A Practical Guide to Informed Consent

With Tools for Providing Simple and Effective Informed Consent in Everyday Clinical Practice

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What is Informed Consent?

Informed consent is the process of communication between a patient and physician that results in the patient’s authorization or agreement to undergo a specific medical intervention [AMA 1998]. For both ethical and legal reasons, patients must be given enough information to be fully informed before deciding to undergo a major treatment, and this informed consent must be documented in writing.

Although this process of patient-physician communication involves much more than getting a patient to sign a written consent form (See Sidebar: “Informed Consent: It’s Not About the Form”), it is the very formality and finality of that signed document that for practical purposes distinguishes full informed consent from the routine patient education that occurs in nearly every clinical encounter. In most institutions, this more formal process requiring a signature is reserved for surgery, anesthesia, and other invasive or complex medical or radiologic procedures. Laws vary from state to state about exactly when and how formal informed consent must be provided, but national standards exist as well.

Note that formal informed consent is usually not required for more common and generally less risky treatments, tests, and medications. The patient’s consent to these more common interactions and therapies is generally “implied.”

Goal of this Guide

The goal of this publication is to help all those involved in the informed consent process as it occurs in everyday clinical practice (i.e., not in the research setting) in order to improve the patient-physician communication that is so crucial in creating truly informed patient decision-making about major treatment options.

Who Should Read this Guide

- Doctors
- Surgeons
- Nurses
- Health Educators
- Pharmacists
- Administrative staff
- Technicians/Specialists
- Risk Managers
- General Legal Counsels/Attorneys
- Interpreters
- Translators
- Patient Advocates Quality/Accreditation Managers

Anybody who requests / develops / writes / reviews / uses Informed Consent forms

And for some very basic procedures—like a whole blood draw—a “basic consent” process involving a simple description and request for verbal approval may be adequate. On the other end of the extreme, the informed consent process for patients volunteering for clinical research is much more complex, involving special Institutional Review Boards and close monitoring. [CFR Title 45 1991]
Why This Guide?
This publication focuses on ways to improve informed consent—both the process and the written forms—as it is employed in everyday (i.e., NOT research) patient care settings. We understand that there are many challenges to the informed consent process in every day practice and we hope this guide can improve the dialogue among various professionals who have the responsibility to improve patients’ understanding of the complexities of their care. We see this guide as a place to start and a mechanism to improve this important dialogue. As you and your organization work to improve your consent process, it is important to ensure that your health care organization remains within both the spirit and the letter of your state laws and institutional policies related to informed consent. We encourage all those setting out to improve their informed consent practices to work closely with their own legal counsels and risk managers.

Informed Consent: “It’s Not About the Form”

Lance Armstrong, the bicyclist who won 7 consecutive Tour de France races, wrote a book called “It’s Not About the Bike.” Just as Mr. Armstrong argues so compellingly that world-class cycling requires much more than a good bike, high-quality informed consent requires much more than a piece of paper to sign. The form (like the bike) is obviously needed, but much more is involved. This publication challenges readers to consider all those other components that contribute to adequate informed consent—including the planning and the process for delivering and then ensuring that the key messages have been truly received and understood. The written form can definitely be tuned up—and we offer specific tips for that—but informed consent is actually a whole mindset and process that needs to be continuously examined and improved as a whole. It’s not about the form!
Why Do We Need to Improve It?

Unfortunately, even after signing a consent form, many patients still do not understand basic information about the risks, benefits and alternatives of their proposed treatment options. There are many potential reasons for this failure of truly informed consent and the ongoing lack of understanding. Patient factors may include low health literacy, limited English proficiency, cognitive impairments, learning disabilities, hearing or vision impairments, confusion about the purpose of the consent process, a feeling of intimidation, and stress or time pressure. In addition to the acknowledged low rates of health literacy and English proficiency seen in an increasingly diverse American society (See Sidebar: “Informed Consent: What Did the Doctor Say?”), the other less well documented human factors that may negatively influence the patient’s comprehension of medical information include memory, education level, and also the timing of the informed consent session. On the provider side, the factors may include lack of time for up-front patient education, overly complex or overly broad written materials, lack of support with interpreters, and wrong assumptions about patient comprehension.

Whatever the reason, the consequences of a lack of truly informed consent can be serious. Beyond the fundamental breach of the ethical and legal duties to inform the patient, there is also the increased potential for medical errors and malpractice claims. For example, recent discussions of consent-related legal problems have stemmed from situations such as:

- A doctor who felt the patient “really needed” the catheterization procedure to avoid a heart attack and so may not have fully explained the procedural risks or emphasized that the patient had a right to refuse;

- A woman with limited English proficiency who refused surgery, scared that she had not given her doctor a complete medical history because her husband was interpreting for her;

- A patient with complications following cosmetic surgery who claims she was never told about the potential side effects in her numerous initial discussions with nurses and doctors—and who says that she signed the informed consent form describing the full risks only when she was on her way to surgery and too medicated to comprehend;

- A young agricultural worker who speaks only Vietnamese and was so intimidated by authority figures in the hospital that he felt he must sign the poorly translated informed consent form agreeing to an invasive diagnostic test in order to get access to pain relief for his emergency condition.
How Can This Guide Help You?

This publication is meant to assist those interested in developing consistently high-quality policies, processes, and written forms that are suitable for informed consent in everyday clinical practice. It is intended not only for the clinician who has the central role in the informed consent process but also for the many other healthcare team members who share this responsibility to ensure that patients truly understand any procedure they are considering. This team includes the full clinical staff (e.g., nurses, nurse specialists, technicians, pharmacists), administrative and clinical leadership, risk managers, legal counsel, health educators, and interpreters.

As with any proposal for change in institutional or personal practices, there may be reluctance to alter established informed consent policies preferring to rely on the status quo. For that reason, any movement for improved informed consent will likely require an internal advocate for change—one person or one team who accepts the responsibility for initiating and achieving change. This Guide is especially intended for that person or team. Throughout this Guide we provide ammunition for this

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Informed Consent: “What Did the Doctor Say?”

This question is the title of a 2007 publication from the Joint Commission on improving health literacy to protect patient safety. [Joint Commission 2007] Many of the facts cited by the Joint Commission also support the need for improved informed consent. For example:

“Approximately 21 million people in the U.S. speak English ‘less than very well.’”

“...substantially higher rates of blacks, Hispanics, and Asians reported having ‘communication problems with their physicians’ than did white patients.”

“One study of health literacy in relation to colorectal cancer screening found that many participants with low health literacy did not know the meaning of commonly used terms, such as ‘polyp,’ ‘tumor,’ ‘lesion,’ or ‘blood in the stool.’ None of the participants knew what the colon or bowel was nor where it was located.”

“...it is estimated that 75 percent of people with chronic physical or mental illness have limited health literacy skills.”

“In the Joint Commission’s sentinel event database, 65 percent of the identified adverse events have been found to have communication failures as the underlying root cause.”

“...among patients who sign an informed consent form, 44 percent do not know the exact nature of the operation to be performed, and most—60 to 70 percent—did not read or did not understand the information contained in the form.”

individual or group—such as the Training Slide Set in Tool 1a and the Tools for reevaluating and improving consent—help raise awareness about the inadequacies of the status quo and motivate colleagues to change. The key potential benefits of improving informed consent that must be conveyed include:

- Greater patient safety and satisfaction
- Attainment of higher ethical standards and organizational morale
- Closer adherence to legal requirements and reduced risk of litigation
- Increased levels of institutional quality (e.g., compliance with accreditation standards)
- Potential time and money savings (or offsets) related to reduced litigation

To help the advocacy team achieve these goals, the Guide has been organized into the following sections:

- The **Background** section provides clinicians and administrators with an introduction to the definitions and published standards for informed consent. Then, based on a review of the literature on informed consent, including an analysis of the main barriers to effective informed consent (all presented in the Appendices A and B), a few suggested solutions are summarized.

- The core of the practical guidance in this publication appears in the **How to Improve Your Informed Consent** section. Here you will find specific suggestions on how to upgrade the quality of your informed consent process and written materials. Several easy-to-photocopy or download **Tools** are included to help you manage the tasks of preparing your organization, prioritizing needs, and then improving your institution’s disclosure procedures.

- An array of other resources including full-page reproductions of actual consent forms can be found in the **Resources** and **Appendices** sections of this guide.

