

[TOOL 3A]

Collected here are a number of tips for drafting simple and clear consent forms and related educational materials. You may want to photocopy this *Style Guide* and place a copy inside each of the separate folders you created for each informed consent form undergoing revision.

These basic recommendations were synthesized based on research studies as well as on the material in excellent public domain guides such as: *Clear & Simple: Developing Effective Print Materials for Low-Literate Readers* from the National Cancer Institute; *Simply Put* from the Centers for Disease Control and Prevention; *Plain Language* from the U.S. federal government.



Use Plain Language

Word choice and sentence length and structure are critical in creating text that is easy to understand. Here are tips to keep in mind while writing:

Words

- Use simple, common words (avoid medical terminology or jargon)
- Pick strong verbs
- Use “you” to address the reader
- Explain technical terms or use the simpler alternative

Examples:

“**Chemotherapy** is the use of drugs to treat cancer”

“**Noninvasive** means without surgery, needles, or cutting skin”

“**arteriovenous fistula** (abnormal opening between any artery and vein)”
“benign (not cancer)”

“**colonoscopy** (internal exam of the bowel using a bendable tube (colonoscope) with an attached camera”

“**hypertension** (high blood pressure)”

- Avoid long words with many syllables
- Avoid unnecessary adjectives
- Avoid legal jargon
- Avoid abbreviations and acronyms if possible
- Use the same words consistently (ie, don’t use a synonym just to avoid repetition, and be careful with use of pronouns)

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Sentences

- Keep sentences short (8 to 10 words is good), direct, and succinct
- Use a conversational tone
- Avoid complex sentence structures (e.g., compound sentences, dependent or embedded clauses, lots of commas)
- Consider breaking into a short list when there are more than 3 points to the sentence
- Use concrete nouns and give clear direction

Don't say:

"Following postsurgical safety precautions can reduce the likelihood of wound infections."

Do say:

"After your surgery:

(1) change your bandage daily,

(2) watch for pus or leakage,

(3) call the doctor if there is any change."

- Use the active voice

Don't say:

"The instrument is inserted by the doctor into the vein"

Do say:

"The doctor inserts the instrument into the vein."

Paragraphs

- Avoid long paragraphs (and dense blocks of text) (3-4 lines or 2-5 sentences is good)
- Start a new paragraph with a new thought

Organize the Flow of Ideas

Present one idea at a time

Rule:

If it does not add information or understanding, delete it.

- Sequence the ideas in the order a patient would want them... or...
- Consider using a standardized sequence of categories for all forms

Example:

The Queensland Government format generally recommends:

A] Interpreter/Cultural Needs

B] Condition and Procedure

C] Anaesthetic

D] General Risks of a Procedure

E] Risks of Procedure

F] Significant Risks and Relevant Treatment Options

G] Patient Consent

H] Interpreter's Statement

I] Doctor's Statement

- Use headings and subheading to "chunk" text together
- Keep these sections short
- Make your heads and subheads work to organize **and** communicate

Don't say:

"Complications of the Surgery."

Do say:

"Infection is the Most Common Complication."

- Use vertical lists to highlight a series of items

[TOOL 3A]

Select a Clear Layout and Design

Type

- Choose a classic and common typeface (e.g., plain serif style like Times New Roman or Garamond are best for print)
- Choose a type size (at least 12 point) that is large enough to read easily
- For visually impaired patients, consider 14 or 16 point text
- Don't use LONG SECTIONS OF ALL CAPITALIZED TEXT LIKE THIS (this can be difficult to read, especially for visually impaired readers)
- Instead, to highlight important points, consider:
 - Changing the **type size**
 - **Using bold face**
 - Underlining
 - Adding a light background screen
- **Don't over-do the use of boldface, though, because this is annoying**
- Use bullets to highlight important points and create lists

White Space and Visual Layout

- Use a lot of white space, around edges and between copy chunks
- Make sure the white space is balanced with words and illustrations
- Use vertical lists to break up text
- Use graphics to break up text
- Use short sections to break up text
- Use shorter rather than longer line lengths (less than 65 characters is best) (FYI, above line is 65 characters exactly)

Figures, Tables, Graphics

- Use visuals like pictures or diagrams when appropriate
- Make sure figures have a heading, description, or caption

Overall

- Standardize the layout throughout the document (e.g., all same typeface, size, similar copy chunking)



[TOOL 3B]

Use this checklist to evaluate the content of new or existing informed consent forms.

