Center for Health Studies

PRISM

PRISM

[Project to Review and Improve Study Materials]

Readability Toolkit.

GroupHealth

If you use this toolkit in your work, please let us know.

We are interested in tracking how it is being used and how effective it is as a tool for addressing readability and health literacy. We invite you to answer some brief questions (see below) by visiting the following Survey Monkey site:
http://www.surveymonkey.com/s.asp?u=428552635115

OR

You may send your comments by email to:

Jessica Ridpath
ridpath.j@ghc.org

- How have you used the toolkit in your work?
- Have you shared the toolkit with colleagues or posted it on a website? If so, which website?
- How effective has the toolkit been in helping you address the readability of your written materials?
- How effective has the toolkit been helping your organization raise awareness of health literacy as concern in research?
- Do you have any suggestions for how the toolkit could be improved?

If you cite the toolkit in your work, please do so as follows:

> Ridpath, Jessica; Center for Health Studies Readability Toolkit. 2nd ed. Seattle: Group Health Center for Health Studies; 2006.

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The Center for Health Studies Readability Toolkit

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Introduction to Using the Readability Toolkit

Why do I need this toolkit?

This toolkit was created to help research teams develop study materials that participants can easily read and understand. Nearly half of American adults read at or below an 8th grade reading level.[1] However, most informed consent documents are written at a 10th grade reading level or higher.[2] Written materials for study participants must explain complex ideas and information, including the purpose of the study, detailed study procedures, and confusing privacy laws. This makes the development of easy-to-read study materials quite a challenge.

Using this toolkit will help study teams more easily describe complicated information in "plain language," that is, language that describes exactly what the reader needs to know without using unnecessary or overly complex words. The toolkit also provides guidance on overall page formatting and how it affects how easy a document is to read.

The following introduction briefly describes each section of this packet. It also provides background information on readability and why it is important in the research context.

- **The Quick Reference Guide for Improving Readability** on page 9 provides an at-a-glance summary of what to consider as you try to improve a document's readability. It summarizes the information contained in this introduction and is an important companion to the Writing Checklist for Participant Materials.

- **The Writing Checklist for Participant Materials** on page 13 is an interactive tool that guides the user through a systematic process to lower the reading level of document. General instructions for using the Writing Checklist are provided on page 11.

- A list of **Alternative Wording Suggestions** for commonly used vocabulary that can be simplified can be found as an appendix on page 17. This list also includes a selection of Internet resources for looking up alternatives to medical jargon.

- Easy-to-read **Template Language** for common topics in consent forms, such as randomization and voluntary participation, is included as an appendix on page 23.

- Other reference materials are also included as appendices, including **Instructions for Checking Readability in Microsoft Word** on page 15. Before and after snapshots of text that has been revised to be more readable are included in **Examples of Improved Readability** on page 33. For people who are interested in learning more about readability, there is also an extensive list of **References and Resources** on page 39.

[1] 2003 National Assessment of Adult Literacy Survey (NAAL), National Center for Education Statistics, www.nces.ed.gov/naal

[2] Paasche-Orlow M, et al. Readability standards for informed consent forms as compare with actual readability. *New England Journal of Medicine.* 2003 Feb 20;348(8).

Why is readability important to researchers?

Many words that are commonly used in medical and research settings are complicated and unfamiliar to the average adult. However, federal regulations require that informed consent documents be written in language that is understandable to the subject.[3] Furthermore, most IRBs recommend or require that participant materials meet a reading level target of 6th-8th grade. In order to conduct compliant and ethical research, study teams should strive to simplify the language they use and ensure that participant materials are as easy as possible to read and understand.

Of special consideration to researchers is that fact that people with chronic mental and/or physical health conditions are among several vulnerable populations whose reading level is below the national average.[4] Considering how often chronic medical conditions are the focus of research, it is imperative for researchers to be mindful of how difficult it might be for certain populations to understand study materials. Regardless of the population under study, research suggests that a majority of adults prefer easy-to-read health care information.[5]

Researchers should ask themselves 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? 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 as study materials are developed.

More about plain language

In general, using plain language involves using common, every day words and active voice. Plain language is written in a conversational style, with ideas organized into short, succinct sentences and paragraphs. You cannot always avoid using complex words and concepts, especially in medical and research materials, but you can use plain language to provide an example or a simplified explanation. Whenever possible, it is a good idea to provide a picture, diagram, or other visual example.

There are many resources that provide detailed information about using plain language. Among the most comprehensive is Pfizer's Principles for Clear Health Communication Handbook, a thorough compilation of strategies and information specifically developed for the health care setting. To access this resource, visit http://pfizerhealthliteracy.com/public-health-professionals/chc-principles.html.

See Appendix E: References and Resources on page 39 for information about other readability resources.

[3] 45 CFR 46

[4] 2003 National Assessment of Adult Literacy Survey (NAAL), National Center for Education Statistics, www.nces.ed.gov/naal

[5] Davis TC, et al. Parent comprehension of polio vaccine information pamphlets. *Pediatrics*. 1996;97:804-810.

