

Center for Health Studies

# PRISM

PRISM

[ Project to Review and Improve Study Materials]

## Readability Toolkit.

## 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.centerforhealthstudies.org/sci resc/readability/readability\\_home.html](http://www.centerforhealthstudies.org/sci resc/readability/readability_home.html)
- 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 April 10, 2008.
- We welcome your feedback about the Toolkit's usefulness, as well as suggestions for improvements or updates. Please send your comments by email to the PRISM team at [PRISM@ghc.org](mailto: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=4\\_2b6cCfUKcjVtUKiwmKE87w\\_3d\\_3d](http://www.surveymonkey.com/s.aspx?sm=4_2b6cCfUKcjVtUKiwmKE87w_3d_3d).

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## Synopsis of PRISM Resources

Project to Review and Improve Study Materials (PRISM) is a Group Health Center for Health Studies initiative to improve the quality of print materials used in communication with research participants. Our primary goal is to create written study materials that are readable and participant-centered.

PRISM consists of three resources that have been tailored for research, but that may be helpful in any health care environment:

- This Readability Toolkit
- A plain language editing service
- A readability training workshop

**The PRISM Readability Toolkit** is a compendium of strategies, real-world examples, and related resources to aid researchers and others in the health care setting create print materials that an audience (such as a potential study participant or patient) can easily understand.

**The PRISM plain language editing service** is available on a fee-for-service basis. Our editors will make sure your materials are clear, readable, and well-organized. We do this by:

- Converting research jargon, medical terminology, and other complex terms into plain language.
- Using reader-friendly sentence structure and formatting.
- Identifying any concepts or procedures that are confusing and suggesting ways to improve overall organization and clarity.
- Correcting errors and ensuring consistency between materials.
- Checking the final reading level of your materials. In many cases, we can get your materials to an 8<sup>th</sup> grade reading level or below.

**The PRISM readability training workshop** promotes health literacy awareness and describes concrete strategies for writing in plain language. It is based on the principles and techniques employed in this Toolkit. We offer a menu of training options and can customize the workshop to meet your needs. Tailored workshops include hands-on editing exercises based on the kinds of print materials you typically develop.

For more information about the PRISM editing service or training workshop, including price and timeline estimates, please contact Jessica Ridpath at **206-287-2032** or [PRISM@ghc.org](mailto:PRISM@ghc.org).

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## How this Toolkit Can Help You

We created this Toolkit to help health care researchers develop print materials that study participants can easily read and understand. Nearly half of American adults read at or below an 8<sup>th</sup> grade reading level.<sup>1</sup> However, most informed consent templates are written at a 10<sup>th</sup> grade reading level or higher.<sup>2</sup> Written materials for research study participants must often explain complex ideas and information, including the purpose of the study, detailed study procedures, and confusing privacy laws. This can make the development of easy-to-read study materials challenging.

Using this Toolkit will help research teams more easily develop consent forms and other participant materials using “plain language.” Plain language is communication (either written or spoken) that an audience can understand the first time they read or hear it. It is clear, concise, and straight-forward and is formatted for easy reading. The underlying principle is that the communication is developed with the reader’s needs in mind. In other words, the process and results are participant-centered.

Although it is primarily geared toward research, many of the guidelines and strategies in this Toolkit can be applied to print materials used in any health care setting. They can also be adapted to work within guidelines or templates you may currently be using. The Toolkit is made up of multiple modules that you can use separately or together. It provides a detailed description of plain language principles, as well as concrete guidelines, tools, examples, and resources to help you adhere to those principles. The modules are:

**[What You Should Know Before Using this Toolkit](#)** – Background information on health literacy, plain language, and why both are important in the research context

**[The Principles of Plain Language](#)** – An explanation of the components of plain language, as well as concrete strategies that support plain language writing

**[How to Determine Reading Level](#)** – Information and advice about using readability formulas to rate the approximate reading level of your materials; see also [Appendix A: Instructions for Checking Readability in Microsoft Word™](#)

**[Quick Reference Guide for Improving Readability](#)** – An at-a-glance summary of plain language principles and strategies, plus other formatting, editing, and proofreading tips

**[Editing Checklist for Participant Materials](#)** – A companion to the Quick Reference Guide that guides users through a systematic process to improve readability, identify unclear concepts, and eliminate proofreading errors

**[Resources for Informed Consent Documents](#)** – Readability advice and resources specifically for consent forms, including a list of common pitfalls, links to helpful consent templates and guidelines, and a selection of easy-to-read template language for common consent topics, such as randomization and voluntary participation

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

<sup>2</sup> Paasche-Orlow M, et al. Readability standards for informed consent forms as compare with actual readability. *NEJM*. 2003 Feb 20;348(8).

[\*\*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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## What You Should Know Before Using this Toolkit

### Background on health literacy and plain language

Recent high-profile reports from the Institute of Medicine (IOM) and the Joint Commission on the Accreditation of Hospitals (JCAHO) have highlighted the problem of limited health literacy in the United States.<sup>3,4</sup> The health care environment is typically so complex that most Americans—even those with average or above average literacy skills—may not be able to understand or act on information that is critical to their health and well-being.

One way we can begin to close this gap is to improve the readability of print materials used in all health care contexts, including health care research. To this end, the U.S. Department of Health and Human Services (DHHS), JCAHO, and the IOM have all recommended that health information be written in plain language.

For a comprehensive summary of why plain language is one promising solution to our nation's health literacy crisis, see Stableford and Mettger's 2007 article, [\*Plain Language: A Strategic Response to the Health Literacy Challenge\*](#).

### Why plain language is especially important in research

Many words and concepts 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.<sup>5</sup> Because nearly half of American adults read at or below an 8<sup>th</sup> grade reading level,<sup>6</sup> most IRBs recommend or require that participant materials meet a reading level target of 6<sup>th</sup>-8<sup>th</sup> grade. In order to conduct compliant and ethical research, research teams should strive to ensure that all print materials used in communication with study participants are as easy as possible to read.

Of special concern to researchers is that people with chronic mental and/or physical health conditions are among several vulnerable populations whose reading level is below the national average.<sup>7</sup> Considering how often chronic medical conditions are the focus of research, it is imperative that the research community be mindful of how difficult it might be for certain populations to read and understand consent forms and other print materials used in health care research. Regardless of the population under study, research suggests that even people with average and above-average reading skills prefer easy-to-read information.<sup>8,9</sup>

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<sup>3</sup> IOM 2004, "Health Literacy: A Prescription to End Confusion"

<sup>4</sup> JCAHO 2007, "What Did the Doctor Say?: Improving Health Literacy to Protect Patient Safety"

<sup>5</sup> 45 CFR 46

<sup>6</sup> 2003 National Assessment of Adult Literacy Survey (NAAL), National Center for Education Statistics, [www.nces.ed.gov/naal](http://www.nces.ed.gov/naal)

<sup>7</sup> 2003 NAAL

<sup>8</sup> Davis TC, et al. Parent comprehension of polio vaccine information pamphlets. *Pediatrics*. 1996;97:804-810.

<sup>9</sup> Kleinmann S, Enlow B. Is plain language appropriate for well-educated and politically important people? Results of research with congressional correspondence. *Clarity*. 2003;50:4-11.

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 important to look out for short words with complex or multiple meanings.

Use plain language word lists to help you **replace or define jargon or other complex words**. See the [Alternative Wording Suggestions](#) on page 37, which is a compilation of selections from several plain language words lists available on the intranet.

You cannot always avoid using complex words and concepts, especially in medical and research materials, but you can **use examples, analogies, and visual aids** to help explain them.

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**

When developing content, try to follow the thought process of your reader. What information is most important to them? How should you order the information items to help it make the most sense? Are there concepts that may not be clear to someone who doesn't know what you know? At times, our writing may be based on assumptions or lack context that will limit how meaningful the message will be to the intended audience. Ironically, we also tend to include significantly more information than the reader really needs in order to understand the key points.

One great way to answer these questions is to **ask someone who is unfamiliar with your project to read your document**, such as a neighbor, friend, or relative who is fairly representative of your audience. You may be surprised at the different impressions or confusing information that an unfamiliar reader identifies.

Provide information in understandable chunks by **using short sentences and limiting paragraphs to one main idea**. Break up sentences joined with semicolons or conjunctions, and aim for an average sentence length of 15 words or less. Varying the length of your sentences will improve flow. Paragraphs should start with a clear topic sentence and should not include unrelated details.

**Avoid information overload** by limiting the content in your document to what the reader truly needs to know. Look carefully for information that does not add value to your document and omit it.

**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 information or assumptions that may not be meaningful (or that may be mis-interpreted or off-putting) within your readers’ cultural or social environment? Do your readers have special needs related to language or other abilities? Use large font for the elderly or for other populations who may have poor eyesight, like people with diabetes or glaucoma. Use the simplest language possible when writing assent forms for minors, and consider using cartoons, pictures, or other graphical methods to describe the study.

### **Use reader-friendly formatting**

Readers are often discouraged by dense-looking pages. Therefore, do not assume that one page is always better than two. One page crammed with information is often more intimidating than multiple pages.

**Adequate white space and margins** provide visual breaks that encourage the reader to keep going. Avoid decreasing margins to force text to fit on one page. Top and bottom margins should be at least 1 inch, and side margins should be at least 1.25 inches. Always consider how best to make use of any white space that may be left over. You may be able to add space between paragraphs or increase the font size of text or headers.

**Break up chunks of dense copy** since this can cause readers to miss important information. Convert long lists embedded in sentences into bulleted lists with one point per line. It is especially important to put lists of critical information, like eligibility criteria, in bullet format. Use a numbered list if the order of items is important.

