade level score based on the US high school grade level system	8th grade or below
Flesch Reading Ease	90-100 = Very easy 80-89 = Easy 70-79 = Fairly easy 60-69 = Standard 50-59 = Fairly difficult 30-49 = Difficult 0-29 = Very confusing	70 or greater
Percent passive sentences	gives the proportion of sentences written in passive voice	0-10%

Things to consider when using readability formulas

Formulas do not take overall organization, formatting, or page density into account, all of which significantly impact readability.

Sometimes we cannot avoid using multi-syllable words like “mammography” or “immunization.” If possible, substitute them with “x-ray of the breast” and “shot.” But if this is not possible, be sure to adequately define them in the materials and acknowledge that this will slightly increase your target grade level.

The number of syllables does not always correspond to how easy a word is to read and understand. For instance, “comprise” is a two-syllable word that is often misunderstood. Similarly, the number of words does not always correspond to how easy a sentence is to read.

Readability formulas will provide an approximate grade level score, however, it is still important to be conscious of the overall quality of the text. It is possible to write using short words and sentences that are still difficult for the average reader to comprehend. Goldfarb and DuBay suggest that it is important to avoid mechanically “writing to the formula,” and provide excellent examples of conscious revisions that make text easier to read, even though they score slightly higher on the Flesch-Kincaid scale.[10]

The Flesch-Kincaid formula looks for periods to identify the end of a sentence. If your text includes a bulleted or numbered list, adding periods at the end of each item will yield a better score. To get the most accurate score, remove periods that don’t end a sentence, as in “Dr.” or “Mr.”

In older versions of Microsoft Word , the Flesch-Kincaid Reading Level formula maxes out at a score of 12th grade. This means that different versions of the software will give different grade-level scores, and text rated at 12th grade may actually be

Quick Reference Guide for Improving Readability

Guiding principles of plain language include:

Use language your audience can easily understand.

Write in a conversational style, as if you were speaking.

Organize and filter content with your readers' needs in mind.

Use reader-friendly formatting so that your document looks easy to read.

The following specific strategies will help you adhere to these principles:

Check the reading level.

Choose a readability formula, but be aware that they all have limitations—getting a "good score" is not a guarantee that your document is easy to read.

Consider the needs of your audience.

Include only the information that your audience really needs to know.

Use large font and/or age-appropriate or culturally-sensitive language to meet the needs of special populations like the elderly, children, minorities, or people with chronic health conditions, etc.

Organize and format your document so that key information is clear and easy to find.

Lead with the most important information, and sequence the information in a logical fashion that the audience can easily follow.

Use bold, larger font, bullets, or graphics to emphasize critical information. Do not use justified margins or put entire sentences in all caps or italics.

Put long lists of items into bulleted lists whenever practical. Use numerical lists whenever if the items need to be understood or completed in order

Use adequate white space and margins.

Break up dense copy by using ample white space between paragraphs and headings. Consider using all white space that may be leftover by adding space between paragraphs or increasing the font size of headers or text.

Avoid decreasing margins to force text to fit on one page. Top and bottom margins should be at least 1", and side margins should be at least 1.25."

Read your document aloud.

This is one of the best ways to find errors and test for overall flow and clarity when you proofread. It can also help you troubleshoot—when you get stuck, try just speaking your thoughts.

Ask others to read and edit the document.

Someone unfamiliar to the project is more likely to notice text that is unclear.

The person who will use the document most—such as the person who will administer informed consent—should always have a chance to review it.

Use fresh eyes when you edit or proofread.

Whenever possible, set the material aside for a day or two and proofread it again after taking a break. This step, along with reading your document out loud, is a good way to find errors that may have been overlooked before.

Double-check names and contact information.

Call all phone numbers and check all links and email addresses. Confirm that all names have been spelled correctly and that all titles are correct.

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Editing Checklist for Participant Materials

Use the editing checklist that follows to improve the readability of participant materials. It was designed for project managers, research assistants, and others who may be coordinating the development of study documents. The checklist is meant as an interactive tool to both guide and track the revision process.

The Quick Reference Guide for Improving Readability on the previous page gives more detail about how to check the various items on the list. Each row on the checklist corresponds sequentially to a point in the guide. If you have any questions, feel free to contact Jessica Ridpath at 206-287-2032 or PRISM@ghc.org.

Notes for using the editing checklist

The checklist is divided into three columns. The first column is for checking off the items listed in the second column. The third column is for tracking important notes and exceptions:

> You will probably want to check some items more than once.
>
> It's a good idea to save completed checklists to keep track of changes and decisions.
>
> Track things like multi-syllable words that impact readability but sometimes cannot be avoided. Two examples are "mammography" and "immunization."
>
> Make note of important dates and the names of people who helped edit the document. The dates and details of decisions or any other information that the user finds helpful can also be tracked in the third column.

The checklist consists of three phases. The phases should be completed in order. The items within each phase may be checked in any order.

