



Informed Consent Toolkit

**Strategies to Make
Informed Consent
Truly Informed**

Terry Davis, Ph.D.
Connie Arnold, Ph.D.
Geoff Lucas, MPP

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Introduction

This toolkit gives you:

- Easy steps to improve the reading ease of consent forms
- Lots of examples – “mini templates”
- Plain language thesaurus
- “Best practices” to improve consent discussion
- Realistic tips on working with IRBs and HRPPs
- Resources

This toolkit gets to the point in helping you write forms that will improve patient understanding and satisfaction.



The Balance Challenge in Writing Consent Forms: Considering Both IRB and Patients

- Identify IRB requirements – what do IRBs look for?
- What templates/standard wording is required?
- What can be simplified?
- What is your key message?
- What information do patients need and want?
- Consider how literacy, motivation, attention, and distractions may affect patient comprehension



CDC. *CDC Clear Communication Index*. May 2013,

<http://www.cdc.gov/healthliteracy/pdf/clear-communication-user-guide.pdf>

Image from www.computerclipart.com

Tips from a Friendly IRB

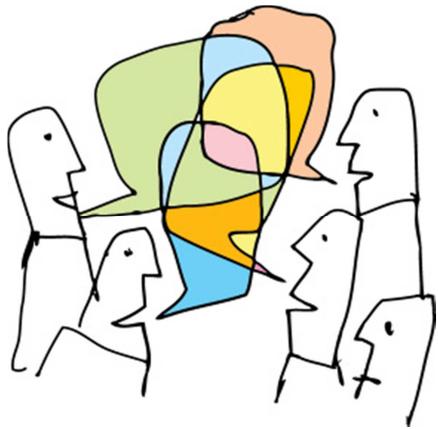
- Be sure you understand your protocol and the type of research you are doing **before** you write the consent document
- Be sure details in your consent form matches the details in your protocol
- Consent requirements differ based on type of research, funding, population, sites, etc.
- Requirements differ in minimal risk studies and those with greater than minimal risk



There is no such thing as 'one size fits all' when putting together a consent document

Community Surveys Indicate Patients Want

- Forms with large print, plain language, pictures, and summaries
- Key points discussed, not read to them
- One-on-one discussions – perhaps more than one meeting
- Group meetings when appropriate



Patients do not want forms read to them.

Write in Plain Language

- Create patient-centered titles
- Use short, simple, direct sentences
- Use familiar words
- Define medical, legal, or scientific words
- Use consistent terms throughout the form
- Avoid abbreviations and acronyms
- Avoid words with 3 or more syllables (if possible)

The templates and thesaurus on the following pages offer specific examples.

The consent form should be in the patient's preferred language. Note this must also be approved by the IRB.

Study-Centered vs. Patient-Centered Titles

Study-Centered Title

Phase III Comparison of Combination Chemotherapy (CAF) & Chemohormonal Therapy (CAF + Zoladex and Tamoxifen) in Premenopausal Women with Axillary-Node Positive. Receptor-Positive Breast Cancer. Intergroup.

VS.

Patient-Centered Title

Breast Cancer. You Can Help Your Doctors Find Better Treatments.

Complex vs. To-The-Point Sentence

Complex Sentence

The goal of the tissue bank or repository is to support the LSUHSC-S Dept. of Surgery research in order to improve our understanding of those molecular factors that contribute to cancer and that may lead to prevention, early detection, and cure.

(41 words)

VS.

To-The-Point Sentence

The goal of this research is to learn what makes cells turn into cancer.

(14 words)

Plain Language vs. Complex Language

Unnecessarily Complicated Language, Long Sentence

You have been selected as a possible participant in this study because you have a moderate to very-high risk pulmonary embolism, and it is not known if retrievable vena cava filters reduce mortality or reduce recurrence of nonfatal pulmonary embolism or if complications of vena cava filters outweigh the benefits in such patients.

(54 word sentence)

VS.

Plain Language, Medical Terms Defined, Shorter Sentence

You are invited to be in the study because you have had a pulmonary embolism (clot that goes from your legs to your lungs).

(24 word sentence)

Plain Language = Understandable Language

Unnecessarily Complicated Language

In order to draw statistical conclusions about the study, data from your medical records may be shared among researchers and research staff involved in the study, both here at our hospital and with other members of the collaborative group.

(39 words)

VS.

Plain Language, Shorter Sentence

In order to get results about the study, your medical records may be shared among the research staff.

(18 words)

Plain Language Thesaurus

Original

Better

Abdomen	Stomach, belly
Abrasion	Cut, scratch, scrape
Acute	Sudden start, quick
Adhere	Stick, follow
Adverse events	Bad side effect, bad reaction
Alternative procedure	Other choices
Authorize	Give your OK in writing
Benefit	Will being in this study help me
Cardiologist	Heart doctor
Central Nervous System	Brain and spinal cord
Clinical trial	Research study
Control Group	People not getting the new treatment
Determine	Decide, find out
Disclosure	Allows us to tell others about information that you give to us
Equilibrium	Balance
Gastric	Relating to the stomach
Ingest	Eat or drink
Mean (statistical)	Average (statistical)
Notify	Tell us

Original

Better

Obtain	Get, get a copy
Participate	Join
Pharmaceutical	Drug
Placebo	A pretend drug or treatment, sugar pill
Principal Investigator (PI)	Head researcher in charge of study
Protocol	Plan for a research study
Procedure	Way of doing things
Pulmonary	Relating to the lungs
Randomized	Selected by chance
Replicable	Can be done again
Retain	Keep
Satisfactory	Okay, fine, good
Sustain	Keep going
Symptomatic	Having symptoms
Systemic	Whole body
Therapy	Treatment
Voluntary Participation	It's your choice to be in this study
Withdrawal from the study	You can leave the study

For more helpful word substitutions visit this site:

[http://hospitals.unm.edu/dei/documents/
plain_language_thesaurus.pdf](http://hospitals.unm.edu/dei/documents/plain_language_thesaurus.pdf)

AHRQ, 2008

Plain Language Checklist

- Create patient-centered title
- Use short, simple, direct sentences
- Use familiar words
- Define medical, legal, or scientific words
- Use consistent terms throughout the form
- Avoid abbreviations and acronyms
- Avoid words with 3 or more syllables (if possible)

Improve Reading Ease

- Make key messages easy to pick out
- Get to the point – avoid information overload
- Aim for 8th grade reading level (or lower)
- Use illustrations if appropriate
- Use personal pronouns (I, you)
- Use active (not passive) voice
 - “your signature” vs “signature of patient”
- Attend to tone

The templates and examples on the following pages give examples.