**Give your readers “road signs”** that help them navigate your document and 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. In many cases, questions like, “What will happen if I take part in this study?” make suitable headers in the research context.

**Emphasize important information** using bold or larger font, borders, or other graphical elements. This will draw the reader’s attention to critical information, even when they are only skimming your document. Avoid using justified margins or putting sentences in italics or all capital letters, as both increase the strain on the reader. It is okay to put 1 or 2 words in italics or all caps.

## 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, 2<sup>nd</sup> Edition\*\*](#) – A classic health literacy textbook for educators that includes information on reader comprehension, tips for using effective visuals, and an incredibly useful tool for assessing the suitability of materials that goes beyond the limitations of readability formulas. The book is now out of print, but is included among a wide range of resources available on the [Health Literacy Website at the Harvard School of Public Health](#) and can be downloaded for free.
- [\*\*Pfizer’s Principles for Clear Health Communication Handbook\*\*](#) – A thorough compilation of strategies and information specifically developed for the health care setting.

Many more helpful resources and websites are listed in [Appendix E: Repository of Readability References and Resources](#) on page 71.

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## 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
<b>Flesch-Kincaid Reading Level</b>	provides a grade level score based on the US high school grade level system	8 <sup>th</sup> grade or below
<b>Flesch Reading Ease</b>	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
<b>Percent passive sentences</b>	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.<sup>10</sup>
- 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 12<sup>th</sup> grade. This means that different versions of the software will give different grade-level scores, and text rated at 12<sup>th</sup> grade may actually be college level or higher. Recent versions (2003 and newer) do not have this limitation and will provide exact college-level scores. If you are using an older version of Microsoft Word™, you may be able to fix the error by downloading the applicable Service Pack.
- You can use the tool in Microsoft Word™ to check the readability of a sentence, a paragraph, or the entire document, however, shorter passages will yield less accurate results. (In fact, some formulas will not work at all unless you use a passage of 100 words or more.) If it is difficult to meet your target, try checking each paragraph individually to identify problematic text.

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<sup>10</sup> Goldfarb N and Dubay WH. Writing good at a seventh-grade reading level. *Journal of Clinical Best Practices*. Vol.2, No.1, Jan 2006

## 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.

#### Choose common, everyday words.

- Replace multi-syllable (or short but complex) words with simpler vocabulary. Avoid research and medical jargon whenever possible. If you must use a complicated term, define it in plain language and provide an example, an analogy, or a visual aid.
- Refer to the list of [Alternative Wording Suggestions](#) and other online resources, as necessary (see page 37).

#### Use active voice.

- The subject of your sentence should act, instead of being acted upon. “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.

- Use pronouns, such as “I,” “we,” and “you.” This encourages the use of active voice and will be clearer and more engaging to the reader.

#### Keep sentences short and to the point.

- Break up sentences joined with conjunctions or semicolons. It’s okay to begin a complete sentence with “And” or “But.”
- Try to vary sentence length. Sentences should average 15 words or less.

#### Limit paragraphs to one main idea.

- Start with a clear and concise topic sentence. Remove or relocate details that do not relate to the central topic. A paragraph of 1 or 2 sentences is okay.

#### Use clear and descriptive headings.

- Meaningful headings that describe the content of different sections will give your readers “road signs” and help them navigate your document more easily.
- Use large font, bold, or other emphasis to ensure the headings stand out.

**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](mailto: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

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
	Reading level	
	Common, everyday words <ul style="list-style-type: none"> <li>• jargon replaced or defined</li> <li>• examples, analogies, visual aids</li> </ul>	
	Active voice	
	First-person	
	Sentences are short and to the point <ul style="list-style-type: none"> <li>• average 15 words or less</li> </ul>	
	Paragraphs have one main idea <ul style="list-style-type: none"> <li>• lead with clear topic sentences</li> </ul>	
	Clear and descriptive headings	

	Context, style, and amount of information are appropriate for the audience	
	Clear organization and format <ul style="list-style-type: none"> <li>• lead with key information</li> <li>• use bold, bullets, or other emphasis as needed</li> </ul>	
	Adequate white space and margins	
	Read aloud to ensure overall clarity and logical flow	Date: _____
<b>PHASE 2 – Secondary Review</b>		
	Reading level	
	Reviewed by others: <ul style="list-style-type: none"> <li>• PI</li> <li>• Staff member</li> <li>• User</li> <li>• Someone unfamiliar to the project</li> </ul>	Name: _____ Date: _____ Name: _____ Date: _____ Name: _____ Date: _____
	Proofread for typos and grammatical errors	Date: _____
<b>PHASE 3 – Final Review</b>		
	Names and contact information are correct	Date: _____
	Signoff from PI and/or project team	Date: _____
	Final reading level	

## Resources for Informed Consent Documents

Writing an informed consent document in plain language is typically not an easy task. This is especially true in biomedical studies that often include descriptions of complex study procedures and complicated risks. Furthermore, the study sponsor, the reviewing IRB, or the research institution will sometimes mandate language that is inaccessible to the typical study participant.

Given that informed consent requirements vary by sponsoring agency, research institution, and level of risk (to name a few), it is important that plain language strategies for consent forms be flexible and adaptable. In essence, there is no “one size fits all” plain language template for informed consent. The informed consent resources in this Toolkit were selected with these variables in mind and might be useful when applied to the process of developing new consent documents or applying existing consent form templates:

- [Avoiding common pitfalls](#)
- [Helpful consent templates](#)
- [Helpful consent guidelines](#)
- [Easy-to-read template language for consent forms](#)

### Avoiding common pitfalls

There is an obvious tension between meeting federal, institutional, and other requirements and creating a short, readable consent form, and no amount of word-smithing can take the place of a rigorous and participant-centered informed consent *process*. However, there are many pitfalls related to informed consent documents that can be avoided. The following insights are derived from our experience editing consent forms and may help researchers overcome some of the unique challenges of creating readable informed consent forms.

- Watch closely for dense formatting. Many consent forms that contain readable language are formatted so densely that comprehending them is still problematic.
- Consent forms often contain significantly more information than may be absolutely necessary, going far beyond the required elements of informed consent. Edit rigorously and consider providing supplemental information in separate handouts.
- Risks and benefits are often the most difficult informed consent concepts to describe and to understand because they often involve complex numerical concepts. The International Cancer Screening Network<sup>11</sup> suggest the following strategies to help make this information understandable:
  - Use visual aids, such as systematic ovals.
  - Use the smallest possible denominator, for instance, report rates per 100 instead of 100,000.
  - Use the same denominator when comparing different probabilities.

---

<sup>11</sup> National Cancer Institute (NCI). *Designing print materials: A communication guide for breast cancer screening*; NIH, 2007. NIH Publication No. 07-6100.  
<http://appliedresearch.cancer.gov/icsn/publications/guide.html>

- 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

As noted elsewhere in this Toolkit, writing in plain language is a continual process of improvement. There may not be any one perfect example of plain language at its best. No matter how readable something is, it seems there are always ways to improve it, especially when the content is as complicated as consent forms tend to be. We have reviewed dozens of informed consent templates and have edited dozens of consent forms, and have found the following to be among the more readable consent form templates:

- [University of South Florida](#) – Templates for biomedical studies, social-behavioral studies, and varying levels of risk, as well as assent forms and parental consent forms. The templates include HIPAA authorization language when required.
- [Johns Hopkins University](#) – Combined informed consent and HIPAA authorization template, assent form template, and short form templates for non-English speakers.
- [Fred Hutchinson Cancer Research Center](#) – Templates for varying levels of risk, as well as for consent to donate extra tissue samples for research. The templates include HIPAA authorization language when required.

## Helpful consent guidelines

- [University of Illinois at Chicago](#) – Policy on informed consent, including specific guidelines about formatting and readability and links to other helpful resources (see pages 9-12 of the policy).
- [Association of American Medical Colleges](#) – “Universal Use of Short and Readable Informed Consent Documents: How Do We Get There,” a summary from a May 2007 strategic planning meeting that includes a review of informed consent literature, potential approaches for improving informed consent, and success stories from the field.

## 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 the Center for Health Studies (CHS), 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
<p>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.'</p>	<p><b>6.2</b></p>
<p>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.</p> <p>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.</p>	<p><b>6.2</b></p>
<p>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.</p> <p>from <a href="#">Chesapeake IRB Informed Consent Template</a></p>	<p><b>6.3</b></p>
<p><b>What you should know about this study:</b></p> <ul style="list-style-type: none"> <li>• You are being asked to join a research study.</li> <li>• This consent form explains the research study and your part in the study.</li> <li>• Please read it carefully. Take as much time as you need.</li> <li>• Please ask the study staff questions about anything you do not understand.</li> <li>• You can ask questions now or anytime during the study.</li> <li>• If you join the study, you can change your mind later.</li> <li>• You can quit the study at any time.</li> <li>• If you decide to quit the study, it will not affect your care at <b>Group Health</b> [insert name of facility or institution].</li> </ul> <p>from <a href="#">Johns Hopkins University</a></p>	<p><b>4.8</b></p>

Introduction/Researchers' Statement	Grade level
<p>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.</p> <p>Everyone who takes part in research at <b>Group Health [insert name of facility or institution]</b> should know that:</p> <ul style="list-style-type: none"> <li>• Being in any study is voluntary.</li> <li>• You may or may not benefit from being in the study. Knowledge we gain from this study may benefit others in the future.</li> <li>• You may leave the study at any time and none of the benefits you normally receive will be taken away.</li> <li>• 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.</li> </ul>	<p><b>6.3</b></p>

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**Table 2**

Request for Permission to Review Medical Records	Grade level
<p>We are asking that you allow us to collect some information from your 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:</p> <ul style="list-style-type: none"><li>• number and types of medications.</li><li>• clinic visits.</li><li>• lab test results.</li><li>• trips to the hospital.</li><li>• [insert others].</li></ul> <p>We will collect this information for a period of about two years [insert time frame], starting one year before your first phone survey [insert event] and ending one year after.</p>	<p><b>6.2</b></p>
<p>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].*</p>	<p><b>8.5</b></p>

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

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**Table 3**

Randomization	Grade level
<p>We will use a computer to randomly assign you 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.</p>	<p><b>3.7</b></p>
<p>There will be about 1500 [insert number] people in this study. They will be assigned randomly to one of three [insert number] study groups:  [insert groups]</p> <p>Which group you will be in is decided by chance, like the flip of a coin*.</p>	<p><b>4.8</b></p>
<p>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 drawing names out of hat*. You will have a 1 in 4 [insert odds] chance of receiving any one of the study treatments.</p> <p>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.</p>	<p><b>6.7</b></p>

\* can also use one analogy or the other, depending on # of study arms— “flipping a coin” works best to describe a 2-arm study; “drawing names out of a hat” works best to describe a study with multiple treatment arms.