> In **Phase 1**, the primary reviewer (usually the project manager) checks the reading level and makes revisions to improve readability.
>
> In **Phase 2**, the primary reviewer checks the reading level again and asks other people to edit the document.
>
> In **Phase 3**, the primary reviewer confirms contact information and other details. The last steps are to get signoff from the project team and log the final reading level.

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Editing Checklist for Participant Materials

	Context, style, and amount of information are appropriate for the audience	
	Clear organization and format lead with key information use bold, bullets, or other emphasis as needed	
	Adequate white space and margins	

Look out for topic sentences that are buried in the middle or end of a paragraph, especially in relation to the purpose of the study.

Be cautious if you cut and paste content from consent forms from previous studies. Sometimes an unnecessary component or some false information will inadvertently be inserted.

Helpful consent templates

Easy-to-read template language for consent forms

The following is a compilation of easy-to-read language for common topics in consent forms. These examples were gathered from actual language in consent forms at Group Health Research Institute (GHRI), as well as consent form templates made available on the public websites of other research institutions.

Notes for users

The Flesch-Kincaid formula was used to rate the approximate grade level of each selection.

Feel free to combine passages from different selections or use excerpts from a specific selection in combination with other language.

Phrases that will need to be revised to reflect individual research settings are highlighted in grey, with instructions for inserting specific information in brackets.

Topics

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Table 1

Introduction/Researchers' Statement	Grade level

You are invited to think about taking part in a research study. This form will tell you about the purpose of the research, its possible risks and benefits, other options that you have, and your rights as a participant in the study. Please take your time to make your decision.

Everyone who takes part in research at Group Health [insert name of facility or institution] should know that:

Being in any study is voluntary.

You may or may not benefit from being in the study. Knowledge we gain from this study may benefit others in the future.

You may leave the study at any time and none of the benefits you normally receive will be taken away.

Table 2

Request for Permission to Review Medical Records	Grade level
We are asking you to let us collect some information from your medical records for this study. We will not need to look at all your records. Instead, we will use a computer to find information about your use of health care services, including:	

Table 3

Randomization	Grade level
We will use a computer to assign you randomly to 1 of the 2 [insert number] study groups. This means we will put you into a group by chance. It is like flipping a coin or drawing names out of a hat.* You will have an equal chance of being in either [OR any] group.	**3.7**
There will be about 1500 [insert number] people in this study. They will be assigned randomly to one of two [insert number] study groups: [list groups] Which group you will be in is decided by chance, like the flip of a coin*.	**4.8**

You will be randomly assigned to one of the four [insert number] study treatments. This means that whichever treatment you get will be decided by chance, like drawing names out of hat*. You will have a 1in 4 [insert odds] chance of getting any one of the study treatments.

We will not tell you which group you are in. Study staff at your visits will not know your group either. But we can quickly find out which group you are in if

Table 4

Blood Draw Procedures
Note: Include volume of blood only in teaspoons or tablespoons, rather than ml, cc, or oz. Use the following equivalents: 5cc = 1 teaspoon 15cc = 1 Tablespoon 1 oz = 2 Tablespoons

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Table 5

Risks of Drawing Blood	Grade level
You may feel a slight needle prick when we draw your blood. Some people may have a slight bruise that will go away in a day or two. Sometimes, people feel light headed or faint.	**ay**

Table 8

Voluntary Participation and Withdrawal	Grade level
Do I have to be in this study? No, being in this study is up to you. You can say no now or to leave the study at any time later. Either way, your decision won't affect your care or benefits at Group Health [insert facility or institution].	**3.4**
Can you leave the study early? You can agree to be in the study now and change your mind later. If you wish to stop, please tell us right away. Leaving this study early will not affect your regular medical care.	**4.2**

from Johns Hopkins University

Voluntary Participation and Withdrawal	Grade level

Table 9

Confidentiality	Grade level
Your confidentiality is one of our main concerns. We will store all of your research records in locked cabinets and secure computer files. We won't place your name on any research data. Instead, we will label your information with a code number. The master list that links your name to your code number will be stored in a locked cabinet. We will keep all the information you give us confidential as provided by law. The only exception is any risk of possible harm to you or others. We won't share your study results with anyone unless you ask us to. Your name won't appear in any reports about this study.	**6.3**

We will keep information about you confidential as provided by law. We will label your audiotapes and survey answers [insert applicable study data] with a study number only. Your study number is not related to your name or Group Health medical record number [insert applicable patient identifier].

Resources for HIPAA Authorization Documents

Despite federal requirements that HIPAA privacy notices and authorizations for research be written in plain language, few HIPAA forms can be considered readable. In fact, a recent study of HIPAA authorizations from over 100 research institutions found that the mean reading level score was between 11th grade and college-level, depending on the readability formula used[12].

As with informed consent, we have reviewed and edited dozens of HIPAA authorizations, but have yet to identify or create a HIPAA form written entirely in plain language. Nonetheless, the HIPAA resources listed here may help researchers make strides toward this goal.