Checklist For Assessing the Informed Consent Form

Form: _____
Department/Clinic: _____
Contact: _____
Date of Review: _____

**Does the Informed Consent Form contain the following required element?
(if No, add needed content on line below)**

YES NO

- The name/nature and purpose of a proposed treatment or procedure

- The benefits of proposed treatment or procedures

- The risks of proposed treatment or procedures

- Alternatives (regardless of costs or extent covered by insurance)

- The risks and benefits of alternatives

- The risks and benefits of not receiving treatments or undergoing procedures

[TOOL 3C]

Pretesting informed consent forms with the intended audience is always a good idea. This is especially true when developing forms for low-literacy patients. While checking content accuracy with clinicians is important, and assessing readability with manual or automated formulas may also be helpful, only pre-testing with actual patients will allow you to assess comprehensibility, identify strong and weak points, determine personal relevance, and gauge confusing, sensitive, or controversial elements. In a way, this is just a preliminary and more formal way of doing the “teach back” that is recommended during each patient encounter. You want to hear the patient tell you what they understand...and then work to supplement, correct, or respond as needed. Assembled here are potential methods, tips, and sample questions to help in pretesting of consent forms.

These suggestions are based on information found in public domain guides such as: *Clear & Simple: Developing Effective Print Materials for Low-Literate Readers* and *Pink Book: Making Health Communications Programs Work*, both from the National Cancer Institute. These excellent publications can be accessed at:

<http://www.cancer.gov/aboutnci/oc/clear-and-simple>

<http://www.cancer.gov/pinkbook/page1>

Patient Pretest

For Assessing the Informed Consent Form

Methods to Consider

- Self-administered surveys/questionnaires (by mail, handout, or computer)
- Individual interviews using surveys/questionnaires (by telephone as follow-up to mail; through central location intercepts; other face-to-face scenarios)
- Group interviews (e.g., 8 to 10 people)

For informed consent forms, interviews and focus groups are generally best. For low-literate audiences, partnering with a local adult education group can provide access to volunteers as well as a comfortable venue for testing. The advantage of the individual interview is that respondents are not influenced by others; the group interview may be more difficult to coordinate.

Tips

When to test?

Since most informed consent forms are not typeset or expensively produced, testing a rough draft that is close to the final version is usually possible.

Where to pretest?

Testing the form in the location where it will most often be used is ideal. Thus, the clinic, hospital, or doctor’s office may be best. Since consent forms are sometimes sent home with patients to be discussed later, this type of “take-home” testing with a follow-up interview may also be appropriate.

[TOOL 3C]

How to introduce?

Make sure test participants know that they are not being tested. Reassure them that there are no “right” or “wrong” responses. Since some patients are not comfortable offering criticism or asking questions, distance yourself from the consent form and assure the test participant that you want their honest assessment. Also, since the consent form should always be used in conjunction with some verbal education, develop a brief introductory session during which you explain the baseline scenario to the patient along with some basic medical facts about the condition, the proposed procedure, and their options.

Who to test?

In recruiting patients for testing, try to match the demographics and general health profiles of the patients who will actually use the form. You can also determine the reading level of pretest participants (e.g., with the Wide Range Achievement Test or the Cloze Technique) to ensure that your volunteers read at the same level as your audience.

Who to do the testing?

Choose people for the recruiting and interviewing who are culturally sensitive and who have good social skills. In some cases, it may be helpful to have the writer, medical educator, or clinician who actually writes the consent form to be present during the interviews.

Sample Questions to Ask

- What’s your general reaction to this draft form?
- Is anything confusing?
- What words do you not understand?
- What questions do you have after reading this form?
- What is the procedure/treatment that is described? What does it do?
- What are the benefits of this procedure? What are the risks? The alternatives?
- Do you understand that you can refuse to have this procedure?
- If you were a patient in that position, what would you do. Why? Would you need more information before you decided? What information?

[TOOL 4A]

Many organizations develop their own checklists for patient use during a clinic visit. In addition to the sample checklist suggested here, see the question builder that is part of the “Questions are the Answer” program for patients found at the website for the Agency for Healthcare Research and Quality: <http://www.ahrq.gov/questionsaretheanswer/>

Checklist for Patients

Preparing for the Informed Consent Process

You will soon talk to your doctor or nurse about a certain type of medical care—a surgery, a test, or another type of treatment. Your doctor or nurse wants to make sure that you understand the purpose, benefits, risks, and alternatives of this care. If you decide to go ahead with this type of care, you might be asked to sign an Informed Consent form to confirm that you are fully informed.