How to determine reading level

There are several formulas available to help researchers determine the approximate reading level of a document. Most provide a grade level score and are based on the average number of syllables per word and words per sentence. 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 manual Fry formula and the Flesch-Kincaid formula. The Fry formula is very accurate, however, the analysis can take 20 minutes or more since computations are done by hand. The Flesch-Kincaid formula has been criticized for being less accurate than the Fry, however, results can be obtained instantly using the readability analysis tool in Microsoft Word.

Despite the fact that the Flesch-Kincaid method may be less accurate than the Fry, the Center for Health Studies (CHS) has chosen to recommend its use because results are so easy to obtain. 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 15. Pfizer's Principle for Health Communication provides a detailed description of how to use the Fry formula (see http://pfizerhealthliteracy.com/public-health-professionals/chc-principles.html).

Readability statistics available in Microsoft Word:

Formula	Description	CHS 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	based on a 0 to 100 point scale; the higher the score, the more readable the text. Text with a score of 70 is readable; text with a score of 30 is not.	60 or greater
Percent passive sentences	gives the proportion of sentences written in passive voice	As close to 0% as possible

Things to consider when using the Flesch formulas to rate readability

- In older versions of MS Word, the Flesch-Kincaid Reading Level formula maxes out at a score of 12th grade. This means that different versions of MS Word will give different grade-level scores, and text rated at 12th grade may actually be college level or higher. Recent versions MS Word (2003 and newer) do not have this error and will provide exact college-level scores. If you are using an older version of MS Word, you may be able to fix the error by downloading the applicable Service Pack.

- You can check the readability of a sentence, a paragraph, or the entire document. If it is difficult to meet your target, check each paragraph individually to identify problematic text.
- The Flesch formulas look for periods to identify the end of a sentence. If your text includes a bulleted or numbered list, add periods at the end of each item before you check readability. (It is not necessary to leave the periods in after checking readability.)
- The Flesch formulas do not take formatting or page density into account, both of which significantly impact the overall readability of a document (see below).
- Sometimes we cannot avoid using multi-syllable words like "mammography" or "immunization." As long as these words are adequately defined, it is okay to use them and to 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.
- Using the Flesch formula 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 more understandable, even though they score slightly higher on the Flesch scale.[6]

Other things that affect readability

Active voice is more readable and more powerful than passive voice.

- Active voice describes a subject performing an action, while passive voice describes a subject as the recipient of an action.
- "We will ask you questions about your health" is active, while "You will be asked questions about your health" is passive.

Multiple items in a list are much easier to read if they are bulleted instead of combined into one long sentence or paragraph.

- Convert sentences that list multiple points separated by commas or semicolons into bulleted lists with one point per line.
- It is especially important to list critical information, like eligibility criteria, participant responsibilities, or complex study procedures, in bullet format.

Overall page formatting significantly impacts readability.

- Do not assume that one page is always better than two. One page crammed with information is often more intimidating than multiple pages. Avoid decreasing margins to force text to fit on one page.

[6] Goldfarb N and Dubay WH. Writing good at a seventh-grade reading level. *Journal of Clinical Best Practices.* Vol.2, No.1, Jan 2006.

- Readers are more likely to become discouraged by dense copy. Adequate white space and margins provide visual breaks that may encourage the reader to keep going.
- Always make use of as much white space as you have available. If you have space left over, consider how best to use it. You may be able to add space between paragraphs or increase the font size of text or headers.

Headers help the reader process information more quickly and effectively.

- A document is easier to read when there are descriptive headers for each section. Headers should be specific and should be graphically emphasized to stand out.

Format your document strategically to help emphasize the most critical information.

- Consider using borders, graphical elements, or different fonts or font sizes to draw the reader's attention to the most important information in your document.
- Avoid using justified margins or putting sentences in all capital letters, as both increase the strain on the reader. It is okay to put short headers in all caps.

Consider the needs of the study population.

- Use large font for the elderly or for other populations who may have poor eye site, like people with diabetes or glaucoma.
- Use the simplest language possible when writing assent forms for minors. Consider using cartoons, picture, or other methods to describe the study.
- Take time to consider other special needs based on what you know about the population's age, culture, ethnicity, or potential chronic health conditions.

People will often read comfortably at a higher grade level than normal if they are interested in the subject matter.

- The more words about people and the more sentences addressed to an audience, the more interesting a document is to read.

Note: Readability statistics for this introduction - Grade level = 11.7, Reading Ease = 42.0, Passive = 14%

Quick Reference Guide for Improving Readability

(a companion to the Writing Checklist for Participant Materials)

Use readability statistics.

- Choose one of the numerous formulas for determining the reading level of a document (most often expressed as a grade level).
- The simplest option is to use the readability statistics tool in the Microsoft Word spellchecker. (see page 15 for instructions).

Use plain language.

- Replace multi-syllable words with simpler vocabulary.
- Avoid research terms & medical jargon whenever possible. If you must use a complicated term, define it in plain language and give an example or use a visual.
- Refer to the list of Alternative Wording Suggestions, as necessary (see page 17).

Use short sentences.

- Break up sentences joined with conjunctions or semicolons.
- Try to get sentences to an average length of 15-20 words or less.
- Use bullets and lists whenever practical.

Use short paragraphs.