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## 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**

<b>Risks of Drawing Blood</b>	<b>Grade level</b>
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.	<b>3.1</b>
There are no major risks of having blood drawn. It can be uncomfortable and can sometimes cause a bruise. In rare cases, it can cause fainting. Only trained people will draw your blood.	<b>3.7</b>
You may feel bothered by the needle stick, and a bruise may form. In rare cases, some people faint or the site becomes infected.	<b>4.3</b>

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**Table 6**

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

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

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**Table 7**

<b>No Guarantee of Direct Benefit to Participants</b>	<b>Grade level</b>
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 <a href="#">Chesapeake IRB Informed Consent Template</a>	<b>5.2</b>
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.	<b>6.7</b>
We don't know if you will benefit from being in this study. However, we hope results of this study will help improve treatment at Group Health [insert facility or institution] and in other health systems around the country.	<b>7.4</b>
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].	<b>7.9</b>

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**Table 8**

<b>Voluntary Participation and Withdrawal</b>	<b>Grade level</b>
<p><b>Can you leave the study early?</b></p> <ul style="list-style-type: none"> <li>• You can agree to be in the study now and change your mind later.</li> <li>• If you wish to stop, please tell us right away.</li> <li>• Leaving this study early will not affect your regular medical care.</li> </ul> <p>from <a href="#">Johns Hopkins University</a></p>	<b>4.2</b>
<p>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.</p>	<b>4.4</b>
<p>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.</p> <p>from <a href="#">Georgetown University</a></p>	<b>4.8</b>
<p>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 <b>Group Health [insert facility or institution]</b>. There are no penalties or loss of benefits if you choose not to take part or to leave the study early.</p> <p>from <a href="#">Children’s Hospital</a></p>	<b>5.0</b>
<p>Taking part in this study is voluntary. If you choose not to b in this study, your care at <b>Group Health [insert facility or institution]</b> will not be affected.</p> <p>You may choose not to participate at any time during the study. Leaving the study will not affect your care at <b>Group Health [insert facility or institution]</b>.</p> <p>from <a href="#">University of Chicago</a></p>	<b>5.8</b>
<p>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.</p> <p>from <a href="#">Chesapeake IRB Informed Consent Template</a></p>	<b>6.2</b>
<p>Your participation in this study is voluntary. You are free to leave this study at any time. Your care at <b>Group Health [insert facility or institution]</b> will not be affected by whether you decide to participate.</p>	<b>6.6</b>

Voluntary Participation and Withdrawal	Grade level
<p><b>Your Rights</b></p> <p>It is important for you to know that:</p> <ul style="list-style-type: none"> <li>• Your participation is voluntary.</li> <li>• 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.</li> <li>• We will tell you about any new information or changes in the study that might affect your willingness to participate.</li> </ul> <p>from <a href="#">University of Massachusetts Medical School</a></p>	<p><b>7.1</b></p>

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**Table 9**

Confidentiality	Grade level
<p>Your confidentiality is one of our main concerns. We will store all of your research records in locked cabinets and secure 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.</p> <p>We will keep all the information you give us confidential as provided by law. The only exception is any risk of possible harm to others or to your self. 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.</p>	<p><b>6.3</b></p>
<p>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].</p> <p>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].</p> <p>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]</p>	<p><b>8.0</b></p>
<p>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]. We will keep the link between your name and your ID number in a separate computer file. Only staff with proper security clearances can access those files. You will not be named in published reports.</p>	<p><b>8.2</b></p>
<p>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.</p> <p>from <a href="#">the US Department of Justice</a></p>	<p><b>8.9</b></p>

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

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**Table 10**

Participant's Statement/Signature	Grade level
<ul style="list-style-type: none"> <li>• I have read this form and the research study has been explained to me.</li> <li>• 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.</li> <li>• I agree to be in the research study described above.</li> <li>• I will receive a copy of this consent form after I sign it.</li> </ul> <p>from <a href="#">Northwestern University</a></p>	<b>4.5</b>
<p>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.</p>	<b>6.2</b>
<p>Please initial each statement you consent to:</p> <p><input type="checkbox"/> To take part in this study.</p> <p><input type="checkbox"/> To allow the researchers to look at my <b>Group Health [insert facility or institution]</b> computerized medical records related to the health care I receive.</p> <p><input type="checkbox"/> To be contacted about this research in the future.</p>	<b>6.8</b>
<ul style="list-style-type: none"> <li>• This study has been explained to me.</li> <li>• I volunteer to take part in this research.</li> <li>• I have had a chance to ask questions, and my questions have been answered.</li> <li>• If I have questions later on about the research, I can ask one of the researchers listed in this form.</li> <li>• If I have questions about my rights as a research subject, I can call the <b>Group Health Human Subjects Division</b> at (206) 287-2919 [insert applicable info].</li> <li>• I agree to allow the researchers to use my medical records as described in this consent form [remove if not applicable].</li> <li>• 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].</li> <li>• I will receive a copy of this consent form.</li> </ul>	<b>7.8</b>

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**Table 11**

<b>Study Staff Statement/Signature</b>	<b>Grade level</b>
<ul style="list-style-type: none"><li>• I have carefully explained to the subject the nature and purpose of this study.</li><li>• The subject has been given enough time and an adequate place to read and review this form.</li><li>• The subject has had a chance to ask questions and receive answers about this study.</li></ul> from <a href="#">Chesapeake IRB</a>	<b>7.3</b>
I have explained the above research study <b>over the telephone [remove if not applicable]</b> . 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 <b>[or “give,” if applicable]</b> a signed copy of the consent form to the participant.	<b>7.5</b>

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## 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 11<sup>th</sup> grade and college-level, depending on the readability formula used<sup>12</sup>.

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

- [Phoenix Health Systems HIPAA Advisory](#) – “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.

### 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.

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<sup>12</sup> Breese P, et al. The Health Insurance Portability and Accountability Act and the informed consent process. *Ann Intern Med.* 2004;141:897-898.

**Flesch-Kincaid grade level score when all excerpts are used together = 7.5**

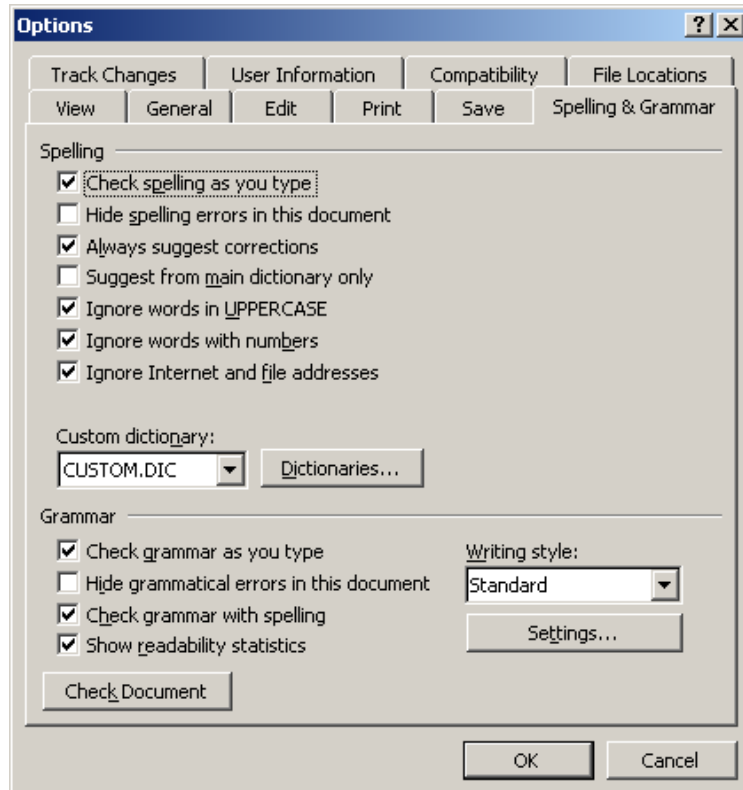
<p><b>How will you protect my privacy?</b></p> <p>Your health information is protected by a federal privacy law called HIPAA. This law applies only to health care organizations and their employees. This law may not apply to researchers who do not work for health care organizations. But there are usually other laws or agreements in place to protect the privacy of your information.</p>	<p><b>Grade level</b> <b>8.5</b></p>
<p>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 <b>Group Health [insert facility or institution]</b> or the funding agency may look at study records to check that we are doing the study honestly and safely. We will not share information that identifies you with anyone else except as required by law.</p>	<p><b>Grade level</b> <b>9.4</b></p>
<p>We plan to use your health information as described in this form for up to 5 years <b>[insert appropriate time frame]</b> after the study ends. At that time, we will destroy any study records that include your name or other information that points to you.</p>	<p><b>Grade level</b> <b>8.8</b></p>
<p><b>What if I change my mind later?</b></p> <p>You may change your mind any time about letting us use your information for this study. If you change your mind, you may take back your consent by writing to:</p> <p style="padding-left: 40px;"><b>Dr. Jane Researcher [insert appropriate info]</b>  <b>Group Health Center for Health Studies</b>  <b>1730 Minor Avenue, Suite 1600</b>  <b>Seattle, WA 98101</b></p> <p>If you take back your consent:</p> <ul style="list-style-type: none"> <li>• It will not affect your health care at <b>Group Health [insert facility or institution]</b>.</li> <li>• Your health plan benefits will not change <b>[delete if irrelevant]</b>.</li> <li>• We may still use the study information we collected before we received the letter taking back your consent. But we will not collect any new information after that point.</li> </ul>	<p><b>Grade level</b> <b>5.4</b></p>

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## 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.