Helpful HIPAA authorization templates

Among the more readable HIPAA templates we have found are:

University of California (system wide) – stand-alone HIPAA template

Seattle Children's Hospital Research Institute – stand-alone HIPAA template

University of South Florida – stand-alone HIPAA template, as well as HIPAA language within the consent templates

Johns Hopkins University – HIPAA language within the consent template

Helpful HIPAA guidelines

Plain Language Principles and Thesaurus for Making HIPAA Privacy Notices More Readable – a summary of plain language strategies tailored for HIPAA privacy notices, but still quite helpful when applied to HIPAA authorizations for research. Prepared for the Health Resources and Services Administration of the U.S. Department of Health and Human Services.

Easy-to-read template language for HIPAA

Institutionally-mandated HIPAA language varies dramatically. As with informed consent, there is no "one size fits all" plain language explanation of HIPAA for research. The following excerpts can be included together or separately within the main study consent form, but you may need to add other language required by your sponsor or your institution.

[12] Breese P, et al. The Health Insurance Portability and Accountability Act and the informed consent process. Ann Intern Med2004;141:897-898.

Flesch-Kincaid grade level score when all excerpts are used together = 6.8

How will you protect my privacy? Your health information is protected by a federal privacy law called HIPAA. The health information we will collect for this study includes: 1. [Your survey answers.] 2. [Your medical record information.] 3. [Your blood sample and results from your blood tests.] 4. [insert others as needed.]	**Grade level** **6.8**
The researchers listed on the front of this form and their staff will only use your health information for research. In rare cases, staff from Group Health [insert facility or institution] or the funding agency may look at our records for study oversight. We will not share information that identifies you with anyone else except as allowed by law.	**Grade level** **8.7**

Group Health [insert names of all facilities or institutions] must follow the federal privacy law. This law does not apply to

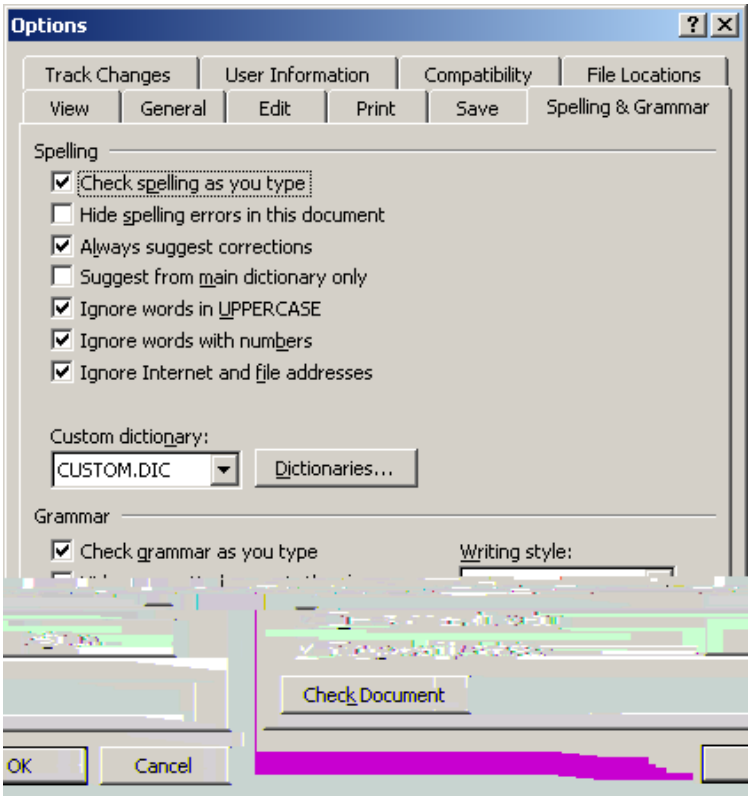
Appendix A: Instructions for Checking Readability in Microsoft Word

Microsoft Word provides a readability analysis tool in the Spellchecker. To activate this tool:

Go to the "Tools" menu and select "Options."

Click on the "Spelling & Grammar" tab.

Check "Show readability statistics" under the "Grammar" heading.



Appendix B: Alternative Wording Suggestions

This list includes a selection of commonly-used medical terms, research jargon, and other complex words paired with suggestions for plain language alternatives. It is a compilation of original entries* and entries selected from a variety of plain language word lists publicly available on the intranet:

> Simple Words and Phrases (plainlanguage.gov)
>
> Glossary of Human Subjects Terminology (University of California at Davis, Office of Research)
>
> Plain Language Principles and Thesaurus for Making HIPAA Privacy Notices More Readable (Health Resources and Services Administration)
>
> Writing Style Guide and Dictionary of Plain English (Duncan Kent & Associates Ltd.)

This list is by no means exhaustive, and we encourage you to refer to other resources as needed. For definitions of more specialized medical terminology, try the University of Michigan Medical School Simplification Guide to Medical Terms; for definitions of research jargon, try the glossary of research terms developed by The Cochrane Collaboration.