Attend to tone – Use a respectful, conversational tone. Consider the patient’s emotional response to messages and certain words.

Make Key Messages Easy to Pick Up: Get to the Point

- Use white space, **bold**, underline, and *italicize*

We are asking you to be in a research study.

You do not have to be in the study.

You can quit at any time.

Your choice will not change your medical care in any way.

Please take as much time as you need to make your choice.

- “Lump and clump” information
 - Use sub-headings

About this document

This document tells you about the study. If you decide to be in the study and to let us use and report on health information about you:

- You will sign the document, and
- We will give you a copy of the document to take home.

What is the goal of the study?

We want to learn if we can improve health care for people with [condition]. We are asking people like you who have [condition] to help us.

Clear vs. Buried Message

Buried

The goal of the tissue bank or repository is to support the LSUHSC-S Dept. of Surgery research in order to improve our understanding of those molecular factors that contribute to cancer and that may lead to prevention, early detection, and cure.

VS.

Clear

The goal of this research is to learn what makes cells turn into cancer.

Avoid Information Overload

Too Much Text (19 lines)

Researchers at X hope to learn what effects, good and/or bad, abiraterone acetate has on you and your prostate cancer. The effect of the prostate cancer will be measured by a blood test (prostatic specific antigen or PSA). You are being asked to take part in this study because you have prostate cancer that is only partially responding to hormone therapy. Abiraterone acetate is a hormonal tablet that has been approved by the Food and Drug Administration (FDA) for more advanced prostate cancer patients who have received chemotherapy. It is considered investigational for your type of prostate cancer. We will be looking to see if abiraterone acetate improves the effectiveness of standard hormonal shots or injections. (The prostate specific antigen (PSA) is a blood test used in prostate cancer screening and also to follow prostate cancer. In this study, we will follow your PSA level to help determine if abiraterone acetate is beneficial. The main goal of this study is to see if abiraterone acetate with prednisone reduces PSA.

VS.

Shorter Text (5 lines)

You're being asked to be in the study because you have prostate cancer which has not totally responded to hormone therapy. The goal of this study is to test whether adding another hormone pill, abiraterone acetate, will work better. We will use blood tests to see if this works.

To-The-Point vs. Overloaded

Overloaded Sentence

The purpose of this study is to try to understand if production of BK virus, JC virus, Merkel Cell Polyomavirus, and Cytomegalovirus vary with hormonal changes during the female menstrual cycle. The study will also test your immune response to BK virus, JC virus, Merkel Cell Polyomavirus, and Cytomegalovirus, if present, and measure hormone levels in urine for correlation with your menstrual cycle.

VS.

To-The-Point Sentence

The purpose of the study is to find out more about how the body controls BK virus.

Check Reading Level – Aim for 8th Grade

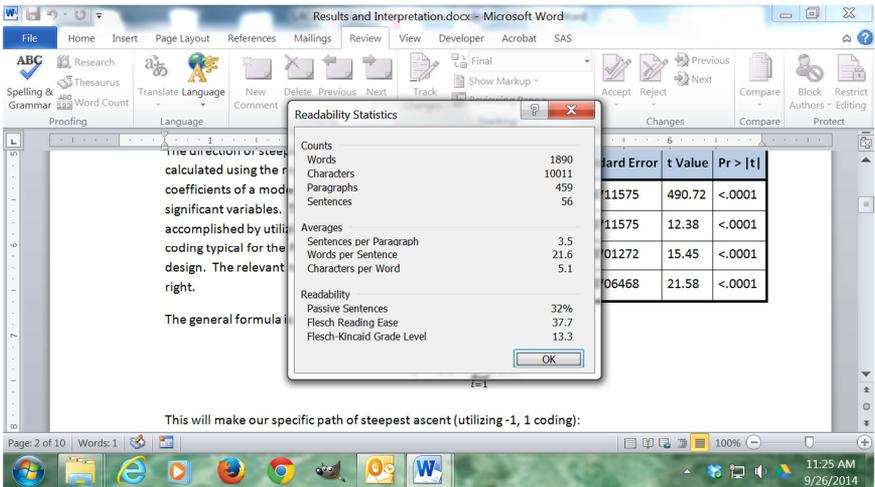
- Average education level of U.S. adults $\geq 12^{\text{th}}$ grade yet average reading level is $\sim 8^{\text{th}}$ grade



Remember reading level is the **tip** of the iceberg in developing good materials.

Estimate Reading Grade Level

- Flesch-Kincaid is an easy tool
- Readability statistics on Microsoft 2007 and 2010
 - Go to 'File' Tab; select 'Options'
 - Click on 'Proofing'
 - Check 'Show Readability Statistics'
 - Go to 'Review' Tab
 - Select 'Spelling & Grammar'
 - Readability statistics will show after spelling has been checked



A Fun Way to Spot Difficult Words

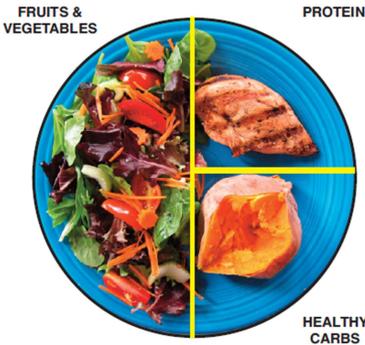
- *Vocabulary Profiler* color codes words in English
- 1000 most frequently used words (K1) (**Blue**)
- Second 1000 frequently used words (K2) (**Green**)
- Academic words frequently used in academic texts (AWL) (**Yellow**)
- Words which are not found on the other lists (off list) (**Red**)