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.

The screenshot shows the 'Readability Statistics' dialog box. It displays the following statistics:

Counts	
Words	144
Characters	655
Paragraphs	2
Sentences	8

Averages	
Sentences per Paragraph	8.0
Words per Sentence	17.7
Characters per Word	4.3

Readability	
Passive Sentences	25%
Flesch Reading Ease	72.0
Flesch-Kincaid Grade Level	7.6

An 'OK' button is located at the bottom right of the dialog box.

## 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](http://plainlanguage.gov) (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](#) (HIPAAAdvisory, Phoenix Health Systems)
- [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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Instead of ...	Try this ... (You may need to use different forms or combinations depending on how the term is used)
<b>A</b> <a href="#">TOP</a>	
abdomen	stomach, tummy, belly
abrasion	scrape, scratch
absorb	take in fluids, soak up
abstain from	don't, don't use, don't have, go without
accompany	go (along) with, come with
accomplish	carry out, do
accordingly	so, for that reason, as a result
accrue	add, gain, build up
accumulate	add, build up, collect, gather
accurate	correct, exact, right

\* Developed in collaboration with the Group Health Plain Language Network

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)
anterior	front
anticipate	expect
anticoagulant	blood thinner
anti-inflammatory	helps swelling go down
apparent	clear, plain, show up
appreciate, appreciation	thankful, thanks
apprise	inform, tell
appropriate(ly)	correct(ly), proper(ly), right
approximate(ly)	about, around, roughly
arrhythmia	irregular heartbeat, when the heart doesn't have a steady beat
arteriosclerosis (or atherosclerosis)	hardening of the arteries
articulate	say, state, tell
ascertain	find out, learn
ascorbic acid	vitamin C
asphyxiate, asphyxiation	choke (ing), suffocate (tion)
aspirate, aspiration	fluid in the lungs
assay	lab test
assess	learn about, study
assessment	review, quiz, rating, report, test, interview
assist, assistance	help, aid
associated with	linked to, related to
asymptomatic	without symptoms
atopic dermatitis	itchy red rash
attain	meet a goal; get
attempt	try
audit	review, inspect, look at
aural	hearing
<b>B</b> <a href="#">TOP</a>	
bacteria	germs
beneficial	helpful, good
benefit (noun)	good effect, advantage
benefit (verb)	help, be useful to
benign	isn't harmful, not cancer
bilateral	on both sides
biopsy	sample of tissue from part of the body

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
<b>C</b> <a href="#">TOP</a>	
calculate	add up, figure out
capable, capability	able, ability
carcinogen	something that can cause cancer
carcinoma	cancer
cardiac	(of/in/related to) the heart
cardiologist	heart doctor
cardiovascular	heart and/or blood vessel
carpal	wrist
category	kind, class, group
catheter	a tube for (putting fluids into/ taking fluids out of) the body
catheterize	put a tube into (part of the body)
caveat	warning; detail to think about
cease	stop
cell culture	tissue sample or a study of the tissue
cellulitis	skin infection
Central Nervous System (CNS)	brain and spinal cord
cerebral hemorrhage (or cerebral accident or cerebrovascular accident or CVA)	stroke, blood clot in the brain
cessation	ending, stop, pause
chemotherapy	drugs to treat cancer
chest film	chest X-ray
cholesterol, HDL cholesterol, LDL cholesterol	types of fat found in the blood, HDL is good cholesterol, LDL is bad cholesterol
chronic	lasting a long time, life-long
clavicle	collarbone
clinical	(related to) medical care
clinical trial	a research study that tests new treatments on patients

Instead of ...	Try this ... (You may need to use different forms or combinations depending on how the term is used)
coagulate	clot, stop flowing
cognitive	learning, thinking
cognizant	aware (of)
coitus	sex
collaborate with	work with
colon/colorectal	large intestine
colonoscopy	an exam of the inside of the large intestine that uses a flexible tube with a lens at the end
commence	begin, start
commitment	promise
commonly	most often
communicate	write, tell, talk, let you know
compensate, compensation	pay, give money
complete	finish, do, fill out, take part in
comply with	follow
component	part, section, phase
comprise	form, include, make up
computed tomography	CT scan or imaging test, 3-D X-ray
conceal(ed)	hide (hidden)
concerning	about, on
condition	how you feel, health problem
conduct(ing)	do(ing)
congenital	present at birth, born with
congenital anomaly	birth defect
congestive heart failure	when the heart isn't pumping hard enough
conjunctivitis	pink eye
consequence	result
consequently	so, because of this, as a result
consider	think about
consolidate	combine, join, put together
contains	has
constitutes	is, forms, makes up
construct	make, build, design
contingent upon	if
continue	go on, keep (on)

Instead of ...	Try this ... (You may need to use different forms or combinations depending on how the term is used)
contraceptive	birth control
contract(ing) [a disease]	get(ing) [a disease]
contraindicated	not recommended, can cause a bad reaction, not allowed
contrast medium	dye
contribute	give, help
controlled trial	a study that compares one treatment to another treatment
contusion	bruise
convene	meet
convenient	handy, works well
conversion	change
convulsion	seizure, shaking
coronary	(in/of/related to) the blood vessels that bring blood to the heart
coronary thrombosis	heart attack
correlation	link
correspond	similar to, be in agreement with
crucial	very important
currently	now
cutaneous	(in/of/about/related to) the skin
<b>D</b> <a href="#">TOP</a>	
debilitating	weakening
decision	choice
decrease	lower, reduce
deem	think, believe, consider
deep vein thrombosis	a blood clot deep in the vein
deficiency	not enough
deficit	shortage
degeneration	getting or gets worse
delete	remove, take out, cut, drop
demonstrate	prove, show
depart	leave
describing	tell about
designate	choose, name, select, appoint
detect	find (out)
determine	decide, find (out), learn (if)
detrimental	harmful, bad

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
<b>E</b> <a href="#">TOP</a>	
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

<b>Instead of ...</b>	<b>Try this ...</b> <b>(You may need to use different forms or combinations depending on how the term is used)</b>
elevate	high, higher, raise
eliminate	get rid of, remove, cut, end, go to the bathroom
elucidate	explain
embolism	lump of blood, clot
embolist/embolus	clot that blocks a blood vessel or artery
emesis	throwing up, vomiting
empirical evidence	proof
employ	use
employment	work
enable	allow, let
encounter	meet, meeting
encourage	urge
endeavor	try
endometrium	lining of the uterus
enlarge	get bigger
enroll	be in, join
ensue	follow(ing), occur after, happen next
ensure	make sure
enumerate	count
enuresis	problems controlling urine, bladder control problems
epidemiologist	scientist who studies diseases
episode	bout or attack
equilibrium	balance
equivalent	equal, the same as
equitable	fair
eradicate	get rid of
eruption (skin)	rash or breakout
especially	mainly, mostly
establish	set up; also, show, prove
etiology	cause
evaluate	look at, study, measure, rate
evidence of	proof of, signs of
evident	clear
exacerbate	make worse
examination	exam
examine	look at, study

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
exhale	breathe out
exhibit	show
expedite, expeditious	speed up, make (something) go faster, make (something) easier, (fast, quick)
expend	spend
experiencing	feeling, going through, having
expire, expiration	end (date), run out
explicit	plain, clear
extensive	A lot (of), wide-spread, throughout the body
external	outside (the body)
exude	ooze
<b>F</b> <a href="#">TOP</a>	
facilitate	help, ease, make (something) easier
failed to	did not
feasible	can be done, possible, workable
febrile	fever
femur	thigh bone, bone that connects the hip and knee
fetus	unborn baby
finalize	complete, finish
forfeit	give up, lose
formulate	work out, form, make
forward	send
fracture(d)	break, (broken)
frequently	often, a lot
fructose	fruit sugar
function	act, role, work
fundamental	basic
furnish	give, send
<b>G</b> <a href="#">TOP</a>	
gastric	(of/in/related to) the stomach
gastroenterologist	doctor who treats problems with digestion
gastroesophageal reflux (GERD=gastroesophageal reflux disease)	heartburn
generalized	wide-spread