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Navigation links: A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Instead of …	Try this … (You may need to use different forms or combinations depending on how the term is used)
acquire	get
activate	begin, start
acute	sudden, new, recent; intense flare-up, serious pain; short-term
addictive	habit-forming
additional	added, extra, more, other
address	talk about, discuss
adequate	enough
adjacent	next to, by
administer	give
advantageous	helpful, useful
adverse	harmful, bad
adversely impact	hurt, set back
affirmative	yes, positive
aggravate	make worse
aggregate	all together, added together, combined
agitation	anxiety, restlessness, nervousness
ailment	sickness, illness, health problem, complaint
allergen	something that causes allergies
allergic rhinitis	hay fever
alleviate	ease, decrease, lessen
allocate	divide, give based on a plan
allow	let
alopecia	hair loss
alternative	choice, option
ameliorate	improve, get better, make better
ambulate	walk
ambulatory	able to walk
amend	change
ameliorate	improve
analgesic	pain killer, pain reliever
analyze	look at, study, examine
anaphylaxis	shock or serious allergic reaction
anesthetic (general)	a drug that puts you to sleep
anesthetic (local)	a drug that numbs an area of your body
angina (or angina pectoris)	chest pain

Instead of …	Try this … (You may need to use different forms or combinations depending on how the term is used)
blood glucose	blood sugar
blood profile	series of blood tests
BMI, body mass index	using your height and weight to measure if you're overweight
bradycardia	slow heart beat
buttocks	butt, backside, rear, rear end

C

Instead of …	Try this …

Instead of …	Try this … (You may need to use different forms or combinations depending on how the term is used)

Instead of …	Try this … (You may need to use different forms or combinations depending on how the term is used)
develop	occur, start to get, happen
diabetic	person who has diabetes
diagnose, diagnosis	(find the) problem or condition
diagnostic procedure	a test to look for a problem
diaphoresis	sweating
difficulties	problems, trouble
diffuse	widespread, scattered
digit	finger or toe
dilute	add liquid, make less strong
diminish(ed)	go down, decrease, less (of), lower
disclose	share, tell, show
discoloration	change in color
disconnect	unhook, separate, divide
discontinue	drop, stop
discover	find (out), learn if
discrepancy	conflict, difference, error, split
disseminate(d)	give, share, send, pass on, (spread out)
diuretic	drug that makes you urinate (OR pee) more
diverticulitis	when your large intestine is swollen or infected
donate	give
double blind	a study where the researchers and the participants don't know what drug the participant is getting
dressing	bandage
due to the fact	because
dysfunction	not working
dysmenorrhea	painful period cramps
dyspepsia	heartburn
dysphagia	trouble swallowing
dyspnea	trouble breathing
E TOP	
echocardiography, echocardiogram	pictures of the heart
edema	swelling
efficacy	how well (a treatment) works
elect	choose, pick
electrolytes	salts in the blood that control the balance of fluids in the body

Instead of …	Try this … (You may need to use different forms or combinations depending on how the term is used)

Instead of …	Try this … (You may need to use different forms or combinations depending on how the term is used)
excise	remove by cutting, cut out

Instead of …	Try this … (You may need to use different forms or combinations depending on how the term is used)

Instead of …	Try this … (You may need to use different forms or combinations depending on how the term is used)
initiate	begin, start
injection	shot
in lieu of	instead (of)
innovation	new idea, new way

Instead of …	Try this … (You may need to use different forms or combinations depending on how the term is used)
moderate (verb)	limit, control
modify, modification	change
monitor	check (on), keep track (of), watch
morbidity	disease rate, illness rate
mortality	death rate, death, dying
motility	movement, ability to move
musculoskeletal	muscles and bones
mutation	genetic defect
myocardial infarction (MI)	heart attack
myopia	nearsighted(ness), when it's hard to see things that are far away
N TOP	
nausea (nauseous)	upset stomach, feeling like throwing up, feel like vomiting
nebulous	vague, not clear
necessary	needed, need to
negligible	small
nephropathy	kidney disease
neuralgia	nerve pain
neuron	nerve cell
nodule	lump
noncompliant	not following a treatment plan
noninvasive	without using surgery, needles, or cutting the skin
notification, notify	to tell, let know
numerate	count
numerous	many
nutrient	food

O TOP

Instead of …	Try this … (You may need to use different forms or combinations depending on how the term is used)
prognosis	outlook
progress (verb), progressive	worsen, get(s) worse
prohibit, prohibitive, prohibited from	prevent, restrict(ive), strict, may not, don't allow
promulgate	make, issue, publish
prone	lying face down, lying on your stomach

Instead of …	Try this … (You may need to use different forms or combinations depending on how the term is used)
reflect	say, show
reflux	heartburn
refractory	hard to treat, hard to manage
regarding	about, of, on
regardless	no matter
regimen	treatment plan
regulate	affect, control
regulations	rules
relapse	slip, backslide, return of a disease
relevant (to)	about, tied in with, related to
relocate	move
remain	stay, wait
remainder	rest, what is left over
remaining	other, (second, last, final), left, left over
remission	cancer that has gone away
renal	(in/of/about/related to) the kidneys