Current profile	
65.98%	Cumul.
4.15	70.1
7.47	77.6
22.41	100

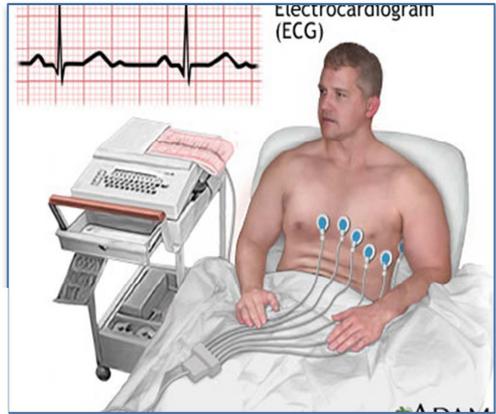
researchers at hope to learn if adding at targeted therapy trastuzumab herceptin to standard treatment with chemotherapy for early stage hernumber low breast cancer from returning tastuzumab is called a targeted therapy because it targets the tumor cells by blocking the hernumber protein on the surface of the cancer cell to slow down or stop cancer growth trastuzumab is a standard treatment for hernumber positive breast cancer in this study trastuzumab is considered to be investigational because it has not been studied for use in treating hernumber low breast cancer studies that already have been done with trastuzumab focused on breast cancers that were strongly hernumber positive however in some of these studies tumor samples were checked in a central laboratory to confirm the hernumber testing results some breast cancers that were thought to be hernumber positive were actually hernumber low the researchers then looked at the results of treatment in patients with hernumber low tumors they found that trastuzumab seemed to have benefit in keeping the cancer from returning even when the hernumber levels were in the normal range the number study is being done to learn more about trastuzumab or treat hernumber low breast cancer

Illustrations Aid Reading Ease

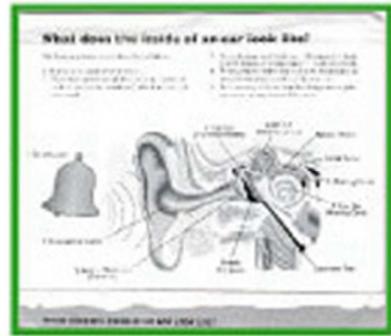
- Pictures can help explain text
- Pictures need to be realistic, familiar, and likely to be understood at a glance
- Locate them next to relevant text
- Place descriptive captions under images
- Color appeals to readers



The diagram on the right is too complex to easily understand.



The electrocardiogram (ECG, EKG) uses sensors on a person's body to find out about how a person's heart is working.



Is Tone Bureaucratic or Patient-Centered?

Does the document...

- Focus on the study and also consider the patient?
- Have a respectful, conversational tone?
- Address the reader (use personal pronouns)?

What is a consent form?

- It tells you about a study we want to do.
- It tells you how you can help.
- It asks you if you will help us.

Why are we doing this study?

- We want to find the best way to treat your kind of breast cancer.

Why me?

- You can be in this study because you have had cancer in your breast that has spread to other places in your body.

Checklist to Improve Reading Ease

- Make key messages easy to pick out
 - Use white space, **bold**, underline, *italicize* words
 - Use bullet points
 - Use sub-headings
- Get to the point – avoid information overload
 - Message is clear, not buried
 - Limit passages to 4 or 5 lines
- Aim for 8th grade reading level (or lower)
- Use illustrations if appropriate
- Create boxes for important points
- Attend to tone
- Use active (not passive) voice

Design a Clean Layout

- Simple headers or questions
- White space
- Bullets, lists
- Bolding
- Short sentences
- Break text info into manageable chunks
 - “lump & clump”
- Use at least 12 point font
- Select easy to read font style
 - Times New Roman, Arial

What is informed consent?

- It is an agreement to take part in a study.
- The research staff will help you with this consent form.
- It gives you facts about the research study so you can decide if you want to take part or not.
- The form will explain the study, tests or procedures you may receive and the benefits and risks.
- It also tells you your rights as a research volunteer.

Why are you being invited to take part in a research study?

- You are invited to be in the study because you have had a pulmonary embolism (clot that goes from your legs to your lungs).

What are your rights?

- You can choose whether you want to be in the study or not.
- You can ask all the questions you want. Feel free to ask the research staff to explain the study to help you decide if you want to participate.
- If you choose not to be in the study you will not be penalized. It will not affect your health care.
- You can agree to be in the study and then change your mind later.
- After the study begins, we will give you any new information that we learn about the research. Then you can decide if you want to continue being in the study.

Which Page Will You More Likely Read?

DEFINITION OF CONSENT FORM

This consent form gives detailed information about the research study which you will be able to discuss with your doctor. It is not meant to frighten or alarm you; it is an effort to make you better informed in order for you to make a decision as to whether or not you wish to participate. This process is known as informed consent.

This is a research study. A research study includes only patients who choose to take part. Please take time to make your decision. However, before you agree to take part, you must understand the statements in this informed consent document. After that, please ask all the questions you want, especially to help you understand completely what will happen if you take part in this study. You will be told of any important new information about the antibiotics used in this study which could change your decision to take part in this study.

Your doctor has diagnosed you with a skin infection. Skin infections happen when your skin is infected with germs called bacteria. Symptoms of a skin infection may include discharge (“pus”) from the skin, warmth, pain, tenderness, redness, swelling, and/or fever. The standard treatment for many skin infections is antibiotic drugs.

Therefore, you should immediately inform the study doctor or staff if you have a history of allergies or problems when taking any antibiotics or other medications.

Your doctor has decided that you will be given antibiotics into your vein to treat your infection. The antibiotics will be given into your vein.

What else do I need to know?

- Some side effects will stop when you finish treatment.
 - Your hair will grow back.
 - Your stomach won't be upset.
- Some side effects might last forever.
- You must not get pregnant while you are getting treatment.
- You must not take birth control pills.
- If your treatment does not work, your doctor may change it.
- There is a very small chance that a side effect could cause death.