As the choices facing patients become ever more complex and as the U.S. population grows even more diverse, the need to improve informed consent will only grow. This is an effort that is ongoing. We hope this publication encourages you and your organization to begin rethinking and improving your entire approach to informed consent. We thank the Robert Wood Johnson Foundation for their support of this important project.
The background information synthesized in this section and in Appendices A and B may help healthcare professionals understand the need for improvement in informed consent—and also appreciate the rationale for the core recommendations and tools provided in the next section. While the standards for informed consent vary from state to state, there are commonalities worth reviewing upfront. Similarly, while the conclusions about the causes and potential solutions for ineffective informed consent vary from study to study, the evidence base is worth mining for practical ideas that can be applied in your institution. Even studies on patient education in general or in research settings can provide ideas on how to improve disclosure in everyday clinical practice. Other excellent resources on informed consent—many available free on the web—are listed at the end of this guide.

Requirements for Informed Consent

Informed consent is an ethical concept—that all patients should understand and agree to the potential consequences of their care—that has become codified in the law and in daily practice at every medical institution. One of the earliest legal precedents in this area was established in 1914 when a physician removed a tumor from the abdomen of a patient who had consented to only a diagnostic procedure (Schloendorff vs. Society of New York Hospital). The judge in this case ruled that the physician was liable for battery because he violated an “individual’s fundamental right to decide what is being done with his or her body.” [Edwards 1998, Wescott 2005] The first case actually defining the elements of informed consent occurred in the late 1950s and involved a question of potential negligence and whether a patient was given sufficient information to make a decision.

The case law and rules pertaining to informed consent have changed over the years and all 50 states now have legislation that requires some level of informed consent. [Pape T 1997] Although the details of these laws vary from state to state, the bottom line is that failure to obtain informed consent renders any U.S. physician liable for negligence or battery and constitutes medical malpractice. [Pizzi 2001] Exceptions are made for emergencies or legally adjudicated mental incompetency or physical incapacity. Several of the common elements required for full disclosure have been summarized by the American Medical Association (Table 1) and other groups representing specialists or quality assurance organizations. [AMA 1998] For example, federal regulations spell out the minimum requirements for a properly executed informed consent form.
and state that this form must be in the patient’s chart before surgery. [CFR Title 42] These regulations also stipulate that the information must be given in a language or means of communication that the patient understands. The U.S. government requires interpretation and translation services for individuals with limited English proficiency at institutions that receive federal funding; these regulations also state that informed consent forms must be translated into languages spoken by 5% or 1,000 of a provider’s patients—whichever is less. [Executive Order 13166]

Which procedures require informed consent? Unfortunately there is no continually updated national list describing exactly when informed consent is required. However, [TABLE 1] provides a list of the basic features of everyday informed consent, and [TABLE 2] lists what is needed on the informed consent form.

### TABLE 1: The Basic Features of Everyday Informed Consent

The physician (not a delegated representative) should disclose and discuss:

- The diagnosis, if known
- The nature and purpose of a proposed treatment or procedure
- The risks and benefits 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

Source: AMA 1998

### TABLE 2: What’s Needed on the Informed Consent Form

- Name and signature of the patient, or if appropriate, legal representative
- Name of the hospital
- Name of procedure(s)
- Name of all practitioners performing the procedure and individual significant tasks if more than one practitioner
- Risks
- Benefits
- Alternative procedures and treatments and their risks
- Date and time consent is obtained
- Statement that procedure was explained to patient or guardian
- Signature of person witnessing the consent
- Name and signature of person who explained the procedure to the patient or guardian

Source: Federal Code (Title 42 C.F.R. § 482.51 (b) (2)) Interpretive Guideline A-0392
consent is required. Again, it varies from state to state and is also influenced by clinician or hospital interpretation of recommendations from professional and specialty groups. For example:

- Pennsylvania state law specifically requires that consent be obtained for blood transfusions, chemotherapy, and methadone use as part of a narcotics treatment program. [PA Law Code]

- Many states have developed specific laws governing breast cancer diagnosis and treatment. [ACS 2007]

- The American College of Obstetrics and Gynecology has developed detailed guidelines for informed consent issues related to sterilization and carrier testing for cystic fibrosis. [ACOG 2004]

Thus, based on guidance from staff and counsel, each institution generally develops its own list of surgeries, procedures, or situations where full informed consent is needed. [Manthous 2003]

In fact, the Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations or JCAHO) has set a standard that hospitals must establish and follow policies that describe which procedures or care, treatment, or services require informed consent. [Joint Commission 2005] One of the first steps recommended in the next section is to clarify your institution’s policies about when informed consent is required.

Another area subject to local interpretation is exactly how much to disclose. How many potential risks must be described, for example, and how many alternatives must be mentioned? While many states rely on a standard of what a “reasonable physician” would provide or what a “reasonable patient” would need, this still leaves room for interpretation. [ACS 2007, Westcott 2005] Most laws describe the need to cover all “material” (i.e., significant) risks. But common sense suggests that not every potential risk can be described in detail and that only the most prevalent and/or serious risks and side effects would be covered. [Wescott 2005] The number and type of complications also may vary widely depending on the severity of the patient’s underlying conditions or comorbidities (e.g., pneumothorax following central vein catheterization may not be life-threatening in a patient admitted for a soft-tissue abscess but could be extremely risky in a patient receiving mechanical ventilation for severe acute respiratory distress syndrome.) [Manthous 2003]

How can a single form cover both situations? Further complicating the issue, of course, is the fact that there are limitations and variations in the capacity of individual patients to comprehend many of these details—and therefore the information needs to be tailored for each individual.

It is precisely these gray areas in the requirements for informed consent—When is it needed? How much is needed? And how can I make sure the patient understands?—that have opened the door for many of the documented failures of informed consent in everyday practice. (See Sidebar: “Informed Consent in Practice” and Appendix A) One common defensive response to the uncertainties about how much to disclose,
for example, is use of “blanket” informed consent forms that contain only boiler-plate generalities that “all potential risks and side effects and alternatives have been explained and understood by the patient.” If such a generic consent form is accompanied by genuine documented education involving appropriate explanation and printed material, this may work. (Attorneys also usually advise clinicians to document the details of this interchange in the patient’s record. [Wescott 2005, AMA 1998]) But on its own, an overly generic consent form without any significant accompanying education and interchange—that is, a quick request for a signature while the patient is on the gurney—is not adequate. On the other hand, an exhaustive list of all the potential risks may be difficult for patients to understand. (Attorneys reviewing such a list would also likely point out that any omission from such a long and seemingly comprehensive list might be a red flag, and that such a form would therefore need to state that the list is not inclusive. [AMA 1998])

### Informed Consent in Practice

- How often does informed consent work as intended?
- How do your practices match up to the national norms for informed consent?
- How does one even begin to measure the “success” of informed consent?

These are complex questions that have been tackled by clinicians and researchers from different settings and perspectives. Many studies have focused on one therapeutic area of interest. Others have analyzed the consent process only in the research setting. And some have evaluated the process in targeted patient groups such as those with low literacy.

Reviewing the results from such studies provides a sense of the problems that must still be overcome in planning for and delivering informed consent in everyday clinical practice. See Appendix A for a review of the clinical literature evaluating what works and what doesn’t work in informed consent. While much of this data comes out of the clinical research setting, many of the broader “lessons learned” in these studies are highly applicable to the setting of everyday informed consent.
Thus, even a brief review of the requirements for informed consent reveals the complexity at multiple levels of ethics, law, and effective medical communications. This guide is meant to help you, in partnership with your legal staff and clinical team, navigate these gray areas and, at the end of the day, be set to provide consistently high-quality informed consent. A key part of the solution that will be repeated throughout this publication is that informed consent requires more than just a good written form—it also requires preparation for a full discussion with the patient and a check to ensure that the messages have been received.