Instead of …	Try this … (You may need to use different forms or combinations depending on how the term is used)
satisfactory	okay, fine, good
sclerosis	when certain tissuern

Instead of …	Try this … (You may need to use different forms or combinations depending on how the term is used)
sustain	keep going
sustenance	support, food
sutures	stitches

Instead of …	Try this … (You may need to use different forms or combinations depending on how the term is used)
urinalysis	urine test
utilize, utilization	use
V TOP	
validate	approve, confirm
variable	factor, changes over time
varicella	chickenpox
variety	many different kinds

Example 2

Original	**Revised**
Grade level = 11.2 Reading Ease = 51.0 71% passive sentences	Grade level = 6.3 Reading Ease = 75.1 9% passive sentences

If you **meet the eligibility requirements and are interested in participating**, you will **have a 1 in 4 chance of being assigned to each of** four groups. **Three in 4 participants will be assigned to** study treatment**, and 1 in**

Example 3

(There are revisions throughout, so changed text has not been emphasized in this example.)

Original Grade level = 13.7 Reading Ease = 44.0 0% passive sentences	**Revised** Grade level = 7.0 Reading Ease = 68.8 0% passive sentences
Group Health Cooperative recognizes the importance of positive health behaviors and their role in building a healthy and rewarding lifestyle. So we want to invite you to participate in a new research study for Group Health members called the SCALP Study. Group Health Cooperative, Kaiser Permanente, and HealthMedia, Inc., a leading multimedia group, are sponsoring this research to test the effectiveness of online programs for helping people prevent and treat dandruff. Before finalizing the programs, we need to pilot test them in a small group of persons who have dandruff. If you are one of the thousands of people who say they want to do something about their dandruff, we would like to ask you to participate in this study. To be eligible to enter the study, you must have dandruff, be a member of Group Health, have an email address and the ability to access the internet at least once or twice per week, and meet certain other eligibility requirements.	Group Health Cooperative knows that positive health behaviors help build a healthy and rewarding lifestyle. If you are one of the thousands of people who say they want to do something about their dandruff, we'd like to invite you to take part in SCALP, a new research study for Group Health members. Group Health Cooperative, Kaiser Permanente, and HealthMedia, Inc., a leading multimedia group, are sponsoring this research. The goal of this project is to create online programs to help people prevent and treat dandruff. To make sure that these programs are as helpful as possible, we first need to test them in a small group of people. To be eligible for the study, you must: Have dandruff. Be a member of Group Health. Have an email address. Be able to access the Internet at least once or twice per week. Meet certain other requirements.

Example 4

Original Grade level = 13.2 Reading Ease = 52.8 0% passive sentences	**Revised** Grade level = 7.5 Reading Ease = 71.7 0% passive sentences
Can you take five minutes **to provide information that will help plan an important** study **to aid** people with arthritis **pain and problems getting** a good night's sleep? I am **an investigator** at Group Health Center for Health Studies **who is** planning a major study to test new ways of helping people with arthritis pain and sleep problems. **In order to plan the research**, I need to know how many **people** have arthritis pain and **sleep problems**. I also need to know **to what extent people with these problems** might be interested in **participating in** a group program **for** arthritis pain and sleep problems **that we want to test** in research funded by the National Institutes of Health.	Can you take five minutes **for a** study **about helping** people with arthritis **get a** good night's sleep? **If you have arthritis, you may know what it's like to have trouble sleeping.** I am **a researcher** at Group Health Center for Health Studies. **I'm writing to ask for your help with** a major study **about** arthritis and sleep problems. **Before we can do the study**, we need to know how many **members of Group Health** have arthritis pain and **trouble sleeping**. We also need to know **if our members** might be interested in a group program **to help people** with arthritis pain and sleep problems. **We want to test this program** in research funded by the National Institutes of Health.

Example 5

Original	Revised
Grade level = 12.6 Reading Ease = 47.8 0% passive sentences	Grade level = 6.9 Reading Ease = 69.6 0% passive sentences

Purpose

We are **interested in understanding** how older adult members of Group Health Cooperative feel about physical activity. We **are also interested in hearing what** their thoughts **are about** the physical activity programs that Group Health offers to its members. **The results of** this study will help us **better understand the needs of** older adult members **regarding** physical activity programs.

Procedures

If you agree to be in this study, **you will take part in a telephone interview**. The **interview** will last about 30 minutes. **The study investigator** will ask questions about your physical **activity, your** use of the Silver Sneakers or EnhanceFitness **programs, and** general questions about yourself and your health. Here are **examples of several questions**, "What kinds of physical activities have you done in the past that you are **noti**