At your next visit, you might want to ask:

- What is my **diagnosis**?
- How serious is this diagnosis?
- What method of **treatment** are you recommending?
- Are other treatment **alternatives** available? What are they?
- What are **the benefits** of the recommended and alternative treatments?
- What are **the risks or complications** of the recommended and alternative treatments?
 - How common are they?
 - What are the immediate, medium-term, and long-term side effects?
- Are there other discomforts associated with the treatments?
 - Are these permanent or temporary?
- How long will treatment last?
- How long before I can resume normal activities?
- How much does the treatment cost?
- What methods can be used to relieve the discomforts?

[TOOL 4A]

- What can I do if I am having trouble understanding my condition and my options?
- Write down any other questions you have:

- You should feel free to take notes during your meeting with your doctor or nurse
- You can also bring a spouse, relative, or friend to the meeting so they can listen and gather information too (your doctor or nurse will ask for your permission to allow this other person to become involved in your decisions)
- If surgery is being discussed, also ask about anesthesia, length of procedure, pain control, who will do the operation (and what are their skills), recovery time, and what to do if you are still uncertain about the surgery (e.g., have another visit later, get a second opinion)
- You can refuse any treatment for any reason

[Appendix C] Sample Consent Forms

LABOR/DELIVERY CESAREAN SECTION DELIVERY CONSENT [ORIGINAL]

Labor/Delivery Cesarean Section Delivery Consent

1. I authorize and direct doctor(s) _____ or his/her designee and other physicians as deemed qualified by him/her to perform upon _____ a Cesarean Section delivery of my child:
____ with Anesthesia
____ with other form of sedation: _____
2. If any conditions are revealed during the operation/procedure which were not anticipated, I consent to and authorize the performance of such additional operations/procedures and extensions to the operations/procedures as deemed advisable in the exercise of my physicians professional judgment in order to avoid the risks associated with undergoing a second operation/procedure.
3. Possible risks of Cesarean Section Delivery include, but are not limited to, injury to my bowel, urinary tract, nerves, and/or pelvic floor; bleeding; infection; fetal laceration. There are also risks associated with anesthesia, which have been discussed with me by an anesthesiologist. If the Cesarean Section Delivery requires a vertical incision in my uterus, I understand that any future child I bear must be delivered by way of a Cesarean Section. If I have chosen to deliver my child by Cesarean Section based in whole or in part upon the results of my rapid HIV test, which has not been confirmed by a second test, I understand that if my rapid HIV test was a false positive, a Cesarean Section delivery may not have been necessary.
4. The alternatives to proceeding with a Cesarean Section delivery include: _____.
5. The nature and purpose of the operation/procedure necessary for my treatment has been explained to me. I am aware that the practice of medicine and surgery is not an exact science and no guarantee about outcome can be made. I have been informed of the medically significant risks and consequences associated with the operation/procedure stated above. I have also been informed of any reasonable alternative courses of treatment and the risks and consequences of these alternative courses of treatment. I have also been informed of the risks and consequences of no treatment is rendered.
6. I understand that there are general risks associated with and surgical or invasive procedure and these risks, which may include infection, bleeding, injury to surrounding structures, stroke, paralysis, and death, have also been explained to me.

[Appendix C] Sample Consent Forms

LABOR/DELIVERY CESAREAN SECTION DELIVERY CONSENT continued [ORIGINAL]

7. I authorize _____ to preserve and use, for any purpose it deems appropriate, and to dispose of in accordance with customary medical practice, any tissue, organs or other body parts removed during the operation/procedure, unless otherwise stated. I disclaim any ownership I may have in such tissue, organ, or other body part once removed.
8. I consent to the taking of photographs for the purpose of medical study or research and the initial reproduction or publication of these photographs in any manner, providing my identity is not revealed. For the purpose of advancing medical education, I also consent to the admittance of observers, technical representatives and participants in the operating room, and understand that I may be subject to a physical examination conducted for educational purposes.
9. **Consent for Administration of Blood and Blood Products:** I understand that during the operation/procedure or other treatments and for the immediate post-operative period (generally not to exceed one week), it may be advisable to administer blood or blood products to me. I am aware that there are certain risks involved in the administration of blood and blood products including, but not limited to: blood reaction with fever, chills, and breathing difficulties; contracting of blood-transmitted diseases which are not capable of detection by the testing of blood before it is administered. I acknowledge that the risks of accepting blood and blood products have been fully explained to me. I consent to the administration of blood or blood products as deemed advisable in my physician's professional judgment.