Understanding the Barriers to Informed Consent

While a few clinicians and patients may mourn the shift from the “good old days” of patients implicitly trusting their doctors and nurses to help them make decisions without a bureaucratic need for signed proof of consent, the fact is that much in the old patient-physician relationship has changed in the past century. Certainly, medicine has become more option-filled and complex. Many patients now expect choices and can easily find more information at their fingertips. The internet has created a society, or at least half of a society, of information-saturated but often knowledge-starved patients. Society has also become more litigious. Meanwhile, there are financial pressures on doctors to keep visits short and there is increasing ethnic, cultural, and linguistic diversity in the country—changes that only increase the chances for imperfect communication. The Joint Commission recently highlighted impacts of this increasing diversity on health literacy; among the facts cited in that report [Joint Commission 2007] [2003 National Assessment of Adult Literacy (NAAL) National Center for Education for Educational Statistics, U.S. Department of Education]:

- A large segment of the American population has basic (29%) to below basic (14%) prose literacy skills
- Even larger segments have basic (33%) or below basic (22%) simple quantitative skills
- Five percent of Americans are non-literate in English

Awareness of these and other barriers to truly informed consent (as summarized in Table 3 and more fully explored in Appendix B) is a good preliminary step toward improving the whole informed consent process.
Understanding the Impact of Health Literacy on Informed Consent

A common theme running through many of the barriers just introduced is the low rate of health literacy seen in the American population. Health literacy has been defined as the ability to read, understand, and act upon health information. [AMA1999] Broadening this definition beyond the individual patient, the Institute of Medicine has recently called health literacy: “...the degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions. But health literacy goes beyond the individual. It also depends upon the skills, preferences, and expectations of health information and care providers: our doctors; nurses; administrators; home health workers; the media; and many others.” [IOM 2004]

However defined, health literacy is in short supply. The 2003 National Assessment of Adult Literacy found that about 36% of adults had Basic or Below Basic health literacy (versus Intermediate or Proficient levels) and that these individuals were more likely to get their information about health issues from radio and television instead of newspapers, magazines, books, or the internet. [NCES 2007] These

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<th>TABLE 3, See Appendix B</th>
<th>Ten Barriers to Effective Informed Consent</th>
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<td>Based on studies such as those reviewed in Appendix A, ten of the main challenges that have been identified in direct relation to informed consent are summarized here. See Appendix B for a full discussion of these barriers, and note that most of these involve the “process” of informed consent rather than written consent form itself.</td>
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<tr>
<td>1] Lack of clinician time</td>
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<td>2] Confusion among clinicians about when informed consent is needed</td>
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<td>3] Physician concerns about giving too much information</td>
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<td>4] Perception of patients that the informed consent form is “just a legal release” for the doctor or hospital to proceed</td>
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<td>5] Patient unawareness that they can refuse the procedure or delay the decision</td>
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<td>6] Patient language and cultural issues</td>
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<td>7] Special patient circumstances and human factors (e.g. IQ, stress, timing)</td>
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<td>8] Poor quality of consent form and related educational materials</td>
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<td>9] Patient misunderstanding of information on the informed consent form or related educational information about the proposed surgery or procedure</td>
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<td>10] Clinician inability to detect patient’s lack of comprehension</td>
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findings seemed to confirm earlier estimates that over 90 million Americans lack basic health literacy skills [Kirsch 2002] and that 47 million Americans, or almost half of the adult population of this country, were either functionally illiterate, or marginally literate. [Kirsch 1993]. It should be noted that those with limited English proficiency were excluded from the NAAL survey and so language barriers cannot explain the findings. Another recent analysis of 85 carefully screened medical research papers found that the prevalence of low health literacy was 26% (95% confidence interval 22% to 29%) and the prevalence of marginal literacy was 20% (95% confidence interval 16% to 23%). [Paasche-Orlow 2005] Even accounting for the bias in these publications for populations with low socioeconomic status, these results imply that nearly half of the population in the reviewed studies had health literacy skills that would impede their understanding of most informed consent forms.

In fact, beyond health literacy, surveys have shown that many Americans have significant deficits in fundamental reading, writing, and numeracy skills, which interferes substantially with their ability to function normally in society. In the 2003 National Assessment of Adult Literacy, for example, 22% of adults were at the lowest possible level of quantitative literacy (Below Basic), indicating that they possessed no more than the most simple and concrete literacy skills. [NCES 2007a] Based on this same report, it is estimated that some 50 million American adults have Below Basic prose literacy, 27 million have Below Basic document literacy, and 46 million have Below Basic quantitative literacy. [NCES 2007b]

The scope of this problem is broad and reaches across ethnic, racial, and economic lines. In sheer numbers, most of those with low literacy skills in the United States are white, native-born Americans. However, specific demographic groups are at higher risk for low literacy. These include: ethnic minorities, the elderly, unemployed persons, and those with a lower level of education or limited income. [Kirsch 1993, Paaschle-Orlow 2005]

Individuals with low or limited literacy skills have poorer health outcomes. They are less likely to seek preventive care or to comply with prescribed treatment. In one recent study, for example, poor literacy was linked to poor HIV medication adherence among African American patients and was cited as a possible cause of HIV health disparities. [Osborn 2007] Another recent study found that limited health literacy was a barrier to patients taking medications for hypertension. [Persell 2007] In addition, patients with low literacy are at higher risk for hospitalization and tend to stay in the hospital longer. Their need for additional care results in annual health care costs four times higher than those with higher literacy skills. [Doak 1996; Weiss 1999; Baker 1996] People with low or limited literacy face significant risks when attempting to navigate the healthcare system [MEPS 2008] and when making truly informed decisions about their care. Identifying individuals
with low health literacy skills may not always be possible, but assuring that every individual understands an informed consent is critical to providing the best possible care—care that is not just medically sound, but also ethically and legally sound.

Evolving Best Practices in Informed Consent

Based on all the information just summarized, two points stand out: (1) Patients have a fundamental right and need to receive information, both orally and written, about their care in a manner they can fully comprehend and that will lead to truly shared decision-making, and (2) current practices of informed consent are often inadequate and are especially hampered by growing rates of health illiteracy in the U.S.

So, what can be done?

A number of studies indicate that improving consent forms and the overall consent process can lead to better patient comprehension and recall. Although the research on improved consent forms has been mixed, some studies have found that when consent forms are improved, patients are more likely to read and understand them before signing. [Pereira 1995, Davis 1998]. Using a consistent informed consent template as a starting point for the creation of forms for various procedures also appears to improve consistency and quality in the forms. [Takimoto 2007] The Queensland Government (Australia) offers a useful example of how consistency in format and content can improve overall quality and anticipate the need for language services (Figure 1). Providing clear and simple information about procedures may also lower patient anxiety levels [Kerrigan 1993, Coyne 2003] and increase understanding and recall in a way that produces a more deliberative decision-making process. [Meade 1999, NWGLH 1998, Campbell 2004, Paaschle-Orlow 2003]

However, a clearly written consent form does not guarantee that patients will read and understand them. A properly constructed and clearly formatted consent form is a necessary but not sufficient condition for ensuring that patients read, understand, and remember the information presented. Thus, a variety of other methods are needed to increase patient involvement in the consent process and improve patient comprehension of the information presented. For example, several recent studies show that repeating information to patients in various formats and modes and at different times can strengthen comprehension and recall. [Alaishuski 2008, Migden 2008, Moseley 2006, Cohn 2007]
Figure 1. Example of Informed Consent Form from Queensland Australia.

Note that the main categories remain consistent from procedure to procedure.
Based on a review of the literature on informed consent and, more broadly, on patient-physician communication (much of which is summarized in Appendices A and B), we have generated recommendations and tools that can help anyone wanting to improve their informed consent. Specifically, these recommendations emphasize (1) gaining consensus within the organization to make the required changes, (2) improving the consistency and quality of the written consent form and the related written educational materials and (3) improving the structure and content of the informed consent process, especially in terms of soliciting feedback from the patient to ensure comprehension. Key “best practices” that we endorse in the next section include:

- Recognize differences in education or literacy levels and provide more help to patients with less education or low literacy.
- Have extended discussions with patients and when possible have other staff (e.g. nurses) provide additional explanation of information presented by the doctor.
- To ensure thoroughness in content and consistency in language, employ a consistent outline or template when starting to create informed consent forms for different procedures.
- Use lower reading levels, better formatting, graphics, shorter lengths, and remove unnecessary material.
- Use consent forms as an outline for discussion with patients (e.g. to ensure that all key information about risks and benefits is presented).
- Give patients information or fact sheets that can be taken home.
- Consider use of multimedia formats (e.g. webcasts, podcasts, DVDs) along with written information to bolster understanding.
- Use a “teach back” method in which patients are asked to repeat back the information that has been presented to them.
- Make sure patients are given an opportunity to decline procedures and are aware of their right to do so.