Example 7

Original	**Revised**
Grade level = 11.2 Reading Ease = 45.9 40% passive sentences	Grade level = 6.9 Reading Ease = 68.5 0% passive sentences
All of your research records **will be maintained indefinitely in our research offices, in locked files and password-protected** computer files. We will not place your name on any research data. We will assign a code number to your **information, and** a master list **identifying you by your code number will be maintained by the Principal Investigator** in a locked **file**. Only **investigators** listed on this consent form and **personnel directly related to** this study will have access to your study records. **Selected** people working for the study sponsors may see **the information about you (both personal, including your name, and other information)** held by the study doctor. **Your information will be examined** to **confirm** that it is correct and that it is related to you. **These persons are required to maintain the confidentiality of your information**. We will not **reveal the results of your participation to anyone unless requested by you**. Your name will not appear in any publications or reports **produced from** this study. **All information and results generated from this study will be kept** indefinitely	**We will keep** your research records **in locked cabinets and secure** computer files. We will not place your name on any research data. **InsteaJ/TT1 1 Tf0.0009 T1<0.00.0069 Tf8.34, wearc1.15343 Tw T**

Example 8

Original Grade level = 14.8 Reading Ease = 38.7 0% passive sentences	**Revised** Grade level = 5.8 Reading Ease = 69.8 0% passive sentences
By signing this form, you **consent to (authorize) the** use **of** health information from your Group Health medical records **needed** for this study, **which would include** your use of health care services such as number and types of medications, clinic visits, **laboratory** test results and **hospitalizations**. **Some of the information collected will be about** mental health medications and visits. We will collect this information for a period of one year before your first **telephone** survey **date** and one year after **your first telephone survey date**.	**If you sign** this form, you **are allowing us to** use health information from your Group Health medical records for this study. **We will not look at your entire medical record. Instead, we will use a computer to collect information about** your use of health care services, **including**: number and types of medicines clinic visits **lab** test results **trips to the hospital** mental health medications and visits We will collect this information for a period of **about two years, starting** one year before your first **phone** survey and **ending** one year after.

Example 9

(There are revisions throughout, so changed text has not been emphasized in this example.)

Original Grade level = 13.6 Reading Ease = 19.7 0% passive sentences	**Revised** Grade level = 5.9 Reading Ease = 74.1 0% passive sentences
POTENTIAL RISKS OR DISCOMFORT A potential risk for participating in the interview is loss of confidentiality. However remote the possibility, it is possible that a confidentiality breach could release participant names. Also, some people feel that providing information for research is an invasion of privacy. Some people feel uncomfortable when an interview is audio recorded.	**Are there any risks to me?** The main risk to you is that someone could find out you were in this study. But we will do our best to keep your information confidential, so we think this risk is very low. Some people may feel uncomfortable having the interview recorded. You may skip any question or stop the interview at any time.

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Appendix D: Examples of Improved Formatting

The following snapshots of common types of participant materials demonstrate how formatting changes can dramatically affect the overall look and feel of a document. Each example also contains a variety of other plain language revisions, which may also be helpful to consider. However, the primary purpose of this section is to illustrate the effect of formatting on readability.

As with other examples in this Toolkit, we report the Flesch-Kincaid grade level scores and the percent of passive sentences for the original and revised documents. To provide a better at-a-glance comparison of the two versions, we converted two-page documents to one page (by adjusting page orientation and reducing font size).

Examples

Advance letter, original……..... 68

Advance letter, revised……..... 69

Consent form, original…….....70

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Study Information Sheet, original…….....72

Study Information Sheet, revised……..... 73

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DATE

Dear Parent or Guardian of [CHILD'S FNAME LNAME]:

Deciding what is best for your teenager's health can be a challenge. Teens aren't children anymore, but they aren't adults yet either. That's why it's important that we do research on teen health. Group Health and the University of Washington are doing a study that we hope will tell us the best way to figure out the needs of our teen patients.

Why are you asking us to be in this study?

We are inviting Group Health teenagers between 13 and 17 years old to take part in this study. [CHILD NAME] was one of [n] teens chosen at random to receive this invitation.

What do we do if we'd like to take part?

First, read over the enclosed consent form and study brochure. Then, talk to [CHILD NAME] and decide together about being in the study. If you choose to take part, please follow these steps:

1) Sign the consent form and put it in the return envelope.
2) Give the survey and the envelope (with the consent form inside) to your teen, so he or she can answer the questions in a private place.
3) Remind your teen to put the finished survey in the envelope with the consent form and mail it back to us. (no postage needed)

What if we don't want to be in the study?

If you don't want to be in the study, please call our toll-free line, 1-877-555-5555. Leave a message with your name, phone number, and your child's full name. Please say that you are calling about the ASC Study.

The $2 is for your teen to keep, whether or not [he/she] does the survey. Being in this study is voluntary. Your decision will not affect the care your family receives at Group Health.

If you have any questions about the study, please call the Project Manager, Susie Manager, at **206-555-5555**.

Sincerely,

Jane Researcher, MD, MPH
Group Health Center for Health Studies

REVISED Grade level = 7.4, 3% passive sentences

Example #2

Introduction
We are inviting your teenage son or daughter to be in a research study. Group Health members between the ages of 13-17 years are being invited to participate. This consent form will give you information about the study, so you can understand enough about the risks and benefits to make an informed decision. This process is called informed consent. Please read it carefully. It will explain the purpose of the study, what we are asking you to do, the possible risks and benefits, and your rights as a volunteer in the study. If you have any questions, please call Susie Manager at 206-555-5555.