[Appendix C] Sample Consent Forms

LABOR/DELIVERY CESAREAN SECTION DELIVERY CONSENT [SUGGESTED REVISION 1]

Cesarean Section Delivery Consent

Patient Name: _____

Print patient name
at top of form

A Cesarean Section is surgery to deliver your baby. The baby is removed through a cut in your lower abdomen.

Box in and
highlight
important
information

I approve and direct Dr. _____, other doctors or others judged qualified by him or her (including residents or fellows) to perform a Cesarean Section delivery of my child(ren):

___ with anesthesia (pain medicine that will keep you from feeling anything)

___ with other sedation (medicines used to make you calm, drowsy, or fall asleep)

Define
complex terms

My doctor may need to do other procedures during the Cesarean Section. This could happen if he or she finds an unexpected condition. If my doctor feels it's needed, I agree to these added procedures. These would be done to avoid the risks of having a second surgery or procedure.

Reduced
density of text

Increased
white space

Cesarean Section Risks

Create sub-headings
and separate

I understand there are risks to a Cesarean Section.

These risks include but are not limited to:

- injury to my bowel, urinary tract, nerves, or pelvic floor
- bleeding
- infection and
- injury to the baby

Bulleted list
of risks

If the doctor makes a vertical cut in my uterus during surgery, I understand that I must have any future child by Cesarean Section.

Anesthesia also has risks. The anesthesiologist (doctor who gives pain medicine) explained these risks to me.

[Appendix C] Sample Consent Forms

LABOR/DELIVERY CESAREAN SECTION DELIVERY CONSENT continued [SUGGESTED REVISION 1]

HIV Risks ← **Sub-heading**

If you are infected with HIV, you could pass this on to your baby during a vaginal delivery. Having a Cesarean Section is one way to lower the chance of passing the infection on to your baby. For this reason, if you have not had an HIV test, you may be given a rapid HIV test before your Cesarean Section. ← **Box in and highlight important information**

I understand the results of rapid HIV tests can be false. These results need to be confirmed by a second test. I may decide to have a Cesarean Section based on the positive result of a rapid test. I know that if it turns out my rapid HIV test was a false positive, a Cesarean Section may not have been necessary. ← **Define complex terms**

General Risks ← **Sub-heading**

I understand there are general risks with surgery or invasive procedures. These risks are:

- infection
- bleeding
- injury to surrounding structures
- stroke
- paralysis
- death

← **Bulleted list**

These risks have been explained to me.

Other Options to Cesarean Section ← **Sub-heading**

The other options to a Cesarean Section delivery are: _____.

Consent for Surgery ← **Sub-heading**

The purpose of this surgery has been explained to me. I know the practice of medicine and surgery is not an exact science. I know that no guarantee can be made about the outcome. I have been told about the medical risks and results related to the surgery. I have also been told of any reasonable alternative treatments and the risks and results of these treatments. I have also been told of the risks and results of no treatment.

Consent for use of tissue, organs, and body parts ← **Sub-heading**

Unless I say otherwise, I allow _____ to save and use any tissue, organs or other body parts removed during the Cesarean Section or other procedures. They may dispose of these by standard medical practice. I give up any claim I may have in this tissue, organ, or other body part once removed.

[Appendix C] Sample Consent Forms

LABOR/DELIVERY CESAREAN SECTION DELIVERY CONSENT continued [SUGGESTED REVISION 1]

Consent to take part in medical research, study or education related to my care

I consent to having pictures taken for medical study or research. I agree to the first copying or publication of these pictures, as long as my identity is kept secret. _____ is a teaching hospital. To advance medical education, I also agree to allow observers, technical representatives and participants in the operating room. I also understand that I may have a physical exam for educational reasons.

Sub-heading

Consent for administration of blood and blood products

I understand that I might need blood or blood products during the Cesarean Section, procedure, or other treatments. I may also need it in the period of time after surgery. This period is not usually longer than a week. I know there are certain risks to receiving blood and blood products.

Sub-heading

These risks include:

- blood reaction with fever, chills, and breathing problems.
- a blood-transmitted disease that can't be found by testing blood before it is given.

There may be other risks. I understand the risks of accepting blood and blood products. I consent to receive blood or blood products as believed needed in my doctor's opinion.