Instead of ...	Try this ... (You may need to use different forms or combinations depending on how the term is used)
gerontological	age-related, (related to) aging
gestation	pregnancy
GI specialist	doctor who treats problems with digestion
glucose	sugar
gradually	slowly, over time
gynecologist	doctor trained in women's health
<b>H</b> <a href="#">TOP</a>	
hazardous	dangerous, not safe
hearing impairment	hearing loss or deafness
heart failure	heart isn't pumping hard enough
hematocrit	amount of red blood cells in the blood
hematoma	bruise
hemorrhage	heavy bleeding
hence	so
hepatic	(of/in/related to) the liver
heritable, hereditary	genetic, traits that are passed down in families
herpes simplex type 1	cold sore
herpes simplex type 2	herpes
herpes zoster	shingles
heterogeneous	different, mixed
hirsutism	unwanted hair growth
homogeneous	same or similar
however	but
hyperopia	farsighted(ness)
hypersensitivity	very sensitive to
hypertension (hypotension)	blood pressure that's too high (blood pressure that's too low)
hyperthyroidism (hypothyroidism)	overactive thyroid, too much thyroid hormone (underactive thyroid, not enough thyroid hormone)
hypothesis	idea being tested
hypoxia	not enough oxygen in the blood
<b>I</b> <a href="#">TOP</a>	
identical	same, exactly alike
identified	found
identify	find (out), pinpoint, name, show



Instead of ...	Try this ... (You may need to use different forms or combinations depending on how the term is used)
idiopathic	we don't know what causes it
immediately	right away, now, at once
immerse	cover in, dip in
immunotherapy	treatment to make the immune system work better (boost immune system)
impact	change, affect
impede	slow, make it harder to
implant	put into the body
implement	carry out, put in place, start
impotent, impotence	when a man either can't get or can't keep an erection
in addition	also, too, and
in vitro	in a test tube or lab
incapacitate	make it hard or impossible to do
inception	start, beginning
incidence	number of new cases, how many times it occurs
incision	cut, slit
including	along with, like, such as
incorrect	wrong, not right
increase, increased	raise, higher
indicate	mean, show, suggest, tell us, fill in, write down
indication	sign, symptom
ineffectual	doesn't work, useless, of no use
infectious (disease)	passed from one person to the next
infection	illness, sickness, disease
infertile	not able to get pregnant
inflammation	swelling, painful swelling
influence	affect
inform	tell
informed consent	deciding to get a certain treatment or be in a research study after thinking about the pros and cons (risks and benefits)
infusion	putting a substance into the body through the blood
ingest	eat or drink
inhale	breathe in
inhibit	stop
inhibitor	drug that slows down or stops something from happening
initial	first

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
inquire	ask
institute	start, set up
instrument	tool
insufficient	not enough, too little
intake	what you eat or drink; what goes into your body
intent, intention	aim, goal, purpose
interface	meet, work with
intermittent	off and on
internal	inside (the body)
interior	inside
internist	doctor of internal medicine
interrupt	stop
intervention	treatment
intramuscular	in a muscle
intravenous	in a vein
intubate	put a tube down your throat into your airway so you can breathe
invasive disease	disease that (can or has) spread to other parts of the body
invasive procedure	to go into the body through a cut, slit, or puncture
investigation	study
investigator(s)	researcher(s), people doing the study
issue	give
<b>J</b> <a href="#">TOP</a>	
jaundice	when the whites of the eyes and the skin look yellow
juvenile (condition)	childhood (condition)
<b>K</b> <a href="#">TOP</a>	
<b>L</b> <a href="#">TOP</a>	
laceration	cut, tear, slit
lactation	breastfeeding
lactose	sugar found in milk
larynx	voice box

Instead of ...	Try this ... (You may need to use different forms or combinations depending on how the term is used)
lateral	side, on the side
lethargic	sluggish; very sleepy
limb	arm or leg
lingual	tongue
lipids	fats in the blood
lipid profile (or lipid panel)	lab test to measure the amount of fats in the blood
locality	place
locally, localized	in one area
locate	find
location	place
lymphoma	cancer of the lymph nodes (or tissues)
<b>M</b> <a href="#">TOP</a>	
magnetic resonance imaging (MRI)	pictures of the inside of the body taken with a special machine, like an x-ray but more detailed
magnitude	size
maintain	keep, support
malaise	general feeling of being sick, feeling bad
malignant, malignancy	harmful, poisonous; cancer that may spread to other parts of the body
malingering	pretending to be sick
majority (of)	most
manifestation	sign
manner	way
materialize	appear
maximum	greatest, largest, most
mean (statistical)	average (statistical)
medication	drug, medicine
menarche	first (menstrual) period
menopause	when a woman doesn't get any more (menstrual) periods
menses, menstruation	(menstrual) period
metabolism, metabolize	how the body breaks down food into energy
metastasize	spread
metastatic	cancer that has spread
miliaria	prickly heat
minimal (minimum)	least, smallest, slight (at least)
minimize	decrease, lower, reduce
mobile (mobility)	able (ability) to move around

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
<b>N</b> <a href="#">TOP</a>	
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
<b>O</b> <a href="#">TOP</a>	
objective	aim, goal
obligate, obligation	require, bind, means that (you) have to, duty
observe	see
obstruct	block or close
obtain	get, take
occasionally	sometimes
occlude (occlusion)	block (blockage)
occupation(al)	job, work
oncologist	doctor who treats cancer

Instead of ...	Try this ... (You may need to use different forms or combinations depending on how the term is used)
oncology	study or treatment of cancer
onset	start
opportunity	chance
optimum, optimal	best, greatest, most
option	choice, way
oral (oral administration)	(given) by mouth
orthopedic	(of/about/related to) the bones
osteoporosis	brittle bone disease, having bones that can break easily
otherwise	if not
otolaryngologist	ear, nose, and throat doctor
outcomes	results, (long-term) changes
<b>P</b> <a href="#">TOP</a>	
palliative	make feel better but not cure, ease symptoms
pallor	paleness
palpate	feel
palpitation	fast heartbeat
parameter	limit, boundary
paresthesia	tingling, prickling, or burning feeling on the skin that can't be explained or doesn't seem to have any cause
participant	person who takes part
participate (ing, ion)	be, do, join, opt in, take part (ing)
parturition	labor and delivery, childbirth
pathogen(esis)	cause of a disease
perforation	hole
perform	do
periodically	from time to time
perioral	around the mouth
peripheral	on the edge, not central
permit(ted)	allow(ed), let
persist	last, keep going, doesn't stop
persistent	lasting
personnel	staff, people
pertaining to	about, of, on
peruse	read, study, examine with care
pervasive	widespread
pharmaceutical,	drug

Instead of ...	Try this ... (You may need to use different forms or combinations depending on how the term is used)
pharmacotherapy	use drugs to treat a disease or condition
pharyngitis	sore throat
physician	doctor
physiological	having to do with the body
pigmentation	color
placebo	a pill that doesn't have any drugs or medicine; a "sugar" pill
placenta	part of the mother's womb that supplies oxygen and nutrition to her unborn baby
plaque (artery)	fatty deposit
plasma	the fluid part of blood
plasma glucose	blood sugar
portion	part
positron emission tomography	PET scan or imaging test; test done to look at organs in the body
possess	have, own
posterior	back
postoperative (post-op)	after surgery
preadolescent	preteen
preclinical	isn't causing symptoms yet, no signs yet
preclude	prevent; rule out
predisposed, predisposition	likely to, inclined to
prenatal	before birth
presently	right now
present with	have
preserve	keep
prevalence, prevalent	how often it happens, common, happens often
prevent	stop, put a stop to, to keep from happening
previous, previously	before, earlier
principal investigator	head researcher, scientist in charge of a study
prior (to)	earlier, before
prioritize	rank, order, put in order of importance
proactive	taking action on your own
procedure	something that is done, a process
proceed	do, go ahead, start, try
procure, procurement	buy, get
proficiency, proficient	skill, skilled

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
prophylaxis	something that prevents disease or infection
prosthesis	replacement for a body part, such as a man-made arm
protocol	plan of study, rule, process
provide	give (us), offer, say
provided that	if
provider	doctor, clinician, person who gives health care
proximal	close, closer to the center of the body
psychopathology	mental illness
psychosocial	mental and social
psychotropic	mind-altering
pulmonary	(in/or/about/related to) the lungs
pulmonary embolism	blood clot in the lung
purchase	buy
pursuant to	by, following, under
<b>Q</b> <a href="#">TOP</a>	
questionnaire	survey, series of questions
<b>R</b> <a href="#">TOP</a>	
radiologist	doctor who specializes in reading X-rays
radiology	X-ray department
ramifications	outcomes, problems, results
randomized/randomization	assigned to a group by chance, like flipping a coin [if there are 2 groups]...like drawing names out of a hat [if there are more than 2 groups]
random(ly)	by chance
random sample	group of (people) chosen by chance; like drawing names out of a hat
range	area, between (x) and (y), from low(est) to high(est)
receive	get
recur	return, come back, happen again
referral	send to see another doctor

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
render	make, give
replicable	can be done again
represents	is
request	ask
require(d), requirement	must do or have, need(ed)
researchers	people doing the study
resect	cut out, take out through surgery, remove
reside, residence	live, house, home
respiration	breathing
restrictions	limits
retain	keep
retinol	vitamin A
retrospective study	a study looking at things that have already happened
revise(d), revision	change(d), new
reveal	give us, show, tell
routinely	often, commonly
rupture	break open, burst
<b>S</b> <a href="#">TOP</a>	
sarcoma	type of cancer



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 tissues of the body get hard and thick
sedative	a drug to make you feel calm or less anxious
sedentary	inactive, not active
seldom	rarely, not very often
selection	choice
sensation	feeling
sepsis	a very serious infection
sequentially	in a row, in order, by number
several	a few, a number of, some
severe	serious, bad
severity	how bad
shall	will
similar (to)	like, alike
similarity	likeness
sinusitis	sinus infection
solely	only
solicit	ask for, request
somnolence	sleepiness
specify	name
specimen	sample
spirometer	a device that measures how much air you're breathing in and out
state-of-the-art	latest
stenosis	getting more narrow
stimulate	excite, trigger
strategy, strategize	(make a) plan
streptococcal	strep
subcutaneous	under the skin
sublingual	medication taken by dissolving under the tongue, under the tongue
submit	give, send
subsequent(ly)	after, later, next, then
substantial	big, large, much
sucrose	sugar
sufficient	enough, plenty
suggest(s)	show(s) there might be
supine	lying on your back