Implementing these practices will require coordinated efforts from administrative and clinical leadership, clinical staff, risk managers and legal counsel. We encourage all those involved in delivering quality healthcare to consider adding the suggestions and tools provided in the next section, “How to Improve Your Informed Consent,” to their ongoing quality improvement efforts.
How to Use the Rest of this Guide

The four activities described next contain dozens of practical recommendations on how to improve informed consent.

1] **Gain Organizational Consensus:** Use these ideas to set the stage for or start the discussion about change within your organization.

2] **Assess Status & Prioritize Needs:** Gather information and evidence from within your own organization to figure out what works, and what doesn’t work, in your current procedures and policies.

3] **Improve Your Written Consent Forms and Other Educational Materials:** Get down to work and improve the language, style, clarity, and content of your written educational materials and consent forms.

4] **Improve Your Consent Process:** Don’t forget that informed consent involves more than a piece of paper—use these ideas to add substance to the full dynamic interaction with patients.

These four main activities could be seen as “steps” to be done in sequence or, alternatively, a user could pick specific activities and ideas that are most needed in his or her setting and concentrate there. Certainly a comprehensive approach would be ideal but spot improvements—a focus in cardiology, an effort to improve Spanish translations, a Grand Rounds talk on informed consent, or even just an attempt to simplify and test a single consent form—are better than nothing. In other words, use as many of the following ideas as possible and keep in mind that the clinical and legal staff within your own organization will likely bring other valuable suggestions for improving your consent procedures while remaining within the necessary legal and organizational bounds. This Guide is simply a starting point or roadmap. As described already, somebody within your organization needs to provide the real spark—by becoming the advocate—to translate these ideas into real progress and improvement.

So, who exactly should take responsibility for all this work? The answer to that question will vary in every institution. In many cases, it will be an individual involved in quality assurance activities or within one busy clinical department, who initiates the discussion for an educational program on informed consent ([1] Gain Organizational Consensus) or a review of existing forms ([2] Assess Status & Prioritize Needs), or generation of newer and better forms ([3] Improve Your Written Consent Forms and Other Educational Materials). In other cases, it may be an ad hoc committee of clinicians working with the organization’s attorney to create a more comprehensive and coordinated plan for review and improvement. There is no one best way to improve. There are many possible ways. Several of these are laid out for your consideration in the remainder of this Guide.
[1] Gain Organizational Consensus

Many of the barriers to attaining more effective informed consent are rooted in long-established practices or patterns of clinical care. Changing these institutional or individual habits will take time. It may also require some up-front training or education of staff who harbor questions such as: "Why are any changes needed? What's the problem with our current informed consent forms? Aren't we just opening a can of worms? My patients are fine with the forms I use."

To set the stage for your improvement efforts, therefore, you may need to devote some time to educating the appropriate clinical and management staff about the purpose of informed consent and the nature of the problem with informed consent in actual practice. In some cases, this first step in the improvement process may just be a simple one-on-one conversation with a department head about the possibility of reviewing and updating informed consent forms for certain procedures. In other cases, you may want to create a memo or newsletter article for all staff describing the purpose of your planned effort. And in some situations, you may have the opportunity to introduce the improvement plan at a departmental staff meeting or even a hospital-wide gathering.

Whatever the venue for your education, information similar to that presented in Introduction and Background sections of this guide may help you in setting the stage for change. To assist you in preparing your case for improvement, many of the key points from the previous sections of this guide and
Appendices A and B have been summarized and reformatted into a presentation format (Tool 1A: Staff Training Slides/Flyer) for your adaptation and use. You will also of course want to customize your presentation—for example by showing examples of actual forms used in your institution; summarizing your institutional policies on informed consent; or describing specific case studies involving problems or successes with informed consent. As in all steps suggested in this guide, close coordination with your institution’s legal counsel is advised.

Note that this first step should be a two-way interchange of information. While you are reminding your colleagues of the ideals and realities of informed consent, they will be telling you about the challenges, questions, or success stories happening within your own organization. As suggested in the next section, you may also want to create a more formal mechanism for assessing your local state of affairs regarding informed consent. Based on this input, you may decide that you need to address issues beyond those suggested in the final sections of this guide. For example, you may need to clarify institutional policies about when informed consent is required, or you may find that a broader CME course on basic patient-physician communication skills would be appropriate.
Staff Training Slides/Flyer

To Gain Organizational Consensus

Use the following materials to create a mini-seminar on informed consent for your staff. To access go to www.tobedetermined.com

It is highly recommended that presentations include not only general background information as provided here but also local, specific, and real-world informed consent issues. For example, your staff attorney may be able to describe specific clinical situations that have led to litigation or, more broadly, state legislation or relevant case law that impacts your own consent policies. A clinician may be able to present a Case Study involving faulty disclosure. An administrator may be able to provide an up-to-date demographic and/or linguistic profile of a department’s patient population. Or a quality assurance administrator may have regional data on consent policies and compliance levels at nearby peer organizations. This is the type of close-to-home information that will engage an audience, make it real and personal, and motivate a group to take action.
Staff Training Slides/Flyer

continued

Why Do We Need Informed Consent?

The Slightly Longer Answer:
- Greater patient safety and satisfaction
- Attainment of higher ethical standards and organizational morale
- Closer adherence to legal requirements and reduced risk of litigation
- Increased levels of institutional quality (e.g., compliance with accreditation standards)
- Potential time and money savings (or offsets) related to reduced litigation

Who is Responsible for Informed Consent?

The clinician has core responsibility... but... a team approach is required with contributions from:
- entire clinical staff (clinician, nurse, technicians, pharmacist)
- administrative and clinical leadership
- legal counsel

When is Informed Consent Required?

In most institutions, for:
- surgery
- anesthesia
- other invasive or complex medical or radiologic procedures

Laws vary from state to state about exactly when and how formal informed consent must be provided.

Why Do We Need to Improve Informed Consent?

Even after signing a consent form, many patients still do not understand basic information about the risks and benefits of their proposed treatment options.

Patient Factors:
- Low health literacy
- Limited English proficiency
- Cognitive impairments
- Confusion about the purpose of consent process
- Feeling of intimidation, and stress or time pressure

Why Do We Need to Improve Informed Consent?

Even after signing a consent form, many patients still do not understand basic information about the risks and benefits of their proposed treatment options.

Provider Factors:
- Lack of time for up-front patient education
- Overly complex or overly broad written materials
- Lack of support with interpreters
- Wrong assumptions about patient comprehension

Low Health Literacy — A Common Theme in Poor Clinician-Patient Communication

“It is likely that almost everyone has been, at some time, put off by densely worded forms, and confused by complex medical regimens, conflicting health care advice, poorly worded instructions, and medical speak that few on the receiving side of health care can understand.”

From “What Did the Doctor Say” Improving Health Literacy to Protect Patient Safety.” The Joint Commission, 2007 www.jointcommission.org
Staff Training Slides/Flyer continued

- Low Health Literacy — A Common Theme in Poor Clinician-Patient Communication
  
  "Many leave the doctor’s office with questions unspoken and unanswered…”

  "The communications gap between the abilities of ordinary citizens, and especially those with low health literacy and low English proficiency, and the skills required to comprehend everyday health care information must be narrowed."

- What’s the Evidence that the Informed Consent Process is Not Working Well?
  
  Braddock et al 1999

  ... found uninformed patients

  Audiotape recordings from 1057 physician-patient encounters

  - Only 9% of decisions were completely informed
  - Only 20% to 38% of the encounters met less stringent criteria for completeness

- What’s the Evidence that Informed Consent Forms are Poorly Written?
  
