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

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[1] 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.

[1] 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:

- **The AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research** – Sample easy-to-read consent documents for informed consent and authorization and a model process for obtaining written consent and HIPAA authorization.
- **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 Group Health Research Institute (GHRI), as well as consent form templates made available on the public websites of other research institutions.

Notes for users

- The Flesch-Kincaid formula was used to rate the approximate grade level of each selection.
- Feel free to combine passages from different selections or use excerpts from a specific selection in combination with other language.
- Phrases that will need to be revised to reflect individual research settings are highlighted in grey, with instructions for inserting specific information in brackets.

Topics

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Table 1

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

Introduction/Researchers' Statement	**Grade level**
You are invited to think about taking part in a research study. This form will tell you about the purpose of the research, its possible risks and benefits, other options that you have, and your rights as a participant in the study. Please take your time to make your decision. Everyone who takes part in research at Group Health [insert name of facility or institution] should know that: • Being in any study is voluntary. • You may or may not benefit from being in the study. Knowledge we gain from this study may benefit others in the future. • You may leave the study at any time and none of the benefits you normally receive will be taken away. • Please ask any questions you have about this study. Please also take whatever time you need to talk about the study with your doctor, study staff, and your family and friends. The decision to be in the study or not is yours. If you decide to take part, please sign and date the end of this form.	**6.3**

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Table 2

Request for Permission to Review Medical Records	Grade level
We are asking you to let us collect some information from your medical records for this study. We will not need to look at all your records. Instead, we will use a computer to find information about your use of health care services, including: • clinic visits • lab test results • trips to the hospital • medicines • [insert others] 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.	**5.1**
Collecting information from medical records is an important part of this study. That's why we are asking you to let us look at your records at Group Health [insert name of facility or institution]. We are interested in the kinds of medicines you take and the kinds of visits you make in the next year and a half [insert time frame].*	**7.2**

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

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Table 3

Randomization	Grade level
We will use a computer to assign you randomly to 1 of the 2 [insert number] study groups. This means we will put you into a group by chance. It is like flipping a coin or drawing names out of a hat.* You will have an equal chance of being in either [OR any] group.	**3.7**
There will be about 1500 [insert number] people in this study. They will be assigned randomly to one of two [insert number] study groups: [list groups] Which group you will be in is decided by chance, like the flip of a coin*.	**4.8**
You will be randomly assigned to one of the four [insert number] study treatments. This means that whichever treatment you get will be decided by chance, like drawing names out of hat*. You will have a 1in 4 [insert odds] chance of getting any one of the study treatments. We will not tell you which group you are in. Study staff at your visits will not know your group either. But we can quickly find out which group you are in if we ever need to know for your safety.	**4.8**

* 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

Risks of Drawing Blood	Grade level
You may feel a slight needle prick when we draw your blood. Some people may have a slight bruise that will go away in a day or two. Sometimes, people feel light headed or faint.	**3.1**
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.	**3.7**
You may feel bothered by the needle stick, and a bruise may form. In rare cases, some people faint or the site becomes infected.	**4.3**

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Table 6

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

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

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Table 7

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

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Table 8

Voluntary Participation and Withdrawal	Grade level
Do I have to be in this study? No, being in this study is up to you. You can say no now or to leave the study at any time later. Either way, your decision won't affect your care or benefits at Group Health [insert facility or institution].	**3.4**
Can you leave the study early? • You can agree to be in the study now and change your mind later. • If you wish to stop, please tell us right away. • Leaving this study early will not affect your regular medical care. from Johns Hopkins University	**4.2**
Being in this study is voluntary. You can decide not to be in the study. If you decide not to be in the study, you will not lose any benefits that you have.	**4.4**
Taking part in this study is up to you. You may choose not to take part or to leave the study at any time. If you choose not to take part or to leave the study, your regular medical care will not be affected. from Georgetown University	**4.8**
Taking part in research is voluntary. You may decide not to be in the study. If you decide to take part, you may leave the study at any time. Your decision will not affect your medical care at Group Health [insert facility or institution]. There are no penalties or loss of benefits if you choose not to take part or to leave the study early. from Children's Hospital	**5.0**
Taking part in this study is voluntary. If you choose not to b in this study, your care at Group Health [insert facility or institution] will not be affected. You may choose not to participate at any time during the study. Leaving the study will not affect your care at Group Health [insert facility or institution]. from University of Chicago	**5.8**
Entering a research study is voluntary. Anyone who is asked to be in a research study may say no. If you start a research study, you may stop at any time. You do not need to give a reason. No doctor will treat you differently if you choose not to be in a research study or later decide to stop participating. If you stop, it is important to tell study staff and follow any instructions that they may give you. from Chesapeake IRB Informed Consent Template	**6.2**