Interpreter and Translation Services Statement

If English is not my first language, an interpreter and or translation services were offered and provided to me during the informed consent process:

yes no N/A

Required Statement

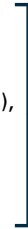
[Appendix C] Sample Consent Forms

LABOR/DELIVERY CESAREAN SECTION DELIVERY CONSENT continued [SUGGESTED REVISION 1]

Signatures

My signature below means that:

- I have read and understand this consent form.
- I have been given all the information I asked for about the procedure(s), risks, and other options.
- All my questions were answered.
- I agree to everything explained above.



Bulleled list

Patient's Signature: _____

Date signed: _____

Doctor's Signature: _____

Date signed: _____

Witness: _____

Date signed: _____

If the patient is not able to consent for herself, complete the following:

Patient _____ is not able to consent because:

Legally responsible person: _____

Relationship to patient: _____

Date signed: _____

If an interpreter was used:

Signature of interpreter: _____

Date of service: _____


[Appendix C] Sample Consent Forms

LABOR/DELIVERY CESAREAN SECTION DELIVERY CONSENT [SUGGESTED REVISION 2]

IMPORTANT!	Cesarean Section Delivery Consent
Your name goes here	Patient Name: _____
Your procedure is explained here	A Cesarean Section is surgery to deliver your baby. The baby is removed through a cut in your lower abdomen.
Types of medicines given are here	I approve and direct Dr. _____, other doctors or others judged qualified by him or her (including residents or fellows) to perform a Cesarean Section delivery of my child(ren): ____ with anesthesia (pain medicine that will keep you from feeling anything) ____ with other sedation (medicines used to make you calm, drowsy, or fall asleep)
Risks are explained here	My doctor may need to do other procedures during the Cesarean Section. This could happen if he or she finds an unexpected condition. If my doctor feels it's needed, I agree to these added procedures. These would be done to avoid the risks of having a second surgery or procedure. Cesarean Section Risks I understand there are risks to a Cesarean Section. These risks include but are not limited to: <ul style="list-style-type: none">• injury to my bowel, urinary tract, nerves, or pelvic floor• bleeding• infection and• injury to the baby
... and here	If the doctor makes a vertical cut in my uterus during surgery, I understand that I must have any future child by Cesarean Section. Anesthesia also has risks. The anesthesiologist (doctor who gives pain medicine) explained these risks to me.
Questions so far?	STOP! Do you have a question? Please ask or write your question below. _____ Please initial after reading this page _____

[Appendix C] Sample Consent Forms

LABOR/DELIVERY CESAREAN SECTION DELIVERY CONSENT continued [SUGGESTED REVISION 2]

IMPORTANT! More consents  ... and other risks Do you need a translator? Questions?	Consent for use of tissue, organs, and body parts Unless I say otherwise, I allow _____ to save and use any tissue, organs or other body parts removed during the Cesarean Section or other procedures. They may dispose of these by standard medical practice. I give up any claim I may have in this tissue, organ, or other body part once removed. I consent to take part in medical research, study or education related to my care. I consent to having pictures taken for medical study or research. I agree to the first copying or publication of these pictures, as long as my identity is kept secret. _____ is a teaching hospital. To advance medical education, I also agree to allow observers, technical representatives and participants in the operating room. I also understand that I may have a physical exam for educational reasons.
	Consent for administration of blood and blood products I understand that I might need blood or blood products during the Cesarean Section, procedure, or other treatments. I may also need it in the period of time after surgery. This period is not usually longer than a week. I know there are certain risks to receiving blood and blood products. These risks include: • blood reaction with fever, chills, and breathing problems. • a blood-transmitted disease that can't be found by testing blood before it is given. There may be other risks. I understand the risks of accepting blood and blood products. I consent to receive blood or blood products as believed needed in my doctor's opinion.
	Interpreter and Translation Services Statement If English is not my first language, an interpreter and or translation services were offered and provided to me during the informed consent process: <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A
	STOP! Do you have a question? Please ask or write your question below. _____

Please initial after reading this page _____

[Appendix C] Sample Consent Forms

CONSENT TO OPERATION AND/OR DIAGNOSTIC PROCEDURES, TRANFUSIONS AND RENDERING OF OTHER MEDICAL PROCEDURES [ORIGINAL]

Consent to Operation and/or Diagnostic Procedures, Tranfusions and Rendering of Other Medical Procedures

1. I authorize and direct doctor(s) _____ or his/her designee and other physicians or dentists as deemed qualified by him/her to perform upon _____ an operation/procedure _____.