What good can come of this?

- If your treatment works, it may:
 - Keep your cancer from coming back.
 - Make it a longer time before your cancer comes back.
 - Give you a longer life.
 - Help you to feel better.

Bullets, Lists, and Less Text

Monitoring Board. If there appears to be a clear advantage of filters plus anticoagulants or anticoagulants without filters, or if there appears to be unwarranted risk from filters, the study will be discontinued. Unless that happens, results of the investigation will not be known by participating physicians or patients until 5 years after the beginning of the investigation. At that time, results will be published, which usually takes another year. You will not be identified in the publication. We will furnish you with a copy of the publication if you ask for a copy when they become available.

4. POTENTIAL BENEFITS:

The potential benefits to you for taking part in this study are that if randomly selected to receive a retrievable vena cava filter in addition to anticoagulants, the filter may save your life by preventing a recurrent pulmonary embolism, or it may prevent a recurrent nonfatal pulmonary embolism, which could have damaging effects. On the other hand, if randomly selected to receive anticoagulants without a filter, it may be that mortality and the incidence of nonfatal pulmonary embolism are the same as in the patients who received filters, and you would be spared the risks of complications of filters and the discomfort of filter insertion and retrieval.

In addition to a possible direct benefit to you, your participation in this study may contribute to the understanding of whether retrievable vena cava filters should be routinely inserted in patients with moderate to very-high risk pulmonary embolism. If the risk reduction of the combination of death or recurrent nonfatal pulmonary embolism is lowered from 20% to 15.6%, the number of patients with pulmonary embolism who would die or suffer nonfatal recurrence in one year would decrease in United States from 26,480 to 20,650. Therefore, 5,800 patients yearly in United States would benefit from a reduced mortality or reduced illness from nonfatal recurrence of pulmonary embolism.

5. POTENTIAL RISKS

Pulmonary embolism carries risks. The usual symptom is shortness of breath that can occur at rest or only during exertion. In most patients, the clots in the arteries of the lung dissolve by natural processes, and the patients recover fully. In some patients, however, some or most of the clots in the arteries of the lung fail to dissolve. Such patients then may have continuing shortness of breath at rest or during exertion. Some patients suffer a recurrence of pulmonary embolism despite treatment with anticoagulants (blood thinners) and despite treatment with thrombolytic agents (clot dissolving drugs). Recurrences of pulmonary embolism can cause further shortness of breath which may or may not resolve, depending on the extent to which the clots in the arteries of the lung dissolve by natural processes or by thrombolytic drugs (clot dissolving drugs) if administered. Clots in the arteries of the lung that fail to dissolve may lead to high blood pressure in the pulmonary arteries. This could lead to heart failure or death. If pulmonary embolism is massive (large clots in major branches of the arteries of the lung), the patient could die from the effects of the clots. In this investigation we will determine if retrievable vena cava filters reduce the incidence of recurrent nonfatal or fatal pulmonary embolism, and we will determine the risks of such retrievable vena cava filters.

The potential risks of participating in this study also relate to failure to insert filters or to use anticoagulants against filters.

What else do I need to know?

- Some side effects will stop when you finish treatment.
 - Your hair will grow back.
 - Your stomach won't be upset.
- Some side effects might last forever.
- You must not get pregnant while you are getting treatment.
- You must not take birth control pills.
- If your treatment does not work, your doctor may change it.
- There is a very small chance that a side effect could cause death.

What good can come of this?

- If your treatment works, it may:
 - Keep your cancer from coming back.
 - Make it a longer time before your cancer comes back.
 - Give you a longer life.
 - Help you to feel better.

Misuse vs. Proper Use of Bullets

The results of this study will be published and presented at professional meetings, but the identities of all research participants will remain anonymous.

7. YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW

- Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.
- You have the right to say no.
- You may change your mind at any time and withdraw.
- You may choose not to answer specific questions or to stop participating at any time.
 - Choosing not to participate or withdrawing from this study will not make any difference in the quality of any treatment you may receive.
 - Whether you choose to participate or not will have no effect on your evaluation or medical care.
 - You will be told of any significant findings that develop during the course of the study that may influence your willingness to continue to participate in the research.
 - If you decide to withdraw from the investigation, you should continue treatment with anticoagulants until your physician indicates that they can be safely discontinued. If you were randomly selected as he/she believes you should continue anticoagulation, you will be treated as appropriate. Failure to appropriately manage anticoagulation may result in severe swelling, bleeding, or other potential risks. You will be treated as appropriate at the appropriate time.

Treating physicians will remove the filter. In that event, you will be treated as necessary for the study) as necessary.

Risks of x-ray contrast

- When the radiologist puts the filter in and takes it out he will inject a dye (radiographic contrast material) to see the vein. Allergic reactions to the dye are rare (less than 1 out of 100 times).
- If you have kidney disease, the dye could damage your kidneys. We will do blood tests to check your kidneys before giving you the dye.

Risks of local anesthetic (numbing medicine)

- The radiologist will give you a shot of numbing medicine when he puts the filter in and takes it out.
- The risks of this medicine are numbness or tingling and nerve damage.
- Allergic reactions could result in death. This is rare.

Risks of sedation

- When the filter is being put in your vein or taken out, the radiologist may give you a medication to make you less anxious. It is possible to become too sedated and stop breathing. If this happens you would be put on the ventilator in the intensive care unit, or even die. This is rare.
- Allergic reactions to the medicines could result in death. These are very rare.

What are the costs of being in the study?

- Since this study is comparing two treatments that are "usual care" for patients who have had a pulmonary embolism, we will bill your health insurance for costs of usual medical care.
- We will help you check with your health plan or insurance company to find out if they will cover the costs. Any deductibles or other costs that are not paid by your insurance will be your responsibility.
- If you do not have insurance and are unable to pay for the care you received in this study, we will cover the costs for putting the filter in and taking it out.
- Under Medicare rules, we cannot pay costs unless you qualify for "indigent care."
- Please talk with Dr. Walter for more information about your particular situation.
- Being in this study may lead to added costs to you or your insurance company. Please ask about any added costs or potential insurance problems.