What is the purpose of the study?
The purpose of this research study is to test how well brief screening questionnaires can identify physical and emotional concerns that might put a teen's health at risk. We plan to use what we learn in this study to help design better ways to identify the health care needs of teens.

Will my teen or I get any benefit from being in the study?
There is no direct benefit for you or for your teen. Information that your teen provides might help physicians take better care of other teens in the future. The results of this survey will not be reported back to you or to your teen's doctor at Group Health.

If I agree to have my teen be in the study, what will he/she have to do?
Teens who choose to participate in this study will be asked to fill out the 8-item survey that is attached to this consent form and to return it by mail. Based on their responses to the questionnaire, some teens and one of their parents will also be invited to participate in a second study.

Are there any risks to the study?
One risk of this study is that your teen might feel uncomfortable answering the survey questions. We have attached the survey to this consent form so that you can look at the questions before giving the survey to your teen. Your teen can choose not to answer any questions that make him or her uncomfortable. Another risk is that, although we have a security plan to keep survey responses confidential, it is possible that someone else may see them.

Confidentiality
The information that your teen provides will be kept confidential as provided by law. Your teen's responses will be identified by study number only and only researchers and staff (listed above) will have access to it. The responses to the survey will not be reported back to your doctors at Group Health or to you.

Privacy
Your/your teen's health information is protected by a federal privacy law (called HIPAA) that applies to health care organizations and thei

ORIGINAL Grade level = 9.4, 32% passive sentences

You can change your mind about being in this study at any time. You may also change your mind at any time about letting us use your teen's survey answers for this study. To do this, please write to Susie Manager at 1730 Minor Ave, Suite 1600, Seattle, WA 98101-1448. Your decision will not affect your family's benefits or care

Your teen may skip any survey questions he or she does not want to answer. We have enclosed a $2-dollar bill as a thank-you for your teen, whether or not s/he chooses to do the survey.

ORIGINAL Grade level = 10.6, 17% passive sentences

Example #3

INFORMATION STATEMENT

Purpose:
The purpose of this study is to identify better ways to help Group Health members deal with certain symptoms of stress and worry. The study is funded by the National Institutes of Health.

What is Involved:
This study consists of several steps. Agreeing to participate in Step 1 does not obligate you to participate in Steps 2 or 3.

Step 1 is completing and returning the enclosed brief questionnaire about stress and worry in your life. The purpose of this questionnaire is to find out if you are eligible to participate in the second step of this study. If your answers on the questionnaire make you eligible for the next step, we will contact you about Step 2. We expect that only a small number of those who complete the questionnaire will be eligible for step 2, and we will only contact those persons. If you do not hear back from us, you may call Sally Manager at 206-555-5555 to find out if you meet our criteria for Step 2.

If you are found eligible for **Step 2,** a study staff member will telephone you within 2 weeks of receiving your questionnaire. If you are willing, they will do a 10 – 15 minute telephone interview which will ask about your general physical and mental health and health behaviors (such as uncontrollable worry). If this interview suggests that our project is right for you, we will invite you to take part in Step 3.

If you remain eligible and interested, you will proceed to **Step 3,** which consists of visiting our clinic for an initial interview lasting 45 – 60 minutes. You would be paid $20 for your time if you complete this interview. If the interview confirms your eligibility and you are interested in participating, you would be assigned by chance to receive one of 3 treatment groups. The three treatments are:

- **Therapeutic Massage:** a gentle massage of the muscles and other soft tissues
- **Thermotherapy:** a gentle heat treatment using heating pads and warm towels
- **Tranquility Treatment:** relaxation therapy involving music and deep breathing

You would then receive a series of 10 one hour relaxation treatments over 3 months. At the end of the 3 months and again 3 months later, we would ask you to visit our clinic for follow-up interviews. You would receive $20 for each of these interviews.

All treatment sessions will take place at our downtown Seattle clinic located at 1730 Minor Ave. Parking will be paid by the study.

ORIGINAL Grade level = 10.6, 17% passive sentences

Study Information Sheet

What is the goal of this study?

The goal of this study is to find better ways to help people deal with symptoms of stress and worry.

Why are you asking me to be in this study?

We are inviting you and other Group Health members who have visited a Group Health provider in the last 6 months to take part in this study.

How do I find out if I am eligible for the study?

Finding out if this study is right for you happens in three steps:

- **Step 1 is to complete and return the enclosed brief survey** about stress and worry in your life. Your answers to the survey will tell us if you are eligible for Step 2. If we find that you are eligible for Step 2, we will call you within 2 weeks of getting your survey.

- **Step 2 is a 10-15 minute phone survey** about your general physical and mental health. There are also some questions about certain health behaviors, such as uncontrollable worry. If your answers to the phone survey show that you are eligible for the study, we will invite you to take part in Step 3.