- Break up paragraphs with more than 1 or 2 main ideas.
- A paragraph of 1-3 sentences is okay.

Use active voice.

- Active voice describes a subject performing an action, while passive voice describes the subject as the recipient of an action.
- "We will ask you questions about your health" is active. "You will be asked questions about your health" is passive.

Use clear and descriptive headings.

- Make sure headings are graphically emphasized to stand out.
- Choose relevant headings that will help improve readers' comprehension.

Use strategic formatting to draw readers' attention to the most critical points.

- Use bold or italic font or graphics to emphasize negatives and other key information.
- Use bullets to clarify complex or critical information, such as eligibility requirements.
- *Do not* use justified margins or put entire sentences in all caps.

Use adequate white space and margins.

- Break up dense copy by using ample white space between paragraphs and headings.
- Avoid decreasing margins to force text to fit on one page. All margins should be at least 1 inch.
- Consider using all white space that may be leftover by adding space between paragraphs, adding graphics, or increasing the font size of headers or text.

Use fresh eyes when you edit or proofread.

- Whenever possible, step away for a few days and proofread the document again.

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 should always have a chance to review it.

Double-check names and contact information.

- Call all phone numbers and check all links and email addresses to make sure they work.
- Confirm that all names have been spelled correctly and that all titles are correct.

Consider the special needs of your study population.

- 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.

Note: Readability statistics for the Quick Reference Guide - Grade level = 7.9, Reading Ease = 43.4, Passive = 2%

General Instructions for Using the Writing Checklist for Participant Materials

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

- You will probably want to **check some items more than once**.
- Feel free to **use multiple copies of the checklist** as you review and refine materials.
- **Save completed checklists** to track changes and decisions.
- **Note the study and document names and the date or version** on the top of each checklist.

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

- 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 this 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 readability statistics.

The **Quick Reference Guide for Improving Readability** on the previous page gives more detail about how to check the various items. 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 ridpath.j@ghc.org.

Note: Readability statistics for these instructions - Grade level = 9.6, Reading Ease = 50.1, Passive = 30%

Writing Checklist for Participant Materials

Study: _____ Initials of primary reviewer: _____

Document: _____ Document date or version: _____

Date final version due: _____ Date due to IRB: _____

Refer to the Quick Reference Guide for Improving Readability as needed.

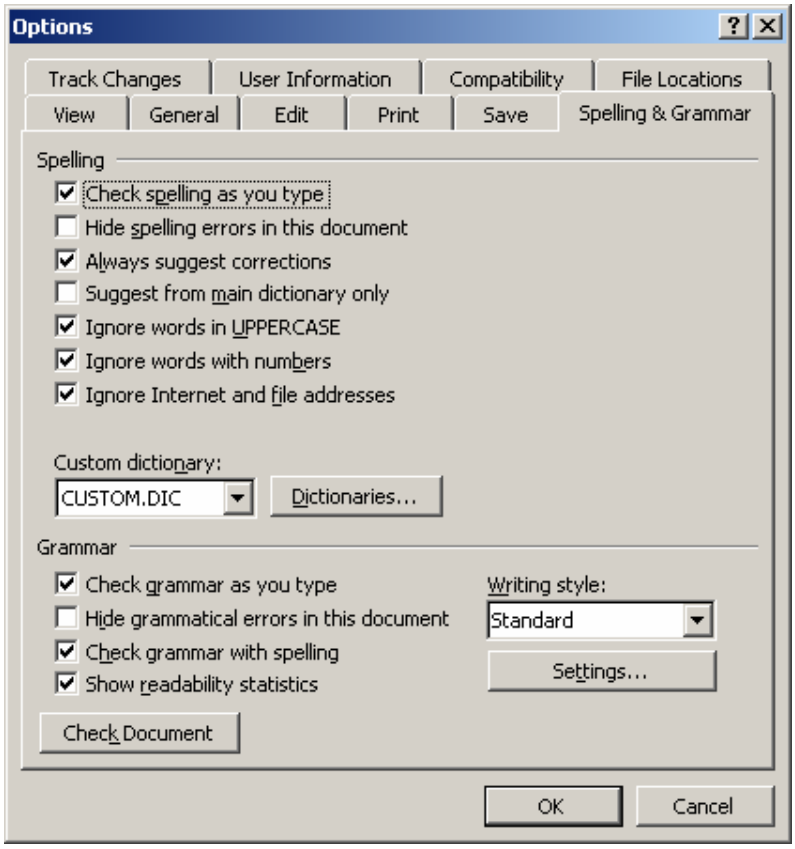
PHASE 1 – Primary Review		
√	**Item to be checked**	**Exceptions, Comments, and Notes**
	Readability statistics	Grade level _____ Reading ease _____ % Passive sentences _____
	Plain language	
	Replace and/or define research terms & medical jargon	
	Short sentences	
	Short paragraphs	
	Active voice	
	Clear and descriptive headings	