What are the benefits of taking part in this research? Will being in this study help you in any way?

- We cannot promise any benefits to you or others for being in this study.
- If you are chosen to get a filter, it may reduce your risk of getting another pulmonary embolism.

Don't Forget the Math

Percentages and probability are challenging for many adults



- Approximately **half** of U.S adults are unable to calculate a tip.
- **20%** of college-educated adults **don't** know which is a higher risk – 1%, 5%, or 10%

Kirsch IS, et al., *Adult Literacy in America*, 1993; Lipkus IM, et al., *Med Decis Making*, 2001

Image from brianfobi.com.

Improve Risk Communication

Provide numeric likelihoods of risks and benefits.

- Describing risks solely with words such as, “*You have a low chance of experiencing a side effect*” has been proven ineffective
- Patients vary in their interpretations of what *low* and *high risk* are

State absolute risk, not relative risk

- Drug X could reduce your risk of breast cancer by 50% (Relative risk)
- Drug X could reduce your 5-year risk from 4% to 2% (Absolute risk)

Drug has same effect in both cases, but reporting the relative risk makes the drug sound more effective.

State absolute risk, not relative risk. Stating risk in relative terms can be misleading and imply unrealistic potential benefits.

More Risk Communication Tips

Keep denominators constant for comparisons.

- It is difficult for patients to compare treatments when different denominators are used (e.g., 1 in 1000 vs. 1 in 500)

Keep time frames constant.

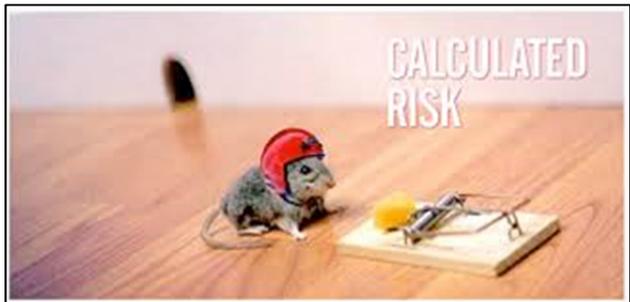
- Use the same time frame when presenting risks and benefits

Provide both positive and negative frames.

- 6 of 10 men who have surgery to treat prostate cancer will be impotent. This means 4 of 10 will not

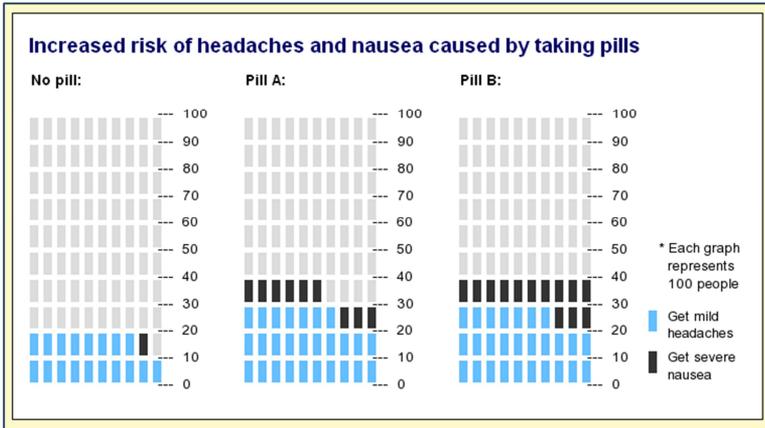
Be careful how you communicate the meaning of important information.

- Describing information in terms of goodness or badness can affect people's risk perceptions

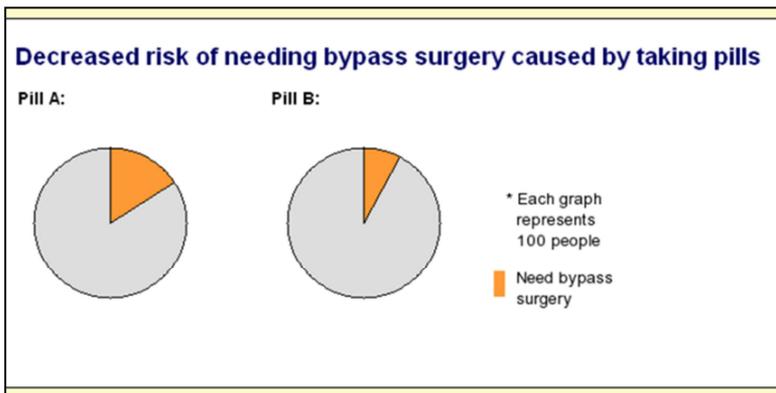


Use Pictographs and Other Visual Aids

- Pictographs have been shown to be the best graphs for communicating both gist and verbatim knowledge



- BUT in our recent research, subjects with low literacy more easily understood pie graphs



Risk Communication Checklist

- Communicate risk in numeric form
- Use absolute risk when possible
- Keep denominators constant
- Keep time frames constant
- Give both positive and negative frames
- Descriptions of risk and benefit are free of loaded meaning
- Use graphs and visual aids when possible

$\sqrt{-1}$ 
Math

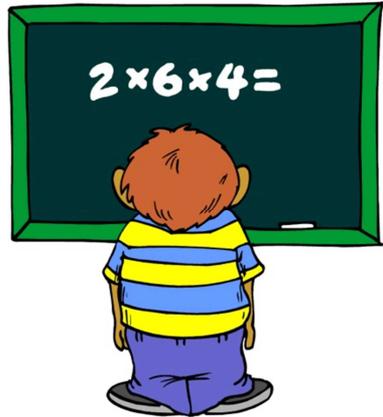


Image from files.ogschool.org.
Image from www.tjed.org.

Pilot Test Your Draft

- Ask for feedback from fellow researchers to limit jargon and increase comprehension
- Ask a friend – probe for honest feedback
- Conduct individual interviews with patients reviewing specific sections



Tip: Pilot testing should be done for each language used.