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
symptomatic	having symptoms
systemic	whole body
<b>T</b> <a href="#">TOP</a>	
tachycardia	very fast heart beat
tap	use a needle to take out fluid
tear a ligament (torn ligament)	sprain
telephone	phone
terminal	not curable, causes death, going to die
terminate, termination	put an end to, stop, end
therapeutic modality	treatment
therapy	treatment
therefore	so, as a result
thoracic	chest
thrombosis	blood clots in the blood vessels
topical (application)	surface, on the skin, (put on, put on the skin)
torso	trunk, main part of your body not including head, arms, or legs
toxic, toxin	poisonous, poison
toxicity	bad side effects
trachea	windpipe
transdermal	through the skin
transmit(ted), transmission	send (sent), spread to, pass on
transpire	happen
trauma	injury, wound
tremor	shaking
<b>U</b> <a href="#">TOP</a>	
ultimate	final
uncommon	rare
undergo	have
understand	learn, see
unequivocal	clear
unnecessary	not needed

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
<b>V</b> <a href="#">TOP</a>	
validate	approve, confirm
variable	factor, changes over time
varicella	chickenpox
variety	many different kinds
vector	an insect or other animal that carries disease
vertigo	dizziness
viable	practical, workable, possible
visualize	picture, see, imagine
vitals, vital signs	heart rate, blood pressure, breathing rate, and temperature
<b>W</b> <a href="#">TOP</a>	
warrant	call for, permit
whereas	because, since
withdraw (from)	drop, leave, take back, take out
<b>X</b> <a href="#">TOP</a>	
<b>Y</b> <a href="#">TOP</a>	
<b>Z</b> <a href="#">TOP</a>	

## Appendix C: Examples of Improved Readability

The following examples came from original and revised text in actual study materials fielded at the Group Health Center for Health Studies. Some examples are based on materials that were fielded prior to the PRISM initiative. (In these cases, study topics and names have been changed or omitted.) Other examples are based on materials that underwent PRISM editing prior to fielding.

The revised versions demonstrate the use of active voice, simpler vocabulary, shorter sentences, shorter paragraphs, bulleting important information, and other plain language strategies. Changes are emphasized using bold font. We used the readability analysis tool in Microsoft Word™ to report the Flesch-Kincaid grade level score, the Flesch Reading Ease, and the percent of passive sentences.

Examples 1 through 4 are excerpted from participant invitation materials, i.e. advance letters and study brochures; Examples 5 through 9 are excerpted from informed consent documents.

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### Example 1

Original	Revised
<ul style="list-style-type: none"> <li>• Grade level = 13.0</li> <li>• Reading Ease = 39.9</li> <li>• 20% passive sentences</li> </ul> <p>If you agree to participate, we will <b>arrange a screening interview</b> with you at our research clinic. During this interview, <b>you will be asked</b> to do some tasks that measure your thinking and problem-solving abilities <b>and answer questions</b> about your <b>medical history and occupational history</b>. If you are willing, a trained technician will <b>obtain</b> a blood sample of <b>approximately</b> two tablespoons. This visit should take <b>approximately</b> two hours. If you are eligible <b>to participate in the study</b>, every two years we will <b>repeat the initial assessment procedures</b> at the Center for Health Studies, <b>and we will periodically review</b> your medical record to see if there is a change.</p>	<ul style="list-style-type: none"> <li>• Grade level = 7.2</li> <li>• Reading Ease = 71.2</li> <li>• 0% passive sentences</li> </ul> <p>If you agree to <b>be in the study</b>, we will <b>invite you to an interview</b> at our research clinic. During this interview, <b>we will ask you</b> to do some tasks that measure your thinking and problem-solving abilities. <b>We will also ask you</b> questions about your <b>medical and work histories</b>. If you are willing, <b>we will take</b> a blood sample of <b>about</b> two tablespoons. This visit should take <b>about</b> two hours.</p> <p>If you are eligible <b>for</b> the study, we will ask you to <b>come in for a similar interview and blood draw</b> every two years. <b>We will also check</b> your medical record <b>from time to time</b> to see if there is a change.</p>

## Example 2

Original	Revised
<ul style="list-style-type: none"> <li>• Grade level = 11.2</li> <li>• Reading Ease = 51.0</li> <li>• 71% passive sentences</li> </ul> <p><b><u>If</u> 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. <u>All</u> 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.</b></p>	<ul style="list-style-type: none"> <li>• Grade level = 6.3</li> <li>• Reading Ease = 75.1</li> <li>• 9% passive sentences</li> </ul> <p><b><u>If</u> you are interested in and eligible for this study, you will be assigned by chance to one of the four study groups. Three groups will receive study treatment. The fourth group will receive usual medical care. You will have a 1 in 4 chance of being in any group.</b></p> <p><b>If you are in a study treatment group, you will make 10 visits over a 7-week period. The study will pay for these visits.</b></p> <p><b><u>Everyone in the study</u> will receive a state-of-the-art book about different ways to care for athlete’s foot. No matter which group you are in, we will call you for three phone surveys that will last about 20 minutes each. These surveys will take place 2, 6, and 12 months after you join the study.</b></p> <p>We cannot guarantee that you will benefit from the treatment you get. However, the knowledge we gain from this study will help improve care for athlete’s foot at Group Health.</p>

### Example 3

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

<p><b>Original</b></p> <ul style="list-style-type: none"> <li>• Grade level = 13.7</li> <li>• Reading Ease = 44.0</li> <li>• 0% passive sentences</li> </ul>	<p><b>Revised</b></p> <ul style="list-style-type: none"> <li>• Grade level = 7.0</li> <li>• Reading Ease = 68.8</li> <li>• 0% passive sentences</li> </ul>
<p>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.</p>	<p>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.</p> <p>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.</p> <p>To be eligible for the study, you must:</p> <ul style="list-style-type: none"> <li>• Have dandruff.</li> <li>• Be a member of Group Health.</li> <li>• Have an email address.</li> <li>• Be able to access the Internet at least once or twice per week.</li> <li>• Meet certain other requirements.</li> </ul>

## Example 4

<p><b>Original</b></p> <ul style="list-style-type: none"> <li>• Grade level = 13.2</li> <li>• Reading Ease = 52.8</li> <li>• 0% passive sentences</li> </ul>	<p><b>Revised</b></p> <ul style="list-style-type: none"> <li>• Grade level = 7.4</li> <li>• Reading Ease = 70.9</li> <li>• 0% passive sentences</li> </ul>
<p>Can you take five minutes <b>to provide information that will help plan an important study to aid</b> people with arthritis <b>pain and problems getting</b> a good night's sleep?</p> <p>I am <b>an investigator</b> at Group Health Center for Health Studies <b>who is</b> planning a major study to test new ways of helping people with arthritis pain and sleep problems.</p> <p><b>In order to plan the research</b>, I need to know how many <b>people</b> have arthritis pain and <b>sleep problems</b>. I also need to know <b>to what extent people with these problems</b> might be interested in <b>participating in</b> a group program <b>for</b> arthritis pain and sleep problems <b>that we want to test</b> in research funded by the National Institutes of Health.</p>	<p>Can you take five minutes <b>for a study about helping</b> people with arthritis <b>get a</b> good night's sleep?</p> <p><b>If you have arthritis, you may know what it's like to have trouble sleeping.</b> I am <b>a researcher</b> at Group Health Center for Health Studies. <b>We are</b> planning a major study about arthritis and sleep problems.</p> <p><b>Before we can do the study</b>, we need to know how many <b>members of Group Health</b> have arthritis pain and <b>trouble sleeping</b>. We also need to know <b>if our members</b> might be interested in a group program <b>to help people</b> with arthritis pain and sleep problems. <b>We want to test this program</b> in research funded by the National Institutes of Health.</p>

## Example 5

<p><b>Original</b></p> <ul style="list-style-type: none"> <li>• Grade level = 12.6</li> <li>• Reading Ease = 47.8</li> <li>• 0% passive sentences</li> </ul>	<p><b>Revised</b></p> <ul style="list-style-type: none"> <li>• Grade level = 6.9</li> <li>• Reading Ease = 69.6</li> <li>• 0% passive sentences</li> </ul>
<p><b>Purpose</b></p> <p>We are <b>interested in understanding</b> how older adult members of Group Health Cooperative feel about physical activity. We <b>are also interested in hearing what</b> their thoughts <b>are about</b> the physical activity programs that Group Health offers to its members. <b>The results of</b> this study will help us <b>better understand the needs of</b> older adult members <b>regarding</b> physical activity programs.</p> <p><b>Procedures</b></p> <p>If you agree to be in this study, <b>you will take part in a telephone interview.</b> The <b>interview</b> will last about 30 minutes. <b>The study investigator</b> will ask questions about your physical <b>activity, your</b> use of the Silver Sneakers or EnhanceFitness <b>programs, and</b> general questions about yourself and your health. Here are <b>examples of several questions</b>, “What kinds of physical activities have you done in the past that you are <b>not</b> doing now?”, “What would help to keep you physically active?”, “When was it most difficult for you to <b>continue</b> with your exercise?”</p>	<p><b>Why are you doing this study?</b></p> <p>We are <b>doing this study to learn more about</b> how older adult members of Group Health Cooperative feel about physical activity. We <b>also want to hear</b> their thoughts <b>on</b> the physical activity programs that Group Health offers to its members. <b>Doing</b> this study will help us <b>find out what kinds of</b> physical activity programs <b>our</b> older adult members <b>need.</b></p> <p><b>What does this study involve?</b></p> <p>If you agree to be in this study, <b>we will ask you to do one phone survey.</b> The <b>call</b> will last about 30 minutes. <b>We</b> will ask questions about your physical <b>activity and your</b> use of the Silver Sneakers or EnhanceFitness programs at Group Health. <b>We will also ask</b> general questions about yourself and your health. Here are <b>some examples:</b></p> <ul style="list-style-type: none"> <li>• What kinds of physical activities have you done in the past that you are <b>NOT</b> doing now?</li> <li>• What would help to keep you physically active?</li> <li>• When was it most difficult for you to <b>keep up</b> with your exercise?</li> </ul>