____ without sedation

____ with minimal sedation

____ with moderate/conscious sedation

____ with deep sedation

____ with anesthesia

The risks, benefits, alternatives and complications have been explained and questions answered. I, the patient or authorized representative have accepted the plan for sedation.

2. If any conditions are revealed during the operation/procedure which were not anticipated, I consent to and authorize the performance of such additional operations/procedures and extensions to the operations/procedures as deemed advisable in the exercise of my physician's professional judgment in order to avoid the risks associated with undergoing a second operation/procedure.

3. The nature and purpose of the operation/procedure necessary for my treatment has been explained to me. I am aware that the practice of medicine, surgery, and dentistry is not an exact science and no guarantee about an outcome can be made. I have been informed of the medically significant risks and consequences including:

_____ and the benefits

including: _____. I have also been informed of any reasonable alternative courses of treatment and the risks and consequences of these alternative courses of treatment. These include, but are not limited to:

_____. I have also been informed of the risks and consequences if no treatment is rendered: _____.

4. I understand that there are general risks associated with and surgical or invasive procedure and these risks, which may include infection, bleeding, injury to surrounding structures, stroke, paralysis, and death, have also been explained to me.

[Appendix C] Sample Consent Forms

CONSENT TO OPERATION AND/OR DIAGNOSTIC PROCEDURES, TRANSFUSIONS AND RENDERING OF OTHER MEDICAL PROCEDURES continued [ORIGINAL]

5. I authorize _____ to preserve and use, for any purpose it deems appropriate, and to dispose of in accordance with customary medical practice, any tissue, organs or other body parts removed during the operation/procedure, unless otherwise stated. I disclaim any ownership I may have in such tissue, organ, or other body part once removed.
6. I consent to the taking of photographs for the purpose of medical study or research and the initial reproduction or publication of these photographs in any manner, providing my identity is not revealed. For the purpose of advancing medical education, I also consent to the admittance of observers, technical representatives and participants in the operating room, and understand that I may be subject to a physical examination conducted for educational purposes.
7. Consent for Administration of Blood and Blood Products: I understand that during the operation/procedure or other treatments and for the immediate post-operative period (generally not to exceed one week), it may be advisable to administer blood or blood products to me. I am aware that there are certain risks involved in the administration of blood and blood products including, but not limited to: blood reaction with fever, chills, and breathing difficulties; contracting of blood-transmitted diseases which are not capable of detection by the testing of blood before it is administered. I acknowledge that the risks of accepting blood and blood products have been fully explained to me. I consent to the administration of blood or blood products as deemed advisable in my physician's professional judgment.
8. I acknowledge that the information provided above has been satisfactorily explained to me and that I fully understand each provision. I further acknowledge that I have been given an opportunity to ask questions that I might have concerning the operation/procedure and associated risks, as well as any alternative courses of treatment and associated risks. Further, I certify that I have been provided all information that I have requested.

I have read and understand this Consent to Operation/Transfusion and hereby

GIVE MY CONSENT AND AUTHORIZATION
TO PERFORM THE OPERATIONS/PROCEDURES.

[Appendix C] Sample Consent Forms

CONSENT TO OPERATION AND/OR DIAGNOSTIC PROCEDURES, TRANSFUSIONS AND RENDERING OF OTHER MEDICAL PROCEDURES [SUGGESTED REVISION 1]

Consent to Surgery, Diagnostic Procedures, Transfusions or Other Medical Procedures

Patient Name: _____

Print patient name at top of form

I approve and direct Dr.(s) _____ or other doctors or dentists judged qualified by him or her to perform a _____.

Sedation and Anesthesia

Create sub-headings and separate

This procedure will be done with:

___ no sedation (medicines used to make you calm, drowsy, or fall asleep)

Define complex terms

___ a small amount of sedation

___ moderate or conscious sedation

___ deep sedation

___ anesthesia (pain medicine that will keep you from feeling anything)

Define complex terms

The risks, benefits, alternatives and complications of sedation have been explained and my questions answered. I, the patient, or someone representing me, has approved the plan for sedation.

My doctor may need to do other procedures during this surgery or procedure. This could happen if he or she finds an unexpected condition. If my doctor feels it's needed, I agree to these added procedures. These would be done to avoid the risks of having a second surgery or procedure.

I understand the purpose of the surgery or procedure needed for my treatment. I know the practice of medicine, surgery, and dentistry is not an exact science. I know that no guarantee can be made about the outcome.