  Mantous et al 2003

  ... found variability in use of informed consent

  National mailed survey of 117 intensivists and 56 internists

  - Found heterogeneity in when physicians obtained informed consent
  - 74% to 93% for transfusion of blood products
  - 77% to 96% for common diagnostic procedures (e.g., lumbar puncture, paracentesis)
  - Many physicians used a “blanket” consent forms to cover invasive medical procedures

- What are the Potential Consequences of Lack of True Informed Consent
  
  Hopper et al. 1998

  616 forms assessed by computer for readability

  - Average were written at grade level of 12.6
  - Just over half could be understood by patient with high school education
  - Only about 5% could be understood by patient with 8th grade reading level

  Lavelle-Jones et al 1993

  Interviewed 230 patients undergoing intrathoracic, intraperitoneal, or vascular surgery

  69% said they did not read the consent form before signing it
A Practical Guide to Informed Consent: Providing Simple and Effective Disclosure in Everyday Clinical Practice

Staff Training Slides/Flyer

continued
Staff Training Slides/Flyer continued

**What Can We Do to Improve Our Informed Consent?**

2. Improve our informed consent process
   - Create the time for it
   - Simplify our language
   - Allow time for questions
   - Make sure the patient understands
   - Plan for language assistance in advance of appointment

3. Improve understanding of informed consent and the responsibilities and liabilities to health care organizations
   - Train support staff, nursing, administrators, interpreters, etc.

4. Improve your capacity to provide informed consent to patients with LEP
   - Train interpreters to sight translate consent forms for patients with LEP
   - Assess whether interpreters have the ability to sight translate consent forms or informed consent discussions effectively
   - Assure the quality of translated consent forms

5. Keep track of incidents related to informed consent process
   - Use CQI processes to monitor incidents related to informed consent
   - Develop targeted remediation to identified problems
Getting a handle on your institution’s current policies and practices on informed consent is a key step in planning an improvement program. Some of this information can probably be gathered from policy manuals and departmental procedures. Samples of informed consent forms will also likely be easy to retrieve from clinic files. An inventory of all forms would be ideal. One-on-one interviews with departmental heads, residency program directors, or other supervising physicians may also be valuable. The main questions you need to answer up front are:

What are our current policies, processes, and forms for informed consent?

What needs to be improved?

Have problems with informed consent (eg, adverse events, legal challenges) been reported within our institution?

Do our consent forms meet the needs of our diverse community?

What are the highest priorities?

How should we make improvements?

Who can help in this process?

How should we measure our progress?

Your interactions with colleagues as proposed in the previous section, Prepare Your Organization, may present an ideal opportunity to gather this type of information. However, assessing clinician understanding and implementation of your informed consent policies and forms may also require a wider survey of staff or a broader series of one-on-one interviews with nonsupervisory clinicians. Reviewing patient files or making rounds with staff are other options for gathering information about the current practices in your facility. This could all be time well spent since it will help you in prioritizing needs in terms of which forms to create or revise first, which departments to train first, or what process or communication skills to emphasize first.
Keep in mind that the question-asking itself can serve as an early form of staff education and awareness-raising that reminds them of the importance of informed consent. The process may also create a “buy in” from clinicians or administrators to follow-up and re-write problematic consent forms or sharpen basic communication skills. In fact, this planning step may allow you to identify a colleague to “champion” the improvement effort (e.g., a chief of surgery? A nursing leader? A risk manager?). A few specific suggestions for initiating the discussion and information-gathering are listed here.

Survey and Questionnaire
Questions to consider asking individual clinicians in e-mail or in-box surveys or one-on-one interviews include:

- Do you know when you are required to obtain informed consent?
- List the top 5 procedures where you ask patients to sign an informed consent form?
- How do you obtain consent?
- Do you get signature(s) yourself?
- How much time (range) do you spend explaining procedure to patient?
- Do you give patient time before deciding? Do you give educational material?
- Do you always ask patients if they understand? How?
- What written forms do you use? Is it a blanket form? (please provide photocopied examples)
- Are you satisfied with the forms you now use? (if not, explain)
- Do language, culture, disabilities, age, or low literacy in your patients impede your informed consent efforts?
- What is the biggest difficulty you have with the informed consent process?

An example of a questionnaire for program directors of critical care units or internal medicine departments or residency programs is included here for your use or adaptation (Tool 2A: Informed Consent Questionnaire). [Manthous 2003] (An added benefit of using the actual questionnaire from Manthous et al. is that you will be able to show your colleagues how they compare to a national sampling of physicians in terms of when they obtain informed consent.) Similar surveys can be created for other departments and specialties that perform many surgeries or procedures.

Mini-Study, Audit, or Inventory
You can also consider a more objective mini-study of select procedures by reviewing patient files to see what percentage of patients having a certain procedure (for which your institutional policy is to obtain informed consent) actually have a completed and signed form within their file. A formal audit that evaluates the process
as well as the form may also be appropriate as a mechanism of quality improvement (See Tool 2B for a sample audit form). Although more difficult, a sampling of patients via phone survey might provide some baseline data on the effectiveness of the informed consent process. Review of facility records to determine the percentage of law suits involving informed consent issues may also provide insight into the current state of affairs. Either as part of this same study or in a separate effort, creation of a full inventory of informed consent practices would be ideal. Such an inventory would help shape training needs and identify high-priority areas for improvement. Such a comprehensive listing of current practices would also establish a baseline for monitoring improvement efforts. Key elements for entries or fields in such an inventory might include:

Procedure/Treatment: ________________________

Department/Clinic: ________________________

Date of Implementation: ________________________

Author/Designer/Contact: ________________________

How/When Used: ________________________

Languages Available: ________________________

Date Translated: ________________________

% Cases Used As Intended: ________________________

In addition to this basic tracking information, an assessment of the style and appropriateness of the written consent form would also be appropriate (see Tool 3B).
Survey to Assess the Status

Of Your Organization’s Informed Consent Procedures

Use the following example as a model to create your own questionnaire(s) to find out how the informed consent process is actually working in your organization. Consider customizing with some of the questions suggested on the previous page. To access this example form go to www.templehealth.org/ictoolkit.

Questionnaire About Informed Consent for Procedures Performed by Internists

Thank you for taking the time to fill out this brief questionnaire, the results of which we hope to use to understand the consenting practices of our fellow practitioners. We are not asking about institutional policies regarding consent but rather how internists at our institution actually practice. You can either enter your answers in the body of the email or in the attached Word document.

Please make an X or embolden those that apply:

_________ We use a “blanket” or “global” consent to cover the below procedures except for those that I have specifically highlighted for which we obtain separate consent

Except in immediately life-threatening situations, internists (including trainees) at my hospital routinely obtain SEPARATE informed consent from a patient or proxy for:

- Arterial catheterization
- Central vein catheterization
- Swan Ganz catheterization
- Femoral vein catheterization
- Thoracentesis
- Paracentesis
- Lumbar puncture
- Blood product transfusions
- Administration of intravenous contrast agents
- Endotracheal intubation
- Bronchoscopy
- Gastrointestinal endoscopy
- Nasogastric intubation
- Foley catheterization
- Medical research

Reprinted with permission from CA Manthous MD, Yale University School of Medicine (Manthous 2003)
Audit for Measuring Compliance with Your Organization’s Informed Consent Procedures

Use the following example (from the Australian state of Queensland) as a model to create your own audit tool to measure compliance with the informed consent process. Consider customizing with some of the questions suggested on the previous page.

How To Improve Your Informed Consent

[3] Improve Your Written Consent Forms and Other Educational Materials

Having worked within your institution to assess the major issues surrounding informed consent, you should emerge with a prioritized list of informed consent forms and related educational materials that you want to create or improve. As described in previous sections, improving the readability of your consent forms and related educational materials will likely be a top priority in helping patients understand the procedure to which they are consenting. Again, the relatively complex sentence structure and vocabulary of most consent forms makes it difficult for the average adult to interpret the information. [Pizzi 2001]

As illustrated in the nearby example, applying the principles of plain language can improve understandability without compromising the message. An added advantage of simplifying and clarifying the consent form is that it will also increase the likelihood of getting a high-quality translation of the consent form for use by non-English-speaking patients.

In this step, we provide general advice on how to improve the readability of these written materials. Much of this advice is based on the types of studies reviewed in the Background section of this guide. Other recommendations are adapted from excellent public domain guides such as:

- *Clear & Simple: Developing Effective Print Materials for Low-Literate Readers* from the National Cancer Institute
### Six Steps for Creating Simple and Effective Disclosure Forms

1. **Review the fundamental target audience, setting, and communication goals**

   Your first step is deciding what you need to say. Be sure to get the following information from clinicians:
   - Will this form be used on its own or with other materials?
   - Will patient read this alone or interactively with clinician?
   - Why is this procedure being suggested? How does it work?
   - What is the main benefit?
   - What are the most common risks or side effects? The most serious?
   - What are the alternatives? Risks and benefits of those?
   - The risks of declining?