## Example 6

<p><b>Original</b></p> <ul style="list-style-type: none"> <li>• Grade level = 9.5</li> <li>• Reading Ease = 57.5</li> <li>• 20% passive sentences</li> </ul>	<p><b>Revised</b></p> <ul style="list-style-type: none"> <li>• Grade level = 4.9</li> <li>• Reading Ease = 84.9</li> <li>• 0% passive sentences</li> </ul>
<p><b>Procedures</b></p> <p>If you agree to <b>participate</b> in this study we will <b>schedule</b> a <b>telephone interview</b> at a time that is best for you. <b>The telephone call</b> will last about 30 to 60 <b>minutes and</b> will ask about your experiences with headaches and mood. <b>The interview will be audiotaped and then transcribed so that we may record your responses.</b> No one other than the research team and the <b>transcriptionists</b> will hear the <b>audiotapes</b>. We will <b>reimburse</b> you \$30 for your time if you <b>participate</b> in the <b>telephone interview</b>.</p>	<p><b>What will happen if I take part in this study?</b></p> <p>If you agree to <b>be</b> in this study, we will <b>set up</b> a <b>phone survey</b> at a time that is best for you. <b>The call</b> will last about 30 to 60 <b>minutes.</b> <b>We</b> will ask about your experiences with headaches and mood.</p> <p><b>We will record the interview on an audiotape and then write down your answers.</b> No one other than the research team and the <b>person who writes down the answers</b> will hear the <b>tapes</b>. We will <b>give</b> you \$30 for your time if you <b>take part</b> in the <b>phone survey</b>.</p>

## Example 7

Original	Revised
<ul style="list-style-type: none"> <li>• Grade level = 11.2</li> <li>• Reading Ease = 45.9</li> <li>• 40% passive sentences</li> </ul> <p><b>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</b></p>	<ul style="list-style-type: none"> <li>• Grade level = 6.9</li> <li>• Reading Ease = 68.5</li> <li>• 0% passive sentences</li> </ul> <p><b>We will keep your research records in locked cabinets and secure 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.</b></p> <p>Only <b>the researchers</b> listed on this consent form and <b>staff who work on</b> this study will have access to your study records. <b>Certain</b> people working for the study sponsors may see <b>your name or other personal information about you. They will look at this information to make sure</b> that it is correct. <b>They must keep your information confidential.</b></p> <p>We will not <b>share your study results with anyone unless you ask us to.</b> Your name will not appear in any reports <b>about</b> this study. <b>We will keep the information and results from this study indefinitely.</b></p>

## Example 8

Original	Revised
<ul style="list-style-type: none"> <li>• Grade level = 14.8</li> <li>• Reading Ease = 38.7</li> <li>• 0% passive sentences</li> </ul> <p><b>By signing</b> this form, you <b>consent to (authorize)</b> the use of health information from your Group Health medical records <b>needed</b> for this study, <b>which would include</b> your use of health care services such as number and types of medications, clinic visits, <b>laboratory</b> test results and <b>hospitalizations</b>. <b>Some of the information collected will be about</b> mental health medications and visits. We will collect this information for a period of one year before your first <b>telephone</b> survey <b>date</b> and one year after <b>your first telephone survey date</b>.</p>	<ul style="list-style-type: none"> <li>• Grade level = 6.5</li> <li>• Reading Ease = 66.4</li> <li>• 0% passive sentences</li> </ul> <p><b>If you sign</b> this form, you <b>are authorizing us to</b> use health information from your Group Health medical records for this study. <b>This means you are giving consent for us to collect some information from your medical records. We will not look at your entire medical record. Instead, we will use a computer to collect information about</b> your use of health care services, <b>including:</b></p> <ul style="list-style-type: none"> <li>• number and types of medications.</li> <li>• clinic visits.</li> <li>• <b>lab</b> test results.</li> <li>• <b>trips to the hospital.</b></li> <li>• mental health medications and visits.</li> </ul> <p>We will collect this information for a period of <b>about two years, starting</b> one year before your first <b>phone</b> survey and <b>ending</b> one year after.</p>

## Example 9

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

<b>Original</b>	<b>Revised</b>
<ul style="list-style-type: none"><li>• Grade level = 13.6</li><li>• Reading Ease = 19.7</li><li>• 0% passive sentences</li></ul> <p><b>POTENTIAL RISKS OR DISCOMFORT</b></p> <p>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.</p>	<ul style="list-style-type: none"><li>• Grade level = 5.9</li><li>• Reading Ease = 74.1</li><li>• 0% passive sentences</li></ul> <p><b>Are there any risks to me?</b></p> <p>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.</p>

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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).

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**Example #1**

DATE

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

We know teens aren't the same as adults, yet we often treat them as if they are. Assessing their health needs can be a challenge. It is important to have health information just about teens.

Group Health and the University of Washington are doing a study to find out more about teen health. We believe that this study tell us the best way to identify the needs of our adolescent patients.

A random sample of Group Health enrollees between the ages of 13 and 17 years are being invited to take part in the study. [CHILD FNAME] is among that group.

**Enclosed is a consent form for you, the parent or guardian. If you are willing to have [CHILD FNAME] participate in the study, please follow these steps:**

- 1) Read and sign the consent form.
- 2) Fold the consent form and put it in the return envelope.
- 3) Give the survey, and the return envelope with the consent for to your child, so s/he can read the survey, and answer the questions in a private place.
- 4) Remind your child that when s/he is done, to put the completed survey in the envelope with the consent form, and mail it back to us. (no postage needed)

**The \$2 is for your child to keep, whether or not s/he does the survey. Participation is voluntary. Whether or not you choose to take part in this study will not affect the care you or your child receives at Group Health.**

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

If you do not want wish to participate, call our toll-free line, 1(877) 555-5555, and leave that message. Please leave your name, phone number, and your child's full name. Please say that you are calling about the ASC Study.

Sincerely,

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

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

## 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 their employees. For this study, Group Health Cooperative will give your/your teen’s health information to the researchers listed on this form and their staff to be used only for research purposes. In addition, authorized staff from Group Health and/or the funding agency may review study records to watch over the honesty and/or safety of the research. Any information shared with others outside of Group Health may no longer be protected under this federal law. However, other laws, regulations and agreements

may protect the information from improper use. Information that identifies you/your teen, collected for this study, will not be shared with anyone else except as permitted by law.

Any benefits you are entitled to will not be affected by whether or not you participate in this study. Unless you take back your permission, this authorization for use of your health information will expire on 7/1/2010, which is 1 year after the end of the study. At any time, you may take back (revoke) your permission for the use of your health information for this study. To do this, you may write to Susie Manager at 1730 Minor Ave, Suite 1600, Seattle, WA 98101-1448. If you take back your permission, the researchers may keep the health information that they have already collected.

### Your Teen’s Participation is Voluntary

Your teen’s participation in this study is completely voluntary. You or your teen may refuse to participate in any part of the study at any time. It will not change the health care your teen receives from Group Health. Your teen may skip any questions he or she does not want to answer. Whether or not you and your teen choose to participate, a \$2-dollar bill is enclosed as a thank-you for your teen.

### Parent/Guardian’s Statement:

I have read this form. I give my consent for my child to take part in this research study. I have been told that if I have any questions, I can ask them at any time by calling the ASC Project Manager, Susie Manager, at 206-555-5555. I have been told that my child or I can withdraw permission at any time. If I have any questions about my child’s rights as a research subject, I can call the Group Health Cooperative Human Subjects Review Office at (206) 555-5555.

PLEASE PRINT

Parent/guardian name

Parent/Guardian Signature

Relationship To Teen

Date



**Introduction**

We are inviting your teenager to be in a research study. This consent form will give you information to help you and your teen decide if you want to take part. 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 this study about?**

We want to find better ways to identify the health care needs of teens. This study will test how well a brief survey can point to the physical and emotional concerns that might put a teen’s health at risk.

**If we agree to be in the study, what will we do?**

If you and your teen decide to be in this study, you will sign this consent form and your teen will fill out the enclosed survey.

- After you sign this form, please put it in the return envelope. Give the envelope (with this signed form inside) and the survey to your teen.
- The survey includes eight questions about your teen’s health. Please make sure your teen has a private place to fill out the survey.
- After your teen has finished the survey, he or she should mail it and the consent form to us in the return envelope (no postage needed).
- We have enclosed a second copy of the consent form for your records.

**Are there any risks involved?**

One risk of this study is that your teen might feel uncomfortable answering some of the survey questions. You can look at the questions before giving the survey to your teen. Your teen can skip any question that s/he does not want to answer.

Another risk is that someone other than study staff may see your teen’s survey answers. We think this risk is very small. We have a security plan to keep survey answers confidential.

**Will we get any benefit from being in the study?**

There is no direct benefit to you or your teen. Results from this study might help doctors take better care of teens in the future.

**Confidentiality**

We will keep the information in your teen’s survey confidential as provided by law. We will keep track of your teen’s answers using a study number instead of his or her name. Only the researchers listed on this form and their staff will have access to survey answers. We will not share your teen’s answers with you or your doctors at Group Health.