	Adequate white space and margins	
	Leftover white space has been used	
	Strategic formatting	
	Proofread for typos and grammatical errors	Date: _____
PHASE 2 – Secondary Review		
	Readability statistics	Grade level _____ Reading ease _____ % Passive sentences _____
	Reviewed by others: • PI • Staff member • User • Someone unfamiliar to the project	Name: _____ Date: _____ Name: _____ Date: _____ Name: _____ Date: _____
	Proofread for typos and grammatical errors	Date: _____
PHASE 3 – Final Review		
	Names and contact information are correct	Date: _____
	Signoff from PI and/or project team	Date: _____
	Final readability statistics	Grade level _____ Reading ease _____ % Passive sentences _____

Appendix A: Instructions for Checking Readability Using Microsoft Word

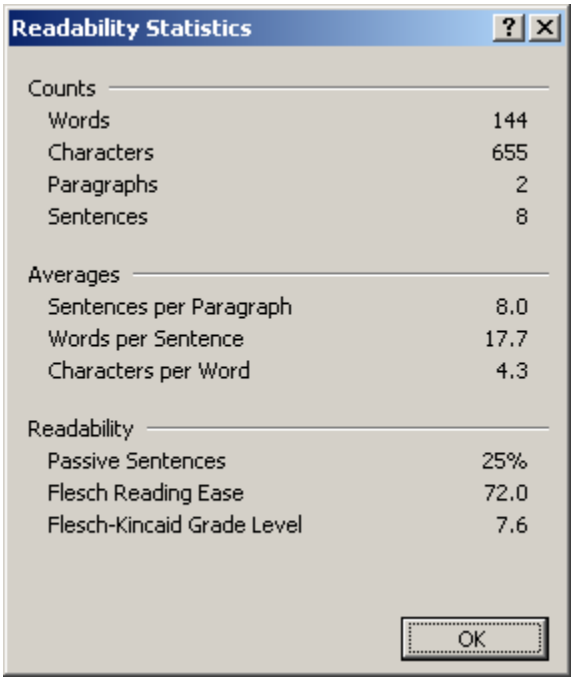
Microsoft Word provides a readability analysis tool in the Spellchecker. To activate this tool:

- Go to the "Tools" menu and select "Options."
- Click on the "Spelling & Grammar" tab.
- Check "Show readability statistics" under the "Grammar" heading.



Each time you check spelling and grammar, you will be given several readability statistics, including:

- The Flesch-Kincaid grade level score (based on the US high school grade level system).
- The Flesch Reading Ease score (based on a 100-point scale; the higher the score, the more readable the text).
- Counts, averages, and percent of passive sentences.



Appendix B: Alternative Wording Suggestions

Resources and guidance for replacing medical jargon

Group Health Cooperative (internal access only)
http://incontext.ghc.org/ccr/identity/editorial/vie_tips.html#avoiding

University of Michigan Medical School
http://www.med.umich.edu/irbmed/guidance/guide.htm

University of California at Davis
http://research.ucdavis.edu//home.cfm?id=OVC,1,1063,1064

Alternatives to overly complex words

(Top 10 CHS favorites are in bold italics)

If you see…	Consider replacing it with…
abstain from	do not
additional	added, more, other, extra
advantageous	helpful
adversely impact	hurt, set back
allow	let
analyze	look at, study
anticipate	expect
appropriate	right, proper
approximate, approximately	roughly, about
assessment	rating, report, interview
assist, assistance	help, aid
associated with	linked to, related to
attempt	try
collaborating with	working with
commence	begin, start
commonly	most often
compensate	pay
complete	fill out, come to, take part in
comply with	follow

If you see…	Consider replacing it with…
component	part
comprise	form, include, make up
concerning	about, on
conducting	doing
consider	think about
crucial	important
decision	choice
deleted	erased
demonstrate	prove show
describing	about
detect	find (out)
determine	find (out), decide, learn if
discontinue	stop, drop
discover	find (out), learn if
disseminate	give, issue, pass on, send
eliminate	cut, drop, end
enrolling	joining, being in
establish	set up, prove, show
evaluate	look at, study
evidence of	signs of, proof of
evident	clear
examine	look at, study
exhibit	show
experiencing	going though, feeling, having
finalize	complete, finish
frequently	often
function	act, role, work
furnish	give, send
general, generalized	wide-spread
identify	find

If you see…	Consider replacing it with…
immediately	at once
implement	carry out, start, put in place
in addition	also, besides, too
including	such as, along with
indicate	show, write down, mean
informed	told
influence	affect
initial	first
initiate	start
investigation	study
investigator	researcher
maintain	keep, support
maximum	greatest, largest, most
minimize	decrease
minimum (a minimum of)	least, smallest (at least)
modify	change
monitor	watch, check (on)
negligible	small
notify	let know, tell
numerous	many
objective	aim, goal
observe	see
obtain	take, get
occasionally	sometimes
occupation(al)	work, job
opportunity	chance
optimum, optimal	best, greatest, most
option	choice, way
participate (ing, ion)	take part, join, do, be(ing)
perform	do

If you see…	Consider replacing it with…
periodically	from time to time
permit	let
permitted	allowed
persist	last
personnel	staff
pertaining to	about, of, on
physician	doctor
portion	part
possess	have, own
previous, previously	earlier, before
proceed	do, go ahead, try
provide	give (us), offer, say
ramifications	problems, results, outcomes
randomly	at random, by chance
receive	get
regarding	about, of, on
regardless	no matter
regulate	affect, control
regulations	rules
relevant (to)	about, tied in with
remain	stay
remaining	other, (second, last, final)
request	ask
require	must, need
retain	keep
reveal	show, give us
satisfactory	okay, fine
selection	choice
several	some, a few, a number of
specimen	sample