---

### Do You Think Plain Language Improves this Consent Form?

<table>
<thead>
<tr>
<th>Consent Form #1 (college level)</th>
<th>Consent Form #2 (8th grade level)</th>
</tr>
</thead>
<tbody>
<tr>
<td>“You voluntarily consent to participate in this research investigation. You may refuse to participate in this investigation or withdraw your consent and discontinue participation in this study without penalty and without affecting your future care or your ability to receive alternative medical treatment at the university.”</td>
<td>“Participation in this study is entirely voluntary. You have the right to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled.”</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Consent Form #3 (4th grade level)</th>
</tr>
</thead>
<tbody>
<tr>
<td>“You don’t have to be in this research study. You can agree to be in the study now and change your mind later. Your decision will not affect your regular care. Your doctor’s attitude toward you will not change.”</td>
</tr>
</tbody>
</table>

Adapted from www.plainlanguage.gov and Stockton 2004

### Tools to help you accomplish these steps are presented on the following pages and samples of actual informed consent forms (including before and after versions) can be found in Appendix C.

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

36
In addition, special questions related to consent for patients who speak little or no English, have low health literacy, or other communication barriers (physical or mental disabilities, old age) must also be considered:

• Should we consider providing this in another language? (And if so, can we ensure that all cultural, linguistic, demographic, educational, and geographic issues as well as the probable setting/context are considered in the translation?)

• Will on-site interpretation or translation be required? (And if so, can we meet HIPAA privacy and confidentiality requirements if family/friends are used for interpretation or support; and can we document the patient’s permission?)

• Will the target population’s cultural values or core beliefs impact consent?

2] Gather feedback on the existing item

• Highlight what works well, what to keep
• Circle or cross out what is confusing or too complex
• Note what’s missing
• Consider testing the existing item with patients (Consider using Tool 3C Patient Pretest, which can also be used to test your own draft)

3] Create a file of ideas for the new/revised item

• Create a file for all information gathered in first two steps
• Add examples of other pieces from other sources (government websites, medical societies, other hospital or clinics)

• Add articles, chapters, background with related content or graphics

4] Write a draft

• Take a deep breath and remind yourself of the reader

Spend just 5 or 10 minutes reading some patient information brochures, books, or Websites from large groups such as the American Cancer Society, American Heart Association, Healthwise, or WebMD. This often helps a clinician-writer “change gears” in terms of overall structure, complexity, and length; some writers keep a file of favorite examples of writing about medicine for lay audiences—from newspaper stories, magazine articles, or brochures—for exactly this purpose of reminding themselves to shift down in complexity.

• Develop a concept/outline:
[www.plainlanguage.com]

1. Create categories for all the needed information (Note that using a standard outline or template may help ensure that you cover all the necessary points—for ideas, see Tool 3B Checklist for Assessing the Informed Consent Form and the sample Queensland informed consent form (Figure 1).

2. Divide the information among the categories

3. Put the categories in appropriate sequences

4. Start creating subcategories
• Flesh out the outline to create a first draft
• Edit and revise
  (See Tool 3A Style Guide for Improving the Informed Consent Form)

5] Test the draft

• Use a checklist for quick evaluation for basic elements
  (See Tool 3B Checklist for Assessing the Informed Consent Form)
• Consider checking readability with a software program or tool [Doak 1998] (but be aware that readability formulas are controversial since they do not assess reader fluency, motivation, anxiety, etc., and since they also ignore text organization, visual design, and difficulty of words other than related to word length (e.g., “lesion” and “cancer” may be considered equally readable) [Anckler 2004]
• Ask clinicians who plan to use the form:
  ○ Everything covered? Anything missing?
  ○ Are the most important points emphasized?
  ○ Words or concepts your typical patient will not understand?
  ○ Specific suggestions for edits?
  ○ Will you be able to use this? How?
• Testing the draft with patients
  (See Tool 3C Patient Pretest)

6] Revise based on evaluations and pretesting

A Note on the “Right” Grade Level for Informed Consent Forms:
Don’t Sweat It... Just Simplify It

As emphasized throughout this Guide, informed consent forms should be written in simple sentences and in the primary language of the patient. Many clinicians and educators are anxious to use a “readability score” to get an objective measure of their progress toward simplification. But simplification is about more than grade level scores. While some research shows that understanding and recall increase when consent forms are written at the 5th grade level, which is considered appropriate for low literacy patients, [Meade 1999, Campbell 2004, Paaschle-Orlow 2003, NWGLH 1998] many organizations aim for an 8th grade level, which is deemed “plain language.” In some cases, forms at both levels (and in multiple languages) may be needed. However, there is so much room for improvement in the typical informed consent form that the difference between 5th grade level and 8th grade level is often academic. Even the results of various software programs for determining the exact grade level have been criticized. [Ancker 2004] So, don’t let the need to attain some supposedly objective measure of readability stifle your efforts to simplify your consent forms. Logical organization of information and format are just as important as grade level. In most cases, almost any change will be an improvement. Let your common-sense guide you. Work as a team. Get feedback. And use the Tools on the following pages to help you accomplish this goal.
Style Guide

For Improving the Informed Consent Form

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.

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)
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
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 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:**

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________
Pretesting informed consent forms with the intended audience is always a good idea. This is especially true when developing forms for low-literate 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. In particular, be sure to address the cultural and linguistic diversity of the target patient audience when recruiting test participants. 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?
[4] Improve the Consent Process
Once you have assessed your needs and partnered with clinicians to develop appropriate written support material for informed consent, you are ready to address the consent process itself. This is the interaction between the patient and the clinician (and, indirectly, with the whole team involved in the development of the informed consent form) to inform the patient about the options and to discuss the patient’s decision. All too often, this process is a mere formality with the consent sheet thrust in front of the patient for signature with minimum explanation. Even in institutions with more regard for the process, there is ample room for improvement.

The steps recommended in the nearby Figure are really quite simple. They call upon the clinician to: (1) acknowledge that informed consent requires more than a signature on a piece of paper; (2) commit to (and create time for) basic patient-physician communication; and (3) ensure that each patient has understood the content of the informed consent form. These same three points can be emphasized to clinicians early in your education process about informed consent. The last thing that clinicians need is another set of multi-page guidelines to follow as they manage their patients. That’s why the detailed suggestions on the following pages may or may not be useful in your discussions with staff. They are mostly reminders.

The key point to emphasize in your discussions with clinicians is that they need to start checking to make sure that their patients have understood the information. Of all the interventions studied to improve understanding after informed consent, this seems to have the most impact. To help both patients and physicians get ready for this important interchange, you can consider providing staff with the checklist of questions for patients (See Tool 4A Checklist for Patients). Note that this same checklist, or the informed consent form itself, can serve as a convenient checklist for clinicians during the patient visit to ensure that they cover the key points.
**Check the Patient’s Understanding:**

**The Single Best Thing A Doctor or Nurse Can Do To Improve Informed Consent**

A variety of methods have been used to increase patient involvement in the consent process and improve patient comprehension. These methods include: having other staff (e.g. nurses) provide additional explanation of information presented by the doctor; giving patients information or fact sheets that can be taken home; using consent forms as an outline for discussion with patients (e.g. to ensure that all key information about risks and benefits is presented), and using a method in which patients are asked to repeat back the information that has been presented to them. Other approaches that may help improve patient understanding in the consent process (the evidence is mixed) take advantage of modern technology and include: audiovisual materials shown in a clinic setting or given to participant to take home; web-based computer interventions; and phone-based interventions.

However, the simplest and most reliable method for improving comprehension involves the “teach back” method described above. In 2003, the National Quality Forum recommended **Safe Practice 10**

calls for the utilization of the “teach back” method during the consenting process. Patients or their designated representatives are asked to repeat back, or “teach back” in their own words all the information they were given during the informed consent. Studies have found that teach back, also called the show me technique, greatly improves recall and retention of information by patients. [NQF 2005]

Asking open-ended questions is another simple method for checking patient understanding. An open-ended question is one that cannot be answered with a simple yes or no. Instead of asking a patient “Do you understand?” ask them “What questions do you have for me?” This will invite a more detailed response from the patient. It gives the provider the opportunity to identify gaps in understanding, or confusion about what was explained. (Kleinman 1986) Comprehension also improves when patients take a more active role in the discussion of their care. [NQF 2003, NQF 2005]
### Informed Consent Process

#### [Step 1] Introduction
Find a private, quiet place for counseling and explain the consent process to the patient/family.