- **Step 3 is a visit to our research clinic** for an interview that will last about 45-60 minutes. If we confirm that you are eligible for the study, we will invite you to take part in one of three treatment groups (described below). We will also give you $20 to thank you for doing in the interview.

Agreeing to take part in Step 1 does not mean you have to do Steps 2 or 3. You can say no to any part of the study at any time.

We expect that only a small number of those who do Step 1 will be eligible for step 2. If you do not hear back from us after Step 1, you may call Sally Manager at 206-555-5555 to find out if you meet our criteria for Step 2.

What happens in the treatment groups?

If you decide to take part in the treatment phase of the study, we will use a computer to randomly assign you to one of three treatment groups. This means you will be put into a group by chance. It is like flipping a coin or drawing names out of a hat.

The three treatments are:

- **Therapeutic Massage** - gentle massage of the muscles and other soft tissues
- **Thermotherapy** - gentle heat treatment using heating pads and warm towels
- **Tranquility Treatment** - relaxation therapy with music and deep breathing

Over the following 3 months, you will come to 10 one-hour treatment sessions. All treatment sessions will take place at our research clinic in downtown Seattle. The address is 1730 Minor Avenue. The study will pay for your parking.

We will also ask you to come to our clinic for two follow-up interviews. One will happen after you finish your series of treatment sessions, and the other will happen 3 months later. We will give you $20 for doing each interview.

What else should I know about this study?

Being in this study is voluntary. Whether or not you take part will not affect the care you receive at Group Health. If you decide to take part, you may leave the study at any time. You may also skip any survey or interview questions that you don't want to answer.

We will keep all the information you give us confidential as provided by law. We will not share your answers to the surveys and interviews with your doctor or put them in your medical record. We won't ask you to take any medications or supplements for this study.

Who do I call if I have questions?

- e 7 45 5skip y1 31indTi

More health literacy Web resources

Agency for Healthcare Research and Quality
Health Literacy and Cultural and Linguistic Competency resource page provides links to research studies, implantation strategies, evidence reports and tools for testing the quality of your materials.

Harvard School of Public Health, Health Literacy Studies
Information for researchers and practitioners in the public health, medical, and adult education

Writing tips and how-to guides

Simply Put **PDF**
Tips for creating easy-to-read print materials from the Centers for Disease Control and Prevention (CDC).

How to Write Easy to Read Health Materials
Tips from the smart folks at Medline Plus, who develop lay-oriented health information.

Health Literacy Style Manual **PDF**
Southern Institute on Children and Families

Guidelines for Developing Easy-to-Read Health Education Materials
State of Washington Department of Health

Patient Education Materials: An Author's Guide
University of Utah, Health Sciences Center

Improving Readability By Design
Tips on seven design elements to improve the readability of patient education materials, from healthcommunications.org.

Three resources especially worthwhile for researchers and IRBs

The AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research
Developed by the Agency for Healthcare Research and Quality (AHRQ), this toolkit aims to make informed consent and HIPAA authorization more meaningful for participants. It includes sample easy-to-read consent documents for informed consent and authorization and a model process for obtaining written consent and HIPAA authorization.

Simplification of Informed Consent Documents
Plain language recommendations from the National Cancer Institute and a consent form template for cancer-related clinical trials.

Universal Use of Short And Readable Informed C

Enhancing provider/patient communication

AskMe3
Sponsored by the Partnership for Clear Health Communication (PCHC). The PCHC serves as an information source regarding the scope and impact of health literacy in the U.S., as well as what providers and patients can do to improve health communication in every provider-patient interaction.

Familydoctor.org
Patient-friendly site has an extensive index of conditions, health tools, including a dictionary of common medical terms, and a section on healthy living. All material is written and reviewed by physicians and patient education professionals.

FDA Easy-to-Read Publications
This site has a collection of easy-to-read brochures in English and Spanish on a variety of health topics. You can print them or order free copies.

FDA Information for Seniors
Easy-to-read articles on a variety of health issues that affect older adults. Topics include arthritis, cancer, nutrition, food safety, and women's health. Also links to other organizations with information for older adults.

KidsHealth
Sections for parents, kids, and teens, including interactive games. The kids' articles are easy to read and written for children. Also appropriate for adult learners with low-literacy skills.

Medline Plus
Interactive tutorials teach about health topics with animated graphics and simple text.

Health in Plain Terms.
A call to action from the Puget Sound Health Alliance. This is a resource for both consumers (helping them get the care they need), and providers (tools to help them talk to their patients in language that is easily understood.

Health Literacy: A Manual for Clinicians.
American Medical Association and American Medical Association Foundation, 2003

An abbreviated list of published articles on literacy and readability in health research (this is an ever-growing bibliography)

Berkman ND, et al. Literacy and health outcomes. Summary, Evidence Report/Technology Assessment No. 87. AHRQ Publication No. 04-E0007-1. Rockville, MD: Agency for Healthcare Research and Quality. Jan 2004.

Bjorn E, Rossel P, Holm S. Can the written information to research subjects be improved – an B

Coyne CA, et al. Randomized, controlled trial of