Reduced density of text

Increased white space

[Appendix C] Sample Consent Forms

**CONSENT TO OPERATION AND/OR DIAGNOSTIC PROCEDURES, TRANFUSIONS AND
RENDERING OF OTHER MEDICAL PROCEDURES continued [SUGGESTED REVISION 1]**

Risks ← Sub-heading

I understand the medical risks and results including:

I also understand there are general risks with surgery or invasive procedures.
These risks are:

- infection
- bleeding
- injury to surrounding structures
- stroke
- paralysis
- death

← Bulleted list

These risks have been explained to me.

Benefits ← Sub-heading

I also know the benefits including: _____.

Other Options ← Sub-heading

I have been told of any reasonable other treatment choices. I know the risks and results of these other choices. These include, but are not limited to:

_____.

I have also been told of the risks and results of having no treatment:

_____.

Consent for Use of Tissue, Organs, and Body Parts ← Sub-heading

Unless I say otherwise, I allow _____ to save and use any tissue, organs or other body parts removed during the surgery or other procedures. They may dispose of these by standard medical practice. I give up any claim I may have to this tissue, organ, or other body part once removed.

[Appendix C] Sample Consent Forms

CONSENT TO OPERATION AND/OR DIAGNOSTIC PROCEDURES, TRANFUSIONS AND RENDERING OF OTHER MEDICAL PROCEDURES [SUGGESTED REVISION 1]

Consent to take part in medical research, study or education related to my care

I agree to have pictures taken for medical study or research. I agree to the first copying or publication of these pictures, as long as my identity is kept secret. _____ is a teaching hospital. To advance medical education, I also agree to allow observers, technical representatives and participants in the operating room. I also understand that I may have a physical exam for educational reasons.

Sub-heading

Consent for Administration of Blood and Blood Products

I understand that I might need blood or blood products during the surgery, procedure, or other treatments. I may also need it in the period of time after surgery. This period is not usually longer than a week. I know there are certain risks to receiving blood and blood products.

Sub-heading

These risks include:

- blood reaction with fever, chills, and breathing problems
- a blood-transmitted disease that can't be found by testing blood before it is given.

Bulleted list of risks

There may be other risks. I understand the risks of accepting blood and blood products. I consent to receive blood or blood products as believed needed in my doctor's opinion.

Interpreter and Translation Services Statement

If English is not my first language, an interpreter and or translation services were offered and provided to me:

yes no N/A

Required Statement

Before you sign....let's make sure you understand everything

To make sure we have explained this well, please answer these questions:

1. The procedure I am having is called a _____.
2. Sedation or anesthesia might be used. Sedation is _____ to make me feel calm, drowsy or _____.
3. I know there are always _____ to general surgery and other procedures. One of these is _____.
4. Along with risks, there are also _____ to this procedure. These are _____.
5. I am agreeing to have my _____ taken for medical research or study.

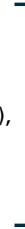
[Appendix C] Sample Consent Forms

**CONSENT TO OPERATION AND/OR DIAGNOSTIC PROCEDURES, TRANFUSIONS AND
RENDERING OF OTHER MEDICAL PROCEDURES continued [SUGGESTED REVISION 1]**

Signatures

My signature below means that:

- I have read and understand this consent form.
- I have been given all the information I asked for about the procedure(s), risks, and alternatives.
- All my questions were answered.
- I agree to everything explained above.



← **Bulleted list**

Patient's Signature: _____

Date signed: _____

Doctor's Signature: _____

Date signed: _____

Witness: _____

Date signed: _____

If the patient is not able to consent for herself, complete the following:

Patient _____ is not able to consent because:

Legally responsible person: _____

Relationship to patient: _____

Date signed: _____

If an interpreter was used:

Signature of interpreter: _____

Date of service: _____

[Appendix C] Sample Consent Forms


**CONSENT TO OPERATION AND/OR DIAGNOSTIC PROCEDURES, TRANFUSIONS AND
RENDERING OF OTHER MEDICAL PROCEDURES continued [SUGGESTED REVISION 2]**