#### [Step 2] Explanation
Provide all relevant information:
- Use simple language and non-technical terms
- Use appropriate media to communicate/demonstrate information
- Consider patient's reading level and primary language spoken

#### [Step 3] Comprehension
Check for understanding
- Ask patient/family open-ended questions
- Use teach-back method

#### [Step 4] Q & A
Allow patient/family to ask questions:
- Answer questions
- Repeat explanation, if necessary

#### [Step 5] Consent
Obtain consent from patient/family
- Allow patient/family time to read consent and consider options
- Obtain signatures
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 A]
Evidence Review: Informed Consent in Practice
While much of the clinical literature evaluating what works and what doesn’t work in informed consent comes out of the clinical research setting, many of the broader “lessons learned” in these studies are highly applicable to the setting of everyday informed consent.

How often does informed consent work as intended? How do the practices within your institution match up to the national norms for informed consent? For that matter, how does one even begin to measure the “success” of informed consent? These are complex questions that have been tackled by clinicians and researchers from different settings and perspectives. Many studies have focused on one therapeutic area of interest. Others have analyzed the consent process only in the research setting. And some have evaluated the process in targeted patient groups such as those with low literacy.

A review of results from such studies will provide the clinician and healthcare administrator with a sense of the problems that must still be overcome in planning for and delivering
informed consent in everyday clinical practice. All too often, the only metric used to monitor the informed consent process in busy hospitals and clinics is the number of complaints or litigation. The results described below suggest that the squeaky wheel method of monitoring success is inadequate for improving quality, safety, and patient satisfaction.

**Evaluating the Process**

**Braddock et al 1999:** Audiotape recordings from 1057 physician-patient encounters were analyzed for completeness of information needed to make informed decisions; overall, only 9% of decisions were completely informed, while only 20% to 38% of the situations met less stringent criteria for completeness.

**Manthous et al 2003:** A national mailed survey of 117 intensivists and 56 internists revealed heterogeneity in the practice of obtaining informed consent in several common procedures. While consent was uniformly low for Foley catheterization (<10%) and uniformly high for endoscopic procedures (>90%), the rates of obtaining consent ranged from 74% to 93% for transfusion of blood products and from 77% to 96% for common diagnostic procedures such as lumbar puncture or paracentesis; further, many physicians used a blanket consent form to cover invasive medical procedures performed during the hospital stay.

**Mark et al 1990:** A prospective survey of 102 patients undergoing colonoscopy found that 82% understood everything they were told and had all their questions answered.

**Saw et al 1994:** Interviews with 55 men who had undergone transurethral resection of the prostate showed that 18% could not recall that retrograde ejaculation was a major risk of the procedure (despite emphasis on this in the informed consent).

**Sudore 2006:** A descriptive study of a modified consent process with 204 ethnically diverse elderly patients (40% with low literacy) found that only 28% answered all comprehension questions correctly. After a second round of education, 80% answered correctly. Low literacy and being black were associated with need for more education.

**Evaluating the Written Form**

**Bottrell et al 2000:** The content of 540 informed consent forms from 157 hospitals was analyzed for four required key elements (nature of procedure, risks, benefits, alternatives); only 26% of the forms included all four elements; less than half the forms provided specific information about risks; alternatives were noted only in 57% of forms.

**Davis et al. 2001:** Focus groups with patients with limited education and low income showed that 60% could not understand a standard informed consent form related to screening for colorectal cancer.
Eisenstaedt 1993: A survey of 81 hospitals in the mid-Atlantic region found that only 50 (62%) required informed consent for blood transfusions; further, these forms were not standardized and often missed key elements such as risks and benefits, alternatives, and confidentiality. For example, only 27 of 48 forms mentioned complications. The reading level of 34 submitted forms was grade 14.6.

Hopper et al. 1998: In one of the largest evaluations of informed consent forms to date, 616 forms from around the U.S. were assessed by computer for readability; of the 616 total forms, 29 were at <8th grade level and 461 were at >12th grade level.

Lavelle-Jones et al 1993: Interviews of 250 patients undergoing intrathoracic, intraperitoneal, or vascular surgery revealed that 69% of patients said they did not read the consent form before signing it; about half of the patients awaiting treatment said they were unhappy with the amount of information they received.

Bergler et al 1980: In multiple-choice quizzes of patients who had entered a clinical trial for blood pressure medications after reading an informed consent statement, the correct response rate was 72% at 2 hours and 62% at 3 months.

Dawes 1994: A survey of 50 patients after surgery found that the purpose of consent forms is often unclear and patients frequently perceive them as a form of legal protection for hospitals and treatment centers rather than a source of information. For example, more than two thirds of patients thought the form they were signing was a legal document and 50% worried about some aspect of their surgery.

Estimating the Consequences of Poor Disclosure

Some studies support the intuitive notion that better patient-physician communication will lead to improved long-term health outcomes. One analysis of randomized controlled trials on patient-physician communication, for example, showed that the quality of the overall communication (e.g., in history taking or treatment discussion) influenced patient outcomes such as emotional health, symptom resolution, blood pressure, or blood sugar levels in 16 of 21 studies. [Stewart 1995] Similarly, individual studies have correlated improved communication with increased adherence, [Bull 2002] lower levels of medical mishaps, [Sutcliffe 2004] and reduced malpractice claims. [Levinson 1997]

However, it must be emphasized that there are no large and well-designed studies directly correlating better informed consent to better clinical outcomes such as lower rates of medical errors. As indicated in the studies summarized...
in the previous section, most of the current evidence base involves the link between informed consent quality and patient comprehension, recall, or attitudes. For example, in an extensive analysis of the impact of one specific effort to improve informed consent, several “success stories” were reported but the results were mainly anecdotal or process-oriented. [NQF 2005] While such surrogate outcomes of patient understanding and comfort level are hypothesized to be important in avoiding errors, in boosting compliance and recovery, and in strengthening the doctor-patient relationship, this has not been shown. [Pizzi 2001]

Nevertheless, based on the belief that informed consent is not only a legal requirement but also a critical just-in-time component of improved patient-physician communications, many institutions and individual clinicians or clinics have initiated efforts to improve their policies and procedures for informed consent. [NQF 2005] As recently summarized by the National Quality Forum, [NQF 2005] the consequences of a poor informed consent process might include:

- Increased chance of a patient safety incident or medical error
- Increased chance for malpractice cases
- Violation of professional and ethical obligation to clinicians to communicate clearly
[Appendix B]
Barriers to Effective Informed Consent

Based on studies such as those cited in Appendix A and also on the rich clinical literature on general patient-physician communications, several barriers to effective informed consent have been identified. While a comprehensive review of general communication pitfalls are beyond the scope of this guide, a list of common barriers published in a recent review by physicians at Temple University is reproduced along with tips for improved communication in the nearby Tables. [Travaline 2005] Ten of the main challenges that have been identified in direct relation to informed consent are summarized here.

1] Lack of clinician time
In most cases, if they had more time, clinicians would likely pay closer attention to the description of the procedure, its benefits, its potential complications, and the alternatives. Given more time, the staff would also likely customize an array of informed consent forms that reflected the group’s attitudes and legal stance. This lack of time is of course a function of the perceived priority of informed consent quality in the institution-and that’s why changing this perception with staff education is one of the first steps in improving an institution’s disclosure practices.

2] Confusion among clinicians about when informed consent is needed
More explicit institutional standards that delineate when informed consent is needed may be required [Manthous 2003]

3] Physician concerns about giving too much information
Liability concerns lead some clinicians or institutions to limit the amount of information given to the patient in order to avoid “leaving something out” if they try to describe all the risks. In some cases, the clinician’s hesitancy in disclosing too much information is based on the belief that full descriptions of the potential side effects may unnecessarily scare the patient away from a potentially life-saving or life-enhancing surgery or procedure.

4] Perception of patients that the informed consent form is “just a legal release” for the doctor or hospital to proceed
The purpose of consent forms is often unclear and patients frequently perceive them as a form of legal protection for hospitals and treatment centers rather than a source of information. [Dawes 1994] One study confirmed that informed consent forms seem to be designed to authorize treatment or protect hospitals or caregivers from liability rather than to clarify information about the procedure or aid patients in decision-making.