If you see…	Consider replacing it with…
submit	give, send
subsequent, subsequently	later, next, after, then
substantial	large, big, much
sufficient	enough
suggested	pointed to
terminate	end, stop
transmitted	passed on to other people
understand	learn, see
utilize, utilization	use
validate	confirm
variety	range
viable	practical, workable
warrant	call for, permit
withdraw (from)	take back, drop, leave

Alternatives to overly complex phrases

If you see…	Consider replacing it with…
…at a time that's convenient for you.	…at a time that works well for you.
…eligible to participate in the second step of this research program.	…eligible for the second step of this research program.
…explain these treatments further.	…explain more about these treatments.
…gain a broader understanding of [ ].	…learn more about [ ].
…give us permission to [ ].	…allow us to [ ].
…learn more about effective management of [insert condition].	…learn more about how to manage [insert condition].
…of the people indicating an interest in participating in this study, only half will be eligible.	…of the people who would like to be in this study, only half will be eligible. …of the people who are interested in this study, only half will be eligible.
…schedule an appointment…	…set a time…
…your understanding of…	…what you know about…

If you see…	Consider replacing it with…
All participants in the study…	Everyone in the study…
At any time during the study, you are free to skip any questions that you would prefer not to answer.	You are always free to skip any questions you do not want to answer.
If you don't want to be contacted by phone…	If you don't want us to call you…
In order to facilitate our reaching you, …	To help us reach you, …
We would prefer that you do not…	Please do not…
You are free to refuse to answer any question or to discontinue the research interviews at any time.	You are free to skip any question or to stop the research interviews at any time.
You should continue to obtain medical care…	You should keep getting medical care…

Appendix C: 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 the Center for Health Studies (CHS), as well as consent form templates made available on the public websites of other research institutions.

CHS is still working to develop template language for HIPAA authorizations, which will be included in a future version of this toolkit.

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

Table 1

Introduction/Researchers' Statement	Grade level
We are inviting you to take part in a research study. The purpose of this consent form is to give you information to help you decide if you want to be in the study. Please read this form carefully and ask study staff to explain anything you do not understand. You will have a chance to ask questions before you make your decision. This process is called 'informed consent.'	**6.2**
We are asking you to be in a research study. Being in this study is voluntary. To make an informed judgment on whether or not you want to be part of this study, you should understand the risks and benefits of participating. This process is known as informed consent. This consent form gives you detailed information about the research study. Please ask any questions you may have about the study or this form before signing it. We will give you a copy of the consent form to keep.	**6.2**
Please read this form carefully. Take time to ask study staff as many questions about the study as you would like. If there are any words or information that you do not understand, study staff will explain them to you. Reading this form and talking to study staff may help you decide whether to participate or not. If you decide to take part in the research study, you must sign the end of this form. *from Chesapeake IRB Informed Consent Template* http://www.chesapeakeirb.com/us/IRBServices/Forms/tabid/83/Default.aspx	**6.3**
What you should know about this study: • You are being asked to join a research study. • This consent form explains the research study and your part in the study. • Please read it carefully. Take as much time as you need. • Please ask the study staff questions about anything you do not understand. • You can ask questions now or anytime during the study. • If you join the study, you can change your mind later. • You can quit the study at any time. • If you decide to quit the study, it will not affect your care at Group Health [insert name of facility or institution]. *from Johns Hopkins University* http://irb.jhmi.edu/Forms/hipaaconsentform.rtf	**4.8**

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 available to you, 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 would normally receive would be limited or taken away. • Please ask any questions you have about this study. Please also take whatever time you need to talk about the study with your doctor, study staff, and your family and friends. The decision to be in the study or not is yours. If you decide to take part, please sign and date the end of this form.	**6.7**

Table 2

Request for Permission to Review Medical Records	Grade level
Checking the medical records of people in the study is an important part of this research. For this reason, we are asking that you allow us to look at your computerized records at Group Health [insert name of facility or institution]. We are interested in seeing what kinds of medicines you take and what kinds of visits you make in the next year and a half [insert time frame].*	**8.5**
We will collect more information about your back pain [insert condition] from your computerized medical records. This will include information about medicines you have been prescribed and visits you have made to your doctor in the past five years [insert time frame].*	**10.4**
We are asking your permission to review information in your medical records. This will include information about visits, medications, and lab tests that you have during the study.* We will use this information to compare people who received extra services with people who did not receive extra services [insert applicable information].	**10.5**

* can also give a range: "...between 2000 and 2006."