Voluntary Participation and Withdrawal	**Grade level**
Your participation in this study is voluntary. You are free to leave this study at any time. Your care at Group Health [insert facility or institution] will not be affected by whether you decide to participate.	**6.6**
Your Rights It is important for you to know that: • Your participation is voluntary. • You may decide not to take part or to leave the study at any time. This will not change the quality of the health care you receive. • We will tell you about any new information or changes in the study that might affect your willingness to participate. from University of Massachusetts Medical School	**7.1**

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Table 9

Confidentiality	Grade level
Your confidentiality is one of our main concerns. We will store all of your research records in locked cabinets and secure computer files. We won't place your name on any research data. Instead, we will label your information with a code number. The master list that links your name to your code number will be stored in a locked cabinet. We will keep all the information you give us confidential as provided by law. The only exception is any risk of possible harm to you or others. We won't share your study results with anyone unless you ask us to. Your name won't appear in any reports about this study.	**6.3**
We will keep information about you confidential as provided by law. We will label your audiotapes and survey answers [insert applicable study data] with a study number only. Your study number is not related to your name or Group Health medical record number [insert applicable patient identifier]. We will keep the audiotapes in a locked cabinet. Information from the interviews will be stored in protected computer files. We will destroy the audiotapes and the link between your name and study number by March 2010 [insert date]. We will never use your name in reports about this study. We will not share your answers with your doctor or anyone else without your permission. However, if we think you are in danger of harming yourself, we are obligated to get help for you. [use this clause only if necessary]	**8.0**
We will keep information about you confidential in accordance with the law. We will use a study number instead of your name to identify your blood sample and survey answers [insert applicable study data]. 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.	**8.2**
[For statements describing risk of breach of confidentiality] **Can anything bad happen to me from being in this study?** Every research study involves some risk to your confidentiality. It's possible that other people could find out you were in the study or see your study information. But we will take every step to keep this from happening, so we think this risk is very low.	**7.5**

*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
• I have read this form and the research study has been explained to me. • I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call. • I agree to be in the research study described above. • I will receive a copy of this consent form after I sign it. from Northwestern University	**4.5**
I have read this form or have had it read to me. I have been told what will happen if I take part in this study, including the risks and benefits. I have had a chance to ask questions, and they have been answered to my satisfaction. I have been told that the people listed in this form will answer any questions I have in the future. Study staff will give me a copy of this consent form for my records. By signing below, I am voluntarily deciding to be in this research study.	**6.2**
Please initial each statement you agree to: __ To take part in this study. __ To let the researchers collect information from my Group Health [insert facility or institution] medical records. __ To be contacted about this research in the future.	**6.2**
• This study has been explained to me. • I volunteer to take part in this research. • I have had a chance to ask questions, and my questions have been answered. • If I have questions later on about the research, I can ask one of the researchers listed in this form. • If I have questions about my rights as a research subject, I can call the Group Health Human Subjects Division at (206) 287-2919 [insert applicable info]. • I agree to allow the researchers to use my medical records as described in this consent form [remove if not applicable]. • I understand that if I am not able to answer questions for this study in the future, study staff will contact a family member or close friend to do this for me [remove if not applicable]. • I will receive a copy of this consent form.	**7.8**

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Table 11

Study Staff Statement/Signature	**Grade level**
• I have carefully explained to the subject the nature and purpose of this study. • The subject has been given enough time and an adequate place to read and review this form. • The subject has had a chance to ask questions and receive answers about this study. from Chesapeake IRB	**7.3**
I have explained the above research study over the telephone [remove if not applicable]. The participant was given time to discuss the study and ask questions. I can be reached at the phone number listed on this form to answer any other questions that the participant may have. I will mail [or "give," if applicable] a signed copy of the consent form to the participant.	**7.5**

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