Steps to Improve Consent Process

- Prepare - know your study
- Allow sufficient time for session
- Arrange quiet, private space
- Let patient include family and friends
- Let patient take form home
- Slow down and connect with patient
- Communicate using everyday language and conversational tone
- “Walk” patient through the form
- Verify and document comprehension



Prepare for Consenting Process

- **Schedule time** to clearly understand study and be able to communicate it in a relaxed manner
- **Practice** – role play with your P.I. and team. Get feedback to improve communication
- **Pair with team member** to consent several patients. The partner is there to help - adding missing points and later giving private feedback
- Prepare a **flip chart with pictures** to aid discussion



You cannot elicit informed consent when you are not informed.



Communication is Key

- Take a few minutes to **connect** with your patient
- **Slow down** – allow enough time
- Speak in **conversational** manner – use plain language and friendly tone
- **Avoid bureaucratic**, stuffy approach
- **Use document** to point out key message
- **Consider** what your words and body language might be signaling
- **Listen** to your patient
- **Watch** face and body language to gauge interest and comprehension



Tip: This link can aid with plain language:

http://hospitals.unm.edu/dei/documents/plain_language_thesaurus.pdf

Confirm Understanding

Unless we confirm understanding, we don't know what patients comprehend (*what's clear to you may not be clear to your patient!*)

- Many patients are passive and don't ask questions or don't know what to ask

Use teach back method after each section or two to confirm understanding

- Allow patients to consult the document when answering (purpose is to check comprehension not memory)
- Correct misunderstanding

Avoid asking:
Do you understand?
Do you have any questions?

Teach Back is Effective

Tell me in your own words...

Goal of the Research and Protocol

- “Why are we doing this research?” “What is the study about?”
- “What will you be doing if you agree to be in this study?”

Benefits

- “Will being in this study help you in any way?”

Risks

- “Is there any way being in this study will be bad for you or hurt you?”
- “Can you tell me 2 risks of being in the study?”

Costs

- “Will being in this study cost you or your insurance company anything?”
- “Will you be paid to be in the study?”



AHRQ, 2008

Image from www.patienteducationupdate.com.

Voluntariness

- “Can you decide you do not want to be in the study?”
- “Will that change the healthcare you receive?”

Discontinuing Participation

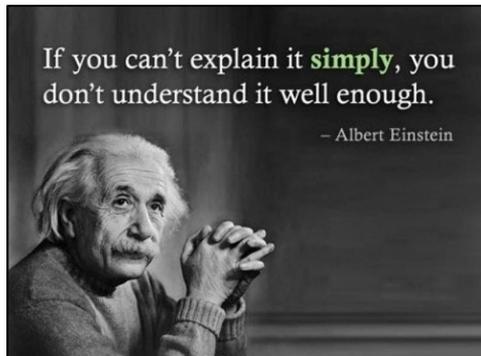
- “What should you do if you change your mind?”
- “What will happen to information we have gotten if you change your mind?”

Privacy

- “Who will be able to see the information you give us?”

Contact Information

- “What should you do if you have any questions or concerns about this study?”



Teach Back Checklist

Is the patient able to describe to you:

- The goal of the research
- Their duties in regard to the research
- Possible benefits
- Costs
- Risks of harm from participating
- That participation is voluntary
- That it will not affect their healthcare if they don't participate
- What to do if they change their mind
- What you will do with information you have gathered before they change their mind
- Who will be able to see their information
- Who to contact if they have questions about the study.

Patients who are not able to comprehend the study protocol despite repeated attempts to explain details should not be enrolled.

Tip: Use this checklist to document completion of teach back

Consent Checklist

- Can patients read and understand form?
- Is it written in plain language?
- Is it formatted for reading ease?
- Is it too long?
- Is information manageable (or overwhelming)?
- What is plan for discussing information with patients?
- Does form and consent discussion help patients make a decision about participation in the study?
- Will IRB approve it?

Summary

Consent Document

- Aim for <8th grade reading level
- Limit jargon – use consistent terms
- State risk numerically – use absolute risk
- Format for reading ease
- Pilot test with a few patients

Consent Process

- Connect with patient - make it conversational
- Use teach back to confirm understanding
- Remember that participation is the patient's choice

IRB – Know Rules, Work Collegially

Bottom Lines

- The “culture” of informed consent is changing
- Time and preparation are key in developing forms and discussing them with patients
- IRB and HRPP can be help-mates

Resources

- The Agency for Healthcare Research and Quality (AHRQ) Informed Consent and Authorization Toolkit for Minimal Risk Research.
<http://www.ahrq.gov/funding/policies/informedconsent/index.html>
- First Clinical Research Glossary for Informed Consent:
 - <http://firstclinical.com/icfglossary/>
 - <http://firstclinical.com/glossary/>
- Doak CC, Doak LG, Root JH. *Teaching Patients With Low Literacy Skills*, 2nd ed., 1996
- Simply Put “A Guide for Creating Easy to Read Print Materials that your audience will be able to read and use.” CDC 2007.
http://www.cdc.gov/healthliteracy/pdf/Simply_Put.pdf
- IOM Health Literacy Roundtable on Informed Consent July 28, 2014
- Thesaurus of simple terms and phrases for writing and speaking in plain language
http://hospitals.unm.edu/dei/documents/plain_language_the_saurus.pdf
- Office for Human Research Protections Informed Consent Checklist <http://www.hhs.gov/ohrp/policy/consentckls.html>
- Shalowitz DI, Miller FG. Journal of the American Medical Association. Disclosing Individual Results of Clinical Research: Implication of Respect for Participants. 2005; 294(6): 737-740.
<http://jama.jamanetwork.com/article.aspx?articleid=201351>

Appendix

Federally Required “Elements of Consent”

Does the consent form:

- State that this is research?
- Explain why it is being done?
- Tell the patients how long they will be in the study?
- Describe what patients are supposed to do during the study?
- Describe what parts are research, and what parts are not experimental?
- Describe the risks/discomforts that are directly related to participating in the research?
- Describe the potential benefits to participants/others reasonably expected during the research?