Table 3

Randomization	**Grade level**
We will use a computer to randomly assign you to one of the study groups. This means that you will be put 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 placed in any group. *adapted from an example at Georgetown University* http://ora.georgetown.edu/irb/pdf/GU-Consent0805.pdf	**3.8**
There will be about 1500 [insert number] people in this study. They will be assigned randomly to one of three [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 receive one of the four [insert number] study treatments. This means that whichever study treatment you receive will be decided purely by chance, like flipping a coin. You will have a 1in 4 [insert odds] chance of receiving any one of the study treatments. We will not tell you which group you are assigned to. Study staff at your visits will not know your group assignment either. But we can quickly find out which group you are in if we ever need to know in order to protect your safety.	**6.7**

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

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.	**3.1**

Risks of Drawing Blood	Grade level
You may feel bothered by the needle stick, and a bruise may form. In rare cases, some people faint or the site becomes infected.	**4.3**
There are no major risks associated with drawing blood. Having your blood drawn can be uncomfortable and can sometimes cause a bruise. In rare cases, it can cause fainting. Only trained people will draw your blood.	**4.9**

Table 6

Risks of Survey Questions	Grade level
You may feel uncomfortable answering some questions on the survey*. You may skip any question that you do not want to answer.	**6.4**
The interview includes some questions that may seem sensitive or personal*. You are free to skip any question or item for any reason.	**7.3**

*IRBs may require that the risks section explicitly mention questions pertaining to sexual history, drug use, alcohol consumption, or other potentially sensitive topics.

Table 7

No Guarantee of Direct Benefit to Participants	Grade level
You may or may not receive any benefit from being in the study. It is possible that you may get better, stay the same, or get worse. If you take part in this study, other people with diabetes [insert condition] may be helped. *from Chesapeake IRB Informed Consent Template* http://www.chesapeakeirb.com/us/IRBServices/Forms/tabid/83/Default.aspx	**5.2**
We do not expect you to benefit from being in this study. Others may benefit in the future from the information we get from this study.	**6.7**
We don't know if you will benefit from being in this study. However, we hope results of this study will hope to improve treatment at Group Health [insert facility or institution] and in other health systems around the country.	**7.4**
We can't guarantee that you will benefit from being in this study. However, we hope to use the information from this study to develop new programs for treating back pain [insert condition].	**7.9**

Table 8

Voluntary Participation and Withdrawal	Grade level
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. *from Johns Hopkins University* http://irb.jhmi.edu/Forms/hipaaconsentform.rtf	**4.2**
Being in this study is voluntary. You can decide not to be in the study. If you decide not to be in the study, you will not lose any benefits that you have.	**4.4**
Taking part in this study is up to you. You may choose not to take part or to leave the study at any time. If you choose not to take part or to leave the study, your regular medical care will not be affected. *from Georgetown University* http://ora.georgetown.edu/irb/pdf/GU-Consent0805.pdf	**4.8**
Taking part in research is voluntary. You may decide not to be in the study. If you decide to take part, you may leave the study at any time. Your decision will not affect your medical care at Group Health [insert facility or institution]. There are no penalties or loss of benefits if you choose not to take part or to leave the study early. *from Children's Hospital* http://research.seattlechildrens.org/rss/irb/institutional-review-board.asp	**5.0**
Taking part in this study is voluntary. If you choose not to participate in this study, your care at Group Health [insert facility or institution] will not be affected. You may choose not to participate at any time during the study. Leaving the study will not affect your care at Group Health [insert facility or institution]. *from University of Chicago* http://ors.bsd.uchicago.edu/IRB/UofCConsentFormTemplate.doc	**5.8**

Voluntary Participation and Withdrawal	Grade level
Entering a research study is voluntary. Anyone who is asked to be in a research study may say no. If you start a research study, you may stop at any time. You do not need to give a reason. No doctor will treat you differently if you choose not to be in a research study or later decide to stop participating. If you stop, it is important to tell study staff and follow any instructions that they may give you. *from Chesapeake IRB Informed Consent Template* http://www.chesapeakeirb.com/us/IRBServices/Forms/tabid/83/Default.aspx	**6.2**
Your participation in this study is voluntary. You are free to leave this study at any time. Your care at Group Health [insert facility or institution] will not be affected by whether you decide to participate.	**6.6**
Your Rights It is important for you to know that: • Your participation is voluntary. • You may decide not to take part or to leave the study at any time. This will not change the quality of the health care you receive. • We will tell you about any new information or changes in the study that might affect your willingness to participate. *from University of Massachusetts Medical School* http://www.umassmed.edu/subjects/human/forms.aspx	**7.1**

Table 9

Confidentiality	Grade level
Your confidentiality is one of our primary concerns. All of your research records will be kept indefinitely in locked cabinets and protected computer files. We will not place your name on any research data. Instead, we will assign a code number to your information. We will keep the master list that links your name to your code number in a locked cabinet. We will not share your study results with anyone unless you ask us to. Your name will not appear in any reports about this study. All information and results from this study will be kept indefinitely. All of the information that you give us will be confidential as provided by law. The only exception is if there is a risk of possible harm to others or to your self.	**7.1**

Confidentiality	Grade level
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]. We will keep the audiotapes in a locked cabinet. Information from the interviews will be stored in protected computer files. We will destroy the audiotapes and the link between your name and study number by March 2010 [insert date]. We will never use your name in reports about this study. We will not share your answers with your doctor or anyone else without your permission. However, if we think you are in danger of harming yourself, we are obligated to get help for you. [use this clause only if necessary]	**8.0**
We will keep information about you confidential in accordance with the law. We will use a study number instead of your name to identify your blood sample and survey answers [insert applicable study data]. The link between your name and your ID number will be kept in a separate computer file. Access to those files will be limited to study staff with proper security clearances. You will not be identified in published reports.	**8.0**
Your privacy is important to us. We will do everything we can to protect the confidentiality of your personal information*. You will be given a study number. We will use this number on your surveys and other research papers instead of your name or Group Health consumer number [insert applicable patient identifier]. We will not include personal information about you in any reports or papers about this study. *from the US Department of Justice* http://www.bop.gov/news/orebp_s606.pdf	**8.9**

*Note: Some IRBs may require "as provided by law" or a similar clause.