**Privacy**

Your family’s health information is protected by a federal privacy law (called HIPAA) that applies to health care organizations and their employees. Only the researchers listed on this form and their staff will look at your teen’s survey answers. We will use the health information we collect from the surveys for research only.

Staff from Group Health and/or the funding agency may look at study records to make sure that we follow the rules. Any information shared with others outside of Group Health may no longer be protected under this federal law. However, other laws, regulations and agreements may protect the information from improper use. We will not share your name or other information that would identify you or your teen with anyone else except as permitted by law.

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 at Group Health.

Unless you change your mind, we will use your teen’s survey answers until July 1, 2010, which is one year after the study ends.

**Being in this study is voluntary**

It is up to you and your teen whether to take part in this study. You or your teen may decide not to be in the study at any time. This decision will not change the health care your family receives from Group Health.

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.

**Parent/Guardian’s Statement**

- I have read this consent form.
- I give consent for my teen to be in this study.
- I can ask questions about the study anytime by calling the Project Manager, Susie Manager, at **206-555-5555**.
- My teen or I can choose to leave the study at any time.
- I have received a copy of this consent form for my records.
- If I have any questions about my child’s rights as a research subject, I can call the Group Health Cooperative Human Subjects Review Office at **206-555-5555**.

\_\_\_\_\_  
Please PRINT Name of Parent/Guardian

\_\_\_\_\_  
Relationship to teen

\_\_\_\_\_  
Parent/Guardian Signature

\_\_\_\_\_  
Date

### 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.

**Other Information About Participating:**

Participation in this study is voluntary and whether or not you participate will not affect the care you receive at Group Health. If you agree to participate, you may choose not to answer any questions you would rather not answer. Also, you may

choose to withdraw from the study at any time without affecting your enrollment or treatment at Group Health Cooperative.

Your answers to questions will remain confidential as provided by law and will not be included in your medical record. You will not be asked to take any medications or supplements for this study.

If you have any questions about the study, feel free to call the project manager, Sally Manager at (206) 555-5555. If you have questions about your rights as a research subject, please call Group Health's Office for Human Subject Research at (206) 555-5555.

***You can find more information about resources on stress management in My Group Health <http://www.ghc.org/>, or by contacting your personal physician.***

**Investigators:**

Jane Researcher, PhD, Group Health Center for Health Studies, (206) 555-5555

Joe Scientist, PhD, Group Health Center for Health Studies, (206) 555-5555

Jennifer Doctor, PhD, Group Health Center for Health Studies, (206) 555-5555

## 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?

- If you have any questions about the study, feel free to call the project manager, Sally Manager at (206) 555-5555.
- If you have questions about your rights as a research subject, please call Group Health's Office for Human Subject Research at (206) 555-5555.

### Who is leading this study?

A team of researchers from Group Health Center for Health Studies are leading this study:

- Jane Researcher, PhD, (206) 555-5555
- Joe Scientist, PhD, (206) 555-5555
- Jennifer Doctor, PhD, (206) 555-5555

The study is paid for by the National Institutes of health.

### Where can I get more information about managing stress?

To find more information and resources on stress management, visit MyGroupHealth online at [www.ghc.org](http://www.ghc.org), or talk to your doctor.

## Appendix E: Repository of Readability References and Resources

### I. Large-scale Health Literacy and Plain Language Initiatives

#### [American Medical Association Foundation Health Literacy Initiative](#)

Working to raise awareness among health care providers about the link between health and literacy. Find out more about their toolkit Health Literacy: A Manual for Clinicians, and train-the-trainers seminar.

#### [National Institutes of Health - Clear Communication: Health Literacy Initiative](#)

Defines health literacy and discusses why it's an issue and how to improve communication strategies for health professionals. Links to current research in health literacy supported by the NIH.

#### [Pfizer Clear Health Communication Initiative](#)

Pfizer supports research in clinical settings to begin to develop solutions that center around clear communication. Tools are provided for clinicians, researchers, the media, and public health professionals.

#### [Plain Language Action and Information Network](#)

Federal government's contribution to the plain language movement. This site provides a history of this movement, examples of documents before and after being rewritten using plain language principles, and links to key articles supporting the use of plain language in organizational settings.

#### [Plain Language Association International](#)

An international group called The Plain Language Network. Members of the network include editors, writers, attorneys, and educators from around the world. Provides links to advice and information on writing and designing clear communication materials using plain language.

#### [U.S. Department of Health and Human Services](#)

One of the primary objectives of Healthy People 2010 is the improvement of health literacy. Read the full text of the objective: Health Literacy Action Plan—Communicating Health: Priorities and Strategies for Progress (2003):

### II. Key background reports on general literacy and health literacy

#### [Results of the 2003 National Assessment of Adult Literacy \(NAAL\)](#)

#### [Health Literacy Report from the 2003 National Assessment of Adult Literacy](#)

#### [Health Literacy: A Prescription to End Confusion](#)

## **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 fields. Links to Easy-To-Read health information sites, grouped by health topic.

### **[Health and Literacy Special Collection](#)**

A clearinghouse of information related to teaching and learning health literacy skills, including links to health education resources, easy-to-read and multilingual health information, and health literacy research.

### **[Health Literacy Consulting](#)**

Resources and articles to help individuals and organizations communicate about health information in ways patients, families, and employees can more easily understand.

### **[Plain Language: A Promising Strategy for Clearly Communicating Health Information and Improving Health Literacy](#) PDF**

From the U.S. Department of Health and Human Services: An overview of plain language and health literacy terms, tips on writing and speaking plainly, and a summary of reasons why plain language has the potential to improve health literacy.

### **[Quick Guide to Health Literacy](#)**

From the U.S. Department of Health and Human Services: A summary of issues related to health literacy, suggestions for improving health literacy in your organization, and examples of health literacy best practices.

### **[Teaching Patients with Low Literacy Skills.](#)**

Second Edition (1996). Doak, Doak, & Root. Considered a classic text in health literacy, the authors are often introduced at health literacy conferences as 'the grandparents' of health literacy.

### **[Low Health Literacy: Implications for National Health Policy.](#)**

This recent report from the University of Connecticut School of Business “dollarizes” the financial burden on the U.S. economy, and advocates that low health literacy be addressed as part of national health care reform.

### **[Medical Library Association](#)**

Contains many hyperlinked resources listed that currently are developing health literacy standards

### **[National Library of Medicine/National Institutes of Health](#) –**

definitions, research findings, economic impact of low health literacy, bibliographies, a compendium of web sites, and health literacy listservs.

**[“What Did the Doctor Say?:” Improving Health Literacy to Protect Patient Safety.](#)** The Joint Commission on Accreditation of Healthcare Organizations developed this comprehensive 2007 report on the real and potential impact of health literacy.

## **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

## **Web pages with lists of alternative wording suggestions for medical and research terminology**

[University of California at Davis](#)

[University of Michigan Medical School](#)

[University of Utah Health Sciences Center](#)

## **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 empirical study. *J of Med Ethics.* 1999;25:263-267
- Cox K. Informed consent and decision-making: patients' experiences of the process of recruitment to phases I and II anti-cancer drug trials. *Patient Educ Couns.* 2002 Jan;46(1):31-8.
- Coyne CA, et al. Randomized, controlled trial of an easy-to-read informed consent statement for clinical trial participation: A study of the Eastern Cooperative Oncology Group. *J of Clinical Oncol.* Mar 1, 2003;21(5):836-842.
- Davis TC, et al. Literacy and misunderstanding prescription drug labels. *Annals Int Med.* Dec 2006;145(12):887-894.
- Davis TC, et al. Informed consent for clinical trials: a comparative study of standard versus simplified forms. *J of Natl Cancer Inst.* May 6, 1998;90(9):668-674.
- Davis TC, et al. Parent comprehension of polio vaccine information pamphlets. *Pediatrics.* 1996;97:804-810.
- Goldfarb NH and DuBay WH. Writing good at a seventh-grade reading level. *J of Clinical Research Best Practices.* Vol.2, No.1, Jan 2006
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- Hopper KD, Tenhave TR, Hartzel J. Informed consent forms for clinical and research imaging procedures: how much do patients understand? *Am J Roentgenol.* 1995 Feb;164(2):493-6.
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- Ratzan SC, Parker RM, 2000. Introduction. In National Library of Medicine Current Bibliographies in Medicine: Health Literacy.
- Sugarman J, Lavori PW, Boeger M, Cain C, Edson R, Morrison V, Yeh SS. Evaluating the quality of informed consent. *Clinical Trials*, Feb 2005; 2: 34 - 41.
- Titus S and Keane M. Do you understand?: an ethical assessment of researchers' description of the consenting process. *J of Clin Ethics*. Spring 1996; 7(1):60-68.
- White L, et al. Informed consent for medical research: common discrepancies and readability. *Academic Emerg Med*. August 1996;3(8):745-750.
- Wolf MS, et al. Health literacy and health risk behaviors among older adults. *Am J Prev Med* 2007;32(1):19-24.
- Williams MV, et al. Inadequate literacy is a barrier to asthma knowledge and self-care. *Chest*. 1998.

## **Two sites especially worthwhile for researchers and IRBs**

### **[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 Consent Documents: How Do We Get There?](#)**

Summary of Strategic Planning Meeting May 30, 2007 held by the American Association of Medical Colleges to review potential approaches and available resources to move the research community toward common usage of informed consent documents that are both short and written in simple and comprehensible language.

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We're happy to update this list with other references or resources you may come across.

Contact Jessica Ridpath at [PRISM@ghc.org](mailto:PRISM@ghc.org) or 206-287-2032 with suggested additions.