If needed, include clarification about availability of interpreters during consent process and during the study.

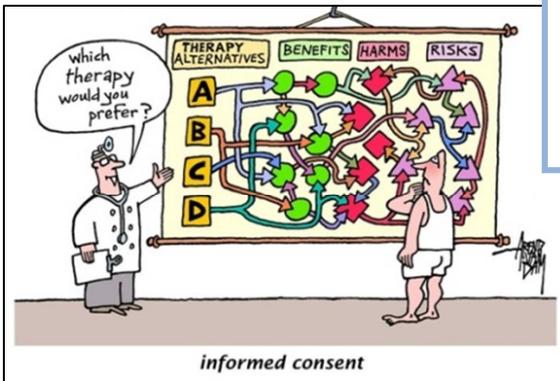
- Describe the alternatives to being in the study?
- State that participation is voluntary?
 - Declining to be in the study will not affect their rights/benefits?
 - They can stop at any time without losing rights/benefits?
- Describe how records identifying the patient will be maintained (for how long, who will they be shared with, under what conditions)?
- Describe what happens if the patient is injured due to participation in the research (more than minimal risk only), including compensation, treatments, etc., and who to call should it happen?
- Who to call with questions and where to get additional information?
- Who to call with questions about subject's rights?

Although not a requirement, you might include how patients will be informed of study results. This is key when conducting community-based participatory research.

Current Challenges & Culture Shifts

- There is growing regulatory oversight (purpose of IRBs and lawyers is to protect the rights and welfare of humans participating in research)
- Federal funding agencies concerned that patient comprehension is poor
- Consent 'culture' is shifting from persuading to teaching
- Clinical research is growing - 2.3 million patients a year sign consent forms
- No standard template for wording, formatting, or comprehension assessment
- Big data will bring new confidentiality concerns

*Consent
will
demand
more time.*



Cohn E, J of Nursing Scholarship, 2007

IOM 2014 Workshop on Informed Consent and Health Literacy: A Workshop

Image from www.cagle.com

The Problem with Consent Forms

- Too long, too complex, too much jargon
- Page density (lack of white space)
- IRBs do not consistently meet their own standards for readability
- Patients do not understand basic concepts being explained

Good news:

Forms can be simplified more than commonly believed

Would you or your patients read this?

and if a respirator is not required is 7-8%. Acute pulmonary embolism is often treated with insertion of an inferior vena cava filter 1) in patients who cannot be treated with anticoagulants, 2) in patients who suffered a pulmonary embolism while receiving full therapeutic doses of anticoagulants, 3) in patients with massive pulmonary embolism in whom the benefits of anticoagulants alone are likely to be insufficient, and 4) in patients with chronic recurrent pulmonary embolism. Such patients are excluded from this investigation because filters are known to help them. To date, no investigation has assessed the risks and benefits of retrievable inferior vena cava filters in patients at moderate to very-high risk of death with pulmonary embolism who are not in these categories. WE DO NOT KNOW IF VENA CAVA FILTERS IN ADDITION TO ANTICOAGULANTS IN PATIENTS WITH PULMONARY EMBOLISM OF THE SEVERITY THAT YOU HAVE REDUCE MORTALITY AND NONFATAL RECURRENCE OR IF TREATMENT WITH ANTICOAGULANTS ALONE CARRIES A SIMILAR MORTALITY AND NONFATAL RECURRENCE RATE WITHOUT THE RISK OF COMPLICATIONS OF FILTERS.

The treatment with anticoagulants that you will receive is currently standard treatment. Treatment with a retrievable vena cava filter in addition to anticoagulants is often used. This happens in about 15% of patients similar to you. Many physicians believe that filters may save lives and reduce the incidence of recurrent nonfatal pulmonary embolism, but filters are not a standard therapy for pulmonary embolism of the severity that you have.

This is a 5-year, 21-hospital study. Eligible patients are aged 21 years or older with acute pulmonary embolism who are at moderate-risk to very high-risk of death. The study will randomly assign by a computerized flip of the coin 1600 eligible patients to receive a retrievable inferior vena cava filter and 1600 not to receive a filter. All patients will receive anticoagulant therapy for at least 3 months, irrespective of group assignment, because anticoagulants are an important treatment in pulmonary embolism. Those assigned to receive filters will have the filters removed within 2 months of insertion because the risk of recurrent pulmonary embolism usually is lower after 2 months. Outcome will be ascertained at hospital discharge and 1, 3 and 6 months after enrollment.

The aims of this trial are to 1) determine whether retrievable inferior vena cava filters reduce the risk of death or experiencing a new pulmonary embolism; 2) assess the safety of retrievable inferior vena cava filters during filter insertion, while inserted, and during retrieval and assess the balance of risks and benefits of retrievable inferior vena cava filters in patients with acute pulmonary embolism.

If filters reduce mortality and symptomatic recurrent nonfatal pulmonary embolism by only 22% in moderate-risk to very-high risk patients, 5,800 patients yearly would benefit from lower mortality or a lower recurrence rate if filters were used routinely in this group. If not beneficial or if the risks are too high, and the findings lead physicians to refrain from inserting filters in moderate-risk to very-high risk patients, \$196.7 million yearly in filter-related costs would be saved and patients would be spared the complications of unnecessary filter insertion.

How much time your participation will take:
Participants will be carefully examined and asked questions, which may take 20 minutes. If selected for insertion of a vena cava filter, the procedure may take an hour for insertion

Why Consider Literacy?