Table 10

Participant's Statement/Signature	Grade level
• I have read this form and the research study has been explained to me. • I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call. • I agree to be in the research study described above. • I will receive a copy of this consent form after I sign it. *from Northwestern University* http://www.research.northwestern.edu/research/OPRS/irb/informedConsent/docs/consentFormInstructions.doc	**4.5**

Participant's Statement/Signature	Grade level
I have read this form or have had it read to me. I have been told what will happen if I take part in this study, including the risks and benefits. I have had a chance to ask questions, and they have been answered to my satisfaction. I have been told that the people listed in this form will answer any questions I have in the future. Study staff will give me a copy of this consent form for my records. By signing below, I am voluntarily deciding to be in this research study.	**6.2**
Please initial each statement you consent to: __ To take part in this study. __ To allow the researchers to look at my Group Health [insert facility or institution] computerized medical records related to the health care I receive. __ To be contacted about this research in the future.	**6.8**
• This study has been explained to me. • I volunteer to take part in this research. • I have had a chance to ask questions, and my questions have been answered. • If I have questions later on about the research, I can ask one of the researchers listed in this form. • If I have questions about my rights as a research subject, I can call the Group Health Human Subjects Division at (206) 287-2919 [insert applicable info]. • I agree to allow the researchers to use my medical records as described in this consent form [remove if not applicable]. • I understand that if I am not able to answer questions for this study in the future, study staff will contact a family member or close friend to do this for me [remove if not applicable]. • I will receive a copy of this consent form.	**7.8**

Table 11

Study Staff Statement/Signature	Grade level
• I have carefully explained to the subject the nature and purpose of this study. • The subject has been given enough time and an adequate place to read and review this form. • The subject has had a chance to ask questions and receive answers about this study. *from Chesapeake IRB* http://www.chesapeakeirb.com/us/IRBServices/Forms/tabid/83/Default.aspx	**7.3**

Study Staff Statement/Signature	Grade level
I have explained the above research study over the telephone [remove if not applicable]. The participant was given time to discuss the study and ask questions. I can be reached at the phone number listed on this form to answer any other questions that the participant may have. I will mail [or "give," if applicable] a signed copy of the consent form to the participant.	**7.5**
My signature below indicates that I have fully explained this study, including its risks and benefits. I will answer any questions that you may have at any time. I also recognize that by answering study questions, you will be sharing personal information with me.	**9.7**

Appendix D: Examples of Improved Readability

The following examples came from original text in actual study materials at the Group Health Center for Health Studies. (Study topics and names have been changed or omitted to protect the innocent.) The revised versions use active voice, simpler vocabulary, shorter sentences, shorter paragraphs, and bullets (when appropriate). Language that has been changed is emphasized using bold font.

Example 1

Original • Grade level = 12.0+ • Reading Ease = 39.9 • 20% passive sentences	Revised • Grade level = 7.8 • Reading Ease = 67.2 • 0% passive sentences
If you agree to participate, we will **arrange a screening interview** with you at our research clinic. During this interview, **you will be asked** to do some tasks that measure your thinking and problem-solving abilities **and answer questions** about your **medical history and occupational history**. If you are willing, a trained technician will **obtain** a blood sample of **approximately** two tablespoons. This visit should take **approximately** two hours. If you are eligible **to participate in the study**, every two years we will **repeat the initial assessment procedures** at the Center for Health Studies**, and we will periodically** review your medical record to see if there is a change.	If you agree to participate, we will **invite you to an interview** at our research clinic. During this interview, **we will ask you** to do some tasks that measure your thinking and problem-solving abilities**. We will also ask you** questions about your **medical and work histories**. If you are willing, a trained technician will **take** a blood sample of **about** two tablespoons. This visit should take **about** two hours. If you are eligible **for the study**, we will ask you to **come in for a similar interview and blood draw** every two years**. We will also** review your medical record **from time to time** to see if there is a change.