<p>IMPORTANT!</p> <p>Risks are explained here</p>	<p>Risks</p> <p>I understand the medical risks and results including:</p> <p>_____</p> <p>I also understand there are general risks with surgery or invasive procedures. These risks are:</p> <ul style="list-style-type: none"> • infection • bleeding • injury to surrounding structures • stroke • paralysis • death <p>These risks have been explained to me.</p>
<p>Benefits are listed here</p>	<p>Benefits</p> <p>I also know the benefits including: _____.</p>
<p>Other options are given here</p>	<p>Other Options</p> <p>I have been told of any reasonable other treatment choices. I know the risks and results of these other choices. These include, but are not limited to:</p> <p>_____.</p> <p>I have also been told of the risks and results of having no treatment:</p> <p>_____.</p>
<p>Consents begin here</p>	<p>Consent for Use of Tissue, Organs, and Body Parts</p> <p>Unless I say otherwise, I allow _____ to save and use any tissue, organs or other body parts removed during the surgery or other procedures. They may dispose of these by standard medical practice. I give up any claim I may have to this tissue, organ, or other body part once removed.</p>
<p style="text-align: center;">↓</p> <p>Questions?</p>	<p>STOP!</p> <p>Do you have a question? Please ask or write your question below.</p> <p>_____</p>

Please initial after reading this page _____

[Appendix C] Sample Consent Forms

CONSENT TO OPERATION AND/OR DIAGNOSTIC PROCEDURES, TRANSFUSIONS AND RENDERING OF OTHER MEDICAL PROCEDURES [SUGGESTED REVISION 2]

<p>IMPORTANT!</p> <p>More consents</p>  <p>Do you need a translator?</p> <p>Questions?</p>	<p>Consent to take part in medical research, study or education related to my care</p> <p>I agree to have pictures taken for medical study or research. I agree to the first copying or publication of these pictures, as long as my identity is kept secret. _____ is a teaching hospital. To advance medical education, I also agree to allow observers, technical representatives and participants in the operating room. I also understand that I may have a physical exam for educational reasons.</p> <p>Consent for Administration of Blood and Blood Products</p> <p>I understand that I might need blood or blood products during the surgery, procedure, or other treatments. I may also need it in the period of time after surgery. This period is not usually longer than a week. I know there are certain risks to receiving blood and blood products.</p> <p>These risks include:</p> <ul style="list-style-type: none">• blood reaction with fever, chills, and breathing problems• a blood-transmitted disease that can't be found by testing blood before it is given. <p>There may be other risks. I understand the risks of accepting blood and blood products. I consent to receive blood or blood products as believed needed in my doctor's opinion.</p> <p>Interpreter and Translation Services Statement</p> <p>If English is not my first language, an interpreter and or translation services were offered and provided to me:</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A</p> <p>STOP! Do you have a question? Please ask or write your question below.</p> <p>_____</p> <p style="text-align: right;">Please initial after reading this page _____</p>
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[Appendix C] Sample Consent Forms

**CONSENT TO OPERATION AND/OR DIAGNOSTIC PROCEDURES, TRANFUSIONS AND
RENDERING OF OTHER MEDICAL PROCEDURES continued [SUGGESTED REVISION 2]**

IMPORTANT!	<p>Before you sign....let's make sure you understand everything</p> <p>To make sure we have explained this well, please answer these questions:</p> <ol style="list-style-type: none"> 1. The procedure I am having is called a _____. 2. Sedation or anesthesia might be used. Sedation is _____, drowsy or _____. 3. I know there are always _____ to general surgery and other procedures. One of these is _____. 4. Along with risks, there are also _____ to this procedure. These are _____. 5. I am agreeing to have my _____ taken for medical research or study.
Did we do a good job?	
Are you ready to sign this consent form?	<p>Signatures</p> <p>My signature below means that:</p> <ul style="list-style-type: none"> • I have read and understand this consent form. • I have been given all the information I asked for about the procedure(s), risks, and other options. • All my questions were answered. • I agree to everything explained above.
You sign here	<p>Patient's Signature: _____</p> <p>Date signed: _____</p>
Your doctor signs here	<p>Doctor's Signature: _____</p> <p>Date signed: _____</p>
A witness signs here	<p>Witness: _____</p> <p>Date signed: _____</p>
Someone who represents the patient may need to sign here	<p>If the patient is not able to consent for herself, complete the following:</p> <p>Patient _____ is not able to consent because:</p> <p>Legally responsible person: _____</p> <p>Relationship to patient: _____</p> <p>Date signed: _____</p>
Did you use a translator? They sign here	<p>If an interpreter was used:</p> <p>Signature of interpreter: _____</p> <p>Date of service: _____</p>

Notes

A series of horizontal dashed lines for taking notes.

**STYLE
GUIDE** | *For Improving
the Informed
Consent Form*

Temple University Health System

Fox Chase Cancer Center

Hablamos Juntos at the University of California San Francisco,
Fresno Center for Medical & Education Research

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