- Louisiana ranks 49th among states in literacy
- Patients rarely reveal difficulty reading

*Patient education level is
not a good indicator of
literacy level.*

- Adults commonly read 3 to 4 grades below last grade completed in school

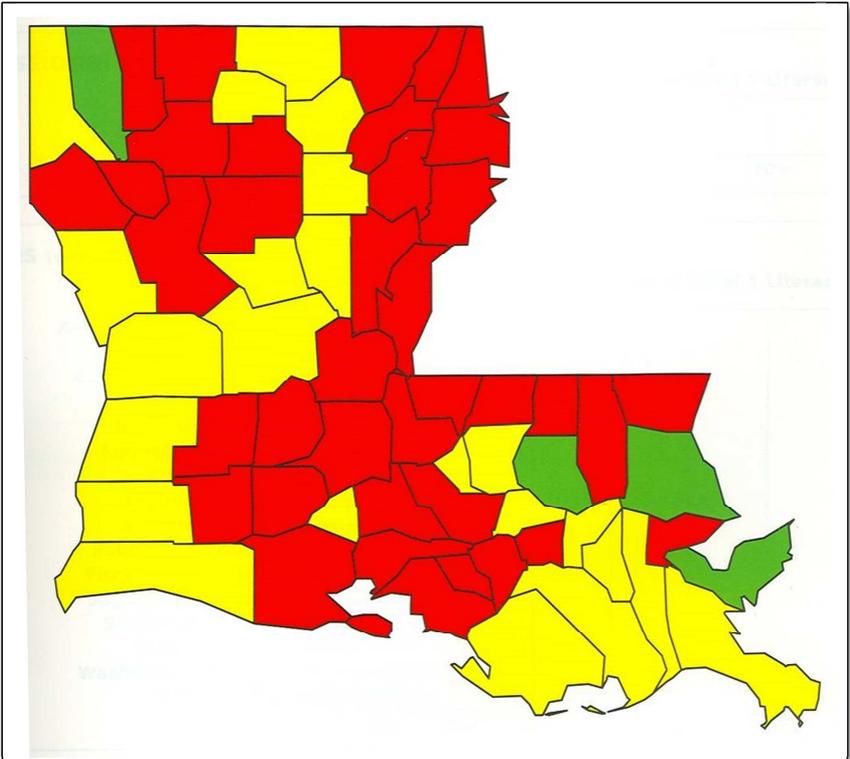
Statistics for adults who read at or below 5th grade level:

- 28% Baton Rouge
- 39% New Orleans
- 28% Shreveport

*Rates are **double** for those with chronic disease, age > 65, low income, and minority groups

*According to the National Assessment of Adult

Literacy Rates by Parish



Percentage of Adults with Level 1 (lowest) Literacy Skills

- | | | | |
|--------------------------------------|------------|---------------------------------------|-----------|
| ■ | > 30% | ■ | 20% - 30% |
| ■ | 15% to 20% | ■ | < 15% |

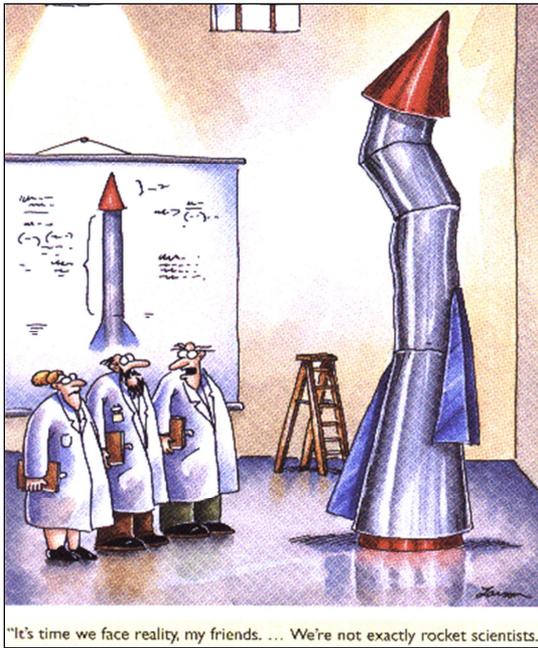
National Household Survey, n = 26,000 adults scored on 5 levels; 1 = lowest

National Institute for Literacy. *The State of Literacy in America: Estimates at the Local, State, and National levels.* Washington, DC: USGPO; 1998

Patients Prefer Simplified Consent Forms

- Patients with high education and income still prefer brief, simple, and easy to read materials.

User-friendly does not mean 'dumbed down.'



Simplifying forms is not rocket science, but harder and more tedious than it seems.

Hidden Problems with Videos & Computer Programs

- Multimedia and computer-based consent have not improved comprehension
- Videos are often too long (limit to 2-4 minutes)
- Too much time with “talking heads”
- Need to show what will happen
- Visuals can be too scientific, complex
- Lack of attention to ‘tone,’ patient emotions
- Private companies developing computer-based consent – will IRBs accept it?

When and where will patients review the video – alone or with educator?

IOM Workshop on Informed Consent, July 28, 2014
The AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research. September 2009, Agency for Healthcare Research and Quality, Rockville, MD. AHRQ Pub. No. 09-0089- EF.
<http://www.ahrq.gov/funding/policies/informedconsent/index.html>

Research on Informed Consent Indicates

- Too much information creates confusion and discourages participation
- Shortened forms may be more likely to be read
- Simplified consent forms improved patient satisfaction but not comprehension
- Consent educator using repetition and teach back has promising results
- Timing is important; people may need a few days to mull it over

Discussion is Key!

IOM Workshop on Informed Consent, July 28, 2014

The AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research. September 2009, Agency for Healthcare Research and Quality, Rockville, MD. AHRQ Pub. No. 09-0089- EF.

<http://www.ahrq.gov/funding/policies/informedconsent/index.html>

“Teach to Goal”: Theory and Design Principles of an Intervention to Improve Heart Failure Self-Management Skills of Patients with Low Health Literacy.

Baker D.W., et al. [Journal of Health Communication](#), Vol. 16, Iss. sup3, 2011

Contact Us Through *LACATS*

Email: Literacy@LACaTS.org

- or -

Visit the Health Literacy Core Website:

<https://lacats.pbrc.edu/key-components/health-literacy-core/>

Give us a Call or Request a Consult.



Terry Davis, Ph.D.
Health Literacy Core Director
LSUHSC Shreveport



Connie Arnold, Ph.D.
Health Literacy Core Co-Director
LSUHSC Shreveport