Example 2

Original	Revised
• Grade level = 11.2 • Reading Ease = 51.0 • 71% passive sentences	• Grade level = 7.1 • Reading Ease = 70.2 • 27% 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 4** will be assigned to usual medical care. **Participants** assigned to the study treatment group will make 10 visits over a 7-week period. These visits will be paid for by the study. **All participants** will receive a state-of-the-art book **describing** many techniques for caring for athlete's foot. **Regardless of group assignment**, all participants will be contacted at **2, 6, and 12 months after the start of the study for about a 20-minute telephone interview**. Although we cannot guarantee that you will benefit from the treatment you are **assigned, knowledge gained** from this study will help improve care for athlete's foot at Group Health.	If you are **interested in and eligible for this study**, you will be assigned by chance to one of four groups. Three groups will receive study **treatment. The fourth group** will receive usual medical care. You will have a one in four chance of being in any group. **People** assigned to a study treatment group will make 10 visits over a 7-week period. These visits will be paid for by the study. **Everyone in the study** will receive a state-of-the-art book **about** different techniques for caring for athlete's foot. **No matter which group you are in**, we will call you for three telephone interviews that will **last about 20 minutes each. These interviews will take place 2, 6, and 12 months after you join the study**. We cannot guarantee that you will benefit from the treatment you may be **assigned. However**, we are confident that knowledge **we gain** from this study will help improve care for athlete's foot at Group Health.

Example 3

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

Original	Revised
• Grade level = 12.0+ • Reading Ease = 44.0 • 0% passive sentences	• Grade level = 7.7 • Reading Ease = 64.9 • 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 play an important role in building 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 eligibility requirements.

Example 4

Original	Revised
• Grade level = 11.2 • Reading Ease = 45.9 • 40% passive sentences	• Grade level = 7.8 • Reading Ease = 63.6 • 18% 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.	All of your research records will be **kept** indefinitely in **locked cabinets and protected** computer files. We will not place your name on any research data. **Instead**, we will assign a code number to your **information. We will keep** the master list **that links your name** to your code number in a locked **cabinet.** Only **the researchers** listed on this consent form and **staff who work on** this study will have access to your study records. **Certain** people working for the study sponsors may see **your name or other personal information about you**. **They will look at this information** to confirm that it is correct. These persons are required to **keep your information confidential**. We will not **share your study results with anyone unless you ask us to**. Your name will not appear in any reports **about** this study. All information and **results from** this study will be kept indefinitely.

Example 5

Original	Revised
• Grade level = 11.4 • Reading Ease = 46.2 • 10% passive sentences	• Grade level = 8.3 • Reading Ease = 63.5 • 0% passive sentences
Procedures If you agree to **participate** in this study we will schedule a telephone interview at a time that is best for you. **The telephone call** will last about 30 to 60 **minutes and** will ask about your experiences with headaches and mood. **The interview will be audiotaped and then transcribed so that we may record your responses**. No one other than the research team and the **transcriptionists** will hear the audiotapes. We will **reimburse** you $30 for your time if you **participate** in the telephone interview. **In our 2002 questionnaire study,** you gave us information about your medical history, headaches, mood, and **characteristics about yourself.** You also gave us permission to collect information about your health care visits from your computerized medical records. For the current interview study, we would like to compare how you are feeling now with your **questionnaire answers and computerized records** from the 2002 study**.** We will not **collect any new data about you from** your medical records. By agreeing to **participate** in this study, you will be agreeing to let us compare your responses now with your responses and records from 2002.	**What will happen if I join this study?** If you agree to **be** in this study**,** we will schedule a telephone interview at a time that is best for you. **The call** will last about 30 to 60 **minutes. We** will ask about your experiences with headaches and mood. **We will record the interview on an audiotape and then write down your answers**. No one other than the research team and the **person who writes down the answers** will hear the audiotapes. We will **give** you $30 for your time if you **take part** in the telephone interview. For the current interview study, we would like to compare how you are feeling now with your **information** from the 2002 study**. In that study,** you gave us information about **yourself**, your medical history, your headaches, and your mood. You also gave us permission to collect information about your health care visits from your computerized medical records. We will not **look at** your medical records again for this study. By agreeing to **be** in this study, you are agreeing to let us compare your responses now with your responses and records from 2002.

Appendix D: References and Resources

Key readability and health literacy websites

- Results of the 2003 National Assessment of Adult Literacy (NAAL)

  http://nces.ed.gov/naal/

- Health Literacy Report from the 2003 NAAL

  http://nces.ed.gov/pubsearch/pubsinfo.asp?pubid=2006483

- American Medical Association Foundation Health Literacy Kit, which includes a documentary and instructional video, an in-depth manual for clinicians, and additional resources for education and involvement.

  http://www.ama-assn.org/ama/pub/category/9913.html

- Developed with the help of health literacy experts, Pfizer's Principles for Clear health Communication Handbook is a valuable resource that provides guidelines and strategies for creating health information that is understandable to a broad audience.

  http://pfizerhealthliteracy.com/public-health-professionals/chc-principles.html.

- The Partnership for Clear Health Communication has launched the "Ask Me 3" initiative to help improve health communications between patients and providers.

  http://askme3.org

- A federal website advocating the use of plain language in all public communication. It includes a quick reference guide, before and after comparisons, and wording suggestions.

  http://www.plainlanguage.gov

- An international group called The Plain Language Network. The website provides information, resources, and plain language handbook.

  http://www.plainlanguagenetwork.org/

- A website within the Harvard School of Public Health that offers a detailed description of "plain language," guidelines for developing materials, and innovative documents.

  http://www.hsph.harvard.edu/healthliteracy

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

  http://www.cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs

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