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 (i.e., don’t use a synonym just to avoid repetition, and be careful with use of pronouns)
[TOOL 3A]

**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.”

**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 subheadings 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
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)
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 3B]

Checklist For Assessing the Informed Consent Form
continued

Does the Form contain details (or space for) the following content:

YES NO

☐ ☐ Name and signature of the patient, or if appropriate, legal guardian;
☐ ☐ Name of the hospital;
☐ ☐ Name of all practitioners performing the procedure and individual significant task if more than one practitioner;
☐ ☐ Date and time consent is obtained;
☐ ☐ Statement that procedure was explained to patient or guardian;
☐ ☐ Space to document that patient is unable to speak English;
☐ ☐ Space for documentation of interpretive services (on site, telephonic, video) and/or of sight translation of form;
☐ ☐ Signature of professional person witnessing the consent; and
☐ ☐ Name and signature of person who explained the procedure to the patient or guardian.

Other comments, questions, or suggestions you have about this Form:
______________________________________________________________________________________
______________________________________________________________________________________
______________________________________________________________________________________
______________________________________________________________________________________
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______________________________________________________________________________________
______________________________________________________________________________________
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/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.
**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?
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
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.
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.
**LABOR/DELIVERY CESAREAN SECTION DELIVERY CONSENT [SUGGESTED REVISION 1]**

Cesarean Section Delivery Consent

| Print patient name at top of form | Box in and highlight important information | Define complex terms | Create sub-headings and separate | Bulleted list of risks |

Patient Name: ________________________________

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

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)

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:

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

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

HIV Risks
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.

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.

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

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

These risks have been explained to me.

Other Options to Cesarean Section
The other options to a Cesarean Section delivery are:______________________________.

Consent for Surgery
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
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.
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:
☐ yes ☐ no ☐ N/A
### 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.

<table>
<thead>
<tr>
<th>Role</th>
<th>Signature</th>
<th>Date signed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s Signature</td>
<td>__________________________</td>
<td>____________</td>
</tr>
<tr>
<td>Date signed</td>
<td>__________________________</td>
<td>____________</td>
</tr>
<tr>
<td>Doctor’s Signature</td>
<td>__________________________</td>
<td>____________</td>
</tr>
<tr>
<td>Date signed</td>
<td>__________________________</td>
<td>____________</td>
</tr>
<tr>
<td>Witness</td>
<td>__________________________</td>
<td>____________</td>
</tr>
<tr>
<td>Date signed</td>
<td>__________________________</td>
<td>____________</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Role</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient ___________________</td>
<td>is not able to consent because:</td>
</tr>
<tr>
<td>Legally responsible person</td>
<td>__________________________</td>
</tr>
<tr>
<td>Relationship to patient</td>
<td>__________________________</td>
</tr>
<tr>
<td>Date signed</td>
<td>__________________________</td>
</tr>
</tbody>
</table>

If an interpreter was used:

<table>
<thead>
<tr>
<th>Role</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature of interpreter</td>
<td>__________________________</td>
</tr>
<tr>
<td>Date of service</td>
<td>__________________________</td>
</tr>
</tbody>
</table>
Cesarean Section Delivery Consent

Patient Name: _____________________________________________

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

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)

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:

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

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.

STOP!
Do you have a question? Please ask or write your question below.

Please initial after reading this page______
HIV Risks
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.

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.

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

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

These risks have been explained to me.

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

Other Options to Cesarean Section
The alternatives to a Cesarean Section delivery are:____________________.

Consent for Surgery
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.

STOP!
Do you have a question? Please ask or write your question below.
[Appendix C] Sample Consent Forms

CONSENT FOR USE OF TISSUE, ORGANS, AND BODY PARTS

Unless I say otherwise, I allow [insert name] 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. [insert name] 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:

☐ Yes ☐ No ☐ N/A

STOP!
Do you have a question? Please ask or write your question below.

Please initial after reading this page
LABOR/DELIVERY CESAREAN SECTION DELIVERY CONSENT continued [SUGGESTED REVISION 2]

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

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

1. The surgery to remove my baby is called a ________________.
2. Anesthesia is _______ _________ used to keep me from feeling anything.
3. There are risks to this surgery. One of the risks is _________.
4. Having a Cesarean Section can lower the risk of passing ____________ infection to a baby.
5. I agreed to allow _______ Hospital to keep any _________, organs, or body parts taken out during my surgery.

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.

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

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

Patient Name: _____________________________________________

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

Sedation and Anesthesia

This procedure will be done with:

___ no sedation (medicines used to make you calm, drowsy, or fall asleep)
___ a small amount of sedation
___ moderate or conscious sedation
___ deep sedation
___ anesthesia (pain medicine that will keep you from feeling anything)

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.
[Appendix C] Sample Consent Forms

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

Risks
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

These risks have been explained to me.

Benefits
I also know the benefits including: ________________________________.

Other Options
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
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.
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.

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.

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:

[ ] yes  [ ] no  [ ] N/A

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.
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.

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

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

Patient Name: _____________________________________________

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

Sedation and Anesthesia

This procedure will be done with:

- [ ] no sedation (medicines used to make you calm, drowsy, or fall asleep)
- [ ] a small amount of sedation
- [ ] moderate or conscious sedation
- [ ] deep sedation
- [ ] anesthesia (pain medicine that will keep you from feeling anything)

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.

STOP!
Do you have a question? Please ask or write your question below.

____________________________________________________

Please initial after reading this page________
CONSENT TO OPERATION AND/OR DIAGNOSTIC PROCEDURES, TRANFUSIONS AND RENDERING OF OTHER MEDICAL PROCEDURES continued [SUGGESTED REVISION 2]

**Risks**
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

These risks have been explained to me.

**Benefits**
I also know the benefits including: ________________________________.

**Other Options**
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**
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.

**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 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.

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.

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:

☐ yes  ☐ no  ☐ N/A

STOP!
Do you have a question? Please ask or write your question below.
[Appendix C] Sample Consent Forms

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

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 ____________________,
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.

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.

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: _____________________________________________

A Practical Guide to Informed Consent: Providing Simple and Effective Disclosure in Everyday Clinical Practice
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