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In fact, many patients don’t read the forms before signing them.

5] **Patient unawareness that they can refuse the procedure or delay the decision**

Patients may be unaware that they have the right to decline procedures, or may not be given an opportunity to do so. They may also not realize that they can ask for more time and request more information before making their decision.

6] **Patient language and cultural issues**

In their responses to a Robert Wood Johnson 2001 survey, 73% of healthcare providers said that a patient’s understanding of treatment advice was the most compromised aspect of care due language barriers and 71% said language issues complicated their patients’ ability to explain symptoms and concerns. [Wescott 2005, Wirthlin 2001] As the U.S. becomes increasingly diverse, these language issues will only grow. According to the 2005 Census, over 11% of US population (33.5 million) was born in another country; about 23 million speak English “less than very well” and nearly 15 million are linguistically isolated. Beyond language, cultural issues will also affect a patient’s understanding of the consent process and content. In some cases, for example, a patient’s community or self-identified group may have a relative lack of background knowledge about a certain disease or risk factor. In other cases, the patient may share a set of core beliefs that essentially rule out a proposed procedure or test (e.g., drawing of blood) or that otherwise powerfully shape the likely response to the proposal for consent. For such situations, the whole context of the consent situation must be integrated into the process and, if necessary, the consent form. Factors to be considered in evaluating a patient’s cultural influences include: cultural values, socioeconomic status, family structure, health-seeking behaviors, immigration status, country of origin, migration history, and decision-making styles (e.g., familial, individual, delegated, deferential).

7] **Special patient circumstances and human factors (e.g. stress, timing)**

Other factors that may limit the ability of patients to understand the medical content and their choices include: emergency situations; mental disabilities, or unconscious states.

8] **Poor quality of consent form and related educational materials**

Most consent forms are too complex for patients. They are often written at a level requiring a high school, college, or graduate degree education. [Krause 2001] Further, the quality of the information is highly variable, often missing key elements and many times being simply too generic to be of any value. Thus, if the form is not improved or supplemented with verbal descriptions or other educational print or audio/visual information, then the patient will not understand the proposed procedure. Also, note that an emphasis on
written documentation may undermine the importance of verbal communication between the patient and the practitioner.

9] **Patient misunderstanding of information on the informed consent form or related educational information about the proposed surgery or procedure**

If patients are unable to understand the information they are reading in a consent form or don’t read the form at all, this clearly undermines and negates the primary purpose of the form (i.e., documenting that the patient has been informed of the risks and benefits of a given medical procedure). Even if the consent form and the accompanying education appear objectively to be superior, and even if they are written and provided in the patient’s native language, there is always the possibility that a patient will simply “not get it.” The patient’s comprehension or lack thereof, in other words, must be separated from the objective quality of the written consent form or the accompanying verbal or written educational descriptions. Comprehension is a separate factor that, as described in the final barrier, requires a separate quality-check step.

10] **Clinician inability to detect patient’s lack of comprehension**

Sometimes even a clear consent form and a careful explanation of the procedure will not be enough for a patient to fully comprehend the situation. Clinicians who have just spent 10 minutes detailing an operation to a patient who seems alert and nods may have trouble believing that the patient does not understand. There is often a perception, for example, that English-speaking patients who do not ask questions are fully informed. This attitude is, of course, incorrect as it does not account for the high levels of low health literacy in the general population. When combined with a patient’s feeling stressed, overwhelmed, or intimidated in the healthcare setting, this silence, even if accompanied by a signature, should not be interpreted as consent.

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**[TABLE 1]**

**General Barriers to Patient-Physician Communication**

- Speech ability or language articulation
- Foreign language spoken
- Dysphonia
- Time constraints on physician or patient
- Unavailability of physician or patient to meet face to face
- Illness
- Altered mental state
- Medication effects
- Cerebrovascular event
- Psychologic or emotional distress
- Gender differences
- Other

### TABLE 2
**Tips on Improving Patient-Physician Communication**

1. Assess what the patient already knows
2. Assess what the patient wants to know
3. Be empathetic
4. Slow down
5. Keep it simple
6. Tell the truth
7. Be hopeful
8. Watch the patient’s body and face
9. Be prepared for a reaction


### TABLE 3
**Communication Traps to Avoid**

- Using highly technical language
- Not showing appropriate concern for problems voiced by patient
- Not pausing to listen to patient
- Not verifying that patient has understood the information presented
- Using an impersonal approach or lacking empathy

[Appendix C]
Sample Consent Forms

There are two sets of consent forms contained in Appendix C. The first form you will see in each set is an original copy of a consent used by a major medical center. The second form in each set is a revision of that original using some of the standard plain language techniques discussed in this guide to increase readability. Down the margins of this revised form, you will see arrows and boxes describing the types of changes that were made for your comparison with the originals. These are mostly formatting changes. The language in the original documents was also changed to reduce the reading level. The third document in each set is a final “stepped up” revision. These third-level forms employ techniques that may or may not be practical in your respective clinical settings, but represent best practices in achieving the best possible comprehension in patients during the informed consent process. These samples are adapted from concepts and approaches by Goldfarb and DuBay (2006) and Queensland Health (retrieved from http://www.health.qld.gov.au)

Note: The content in the original consent forms was produced by the medical institution that kindly shared them. Our use of these particular forms was for illustrative purposes only and should not be construed as a suggestion on our part that the content is an ideal outline or template for use in other institutions. That decision is partially regulated by state and federal law and regulations, and ultimately determined by each individual health care organization. The goal of providing these “typical” samples is simply to show how the techniques discussed in this guide can be applied to increase the readability of your consent forms and provide improved patient understanding.
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.
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.
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.
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[Appendix C] Sample Consent Forms

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

[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.

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: ___________________________________________________
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.
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:

☐ yes  ☐ no  ☐ N/A

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

5. I authorize _________________ to preserve and use, for any purpose it deems appropriate, and to dispose of in accordance with customary medical practice, any tis-
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 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.
CONSENT TO OPERATION AND/OR DIAGNOSTIC PROCEDURES, TRANSFUSIONS 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, TRANSFUSIONS 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, TRANSFUSIONS 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, TRANSFUSIONS AND RENDERING OF OTHER MEDICAL PROCEDURES continued [SUGGESTED REVISION 2]

IMPORTANT! 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 ______
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. Hospital 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.

Please initial after reading this page _______
**CONSENT TO OPERATION AND/OR DIAGNOSTIC PROCEDURES, TRANSFUSIONS 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 ____________________.
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: ____________________
References


CFR Title 45. 482.51 (b)(2) Federal requirement of informed consent.


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


[PA Law Code] 40 P.S. § 1303.504 (a) and Pa. Code § 715.12 (1) - (4)

Pape T. Legal and ethical considerations of informed consent. AORN J 1997;65:1122-1127.


A Practical Guide to Informed Consent: Providing Simple and Effective Disclosure in Everyday Clinical Practice
Top Choices:
Informed Consent Issues
“What Did the Doctor Say?:” Improving Health Literacy to Protect Patient Safety.
from the Joint Commission:
www.jointcommission.org

Improving Patients Safety Through Informed Consent for Patients with Limited Health Literacy.
from the Quality Forum:
www.qualityforum.org

from the National Quality Forum:
www.qualityforum.org

Top Choices:
Writing/Editing/Design for Readability in Health Information
Clear & Simple: Developing Effective Print Materials for Low-Literate Readers
from the National Cancer Institute:

Pink Book: Making Health Communications Programs Work
from the National Cancer Institute:
http://www.cancer.gov/pinkbook/page1

Plain Language: Improving Communication From the Federal Government to the Public from the U.S. government:
www.plainlanguage.gov.

Simply Put: Tips for creating easy-to-read print materials your audience will want to read and use from the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry:

Organizations with More Information on Informed Consent Issues

Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
(301) 427-1363
http://www.ahrq.gov

- Next Steps after Your Diagnosis
- Literacy and Health Outcomes — Evidence Report/Technology Assessment

American Medical Association Foundation
www.amafoundation.org

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

ECRI
5200 Butler Pike
Plymouth Meeting PA 19462
(610) 825-6000
Fax (610) 834-1275
www.ecri.org
- Informed Consent

First Clinical Research, LLC
836 Ramona Street, Suite 100
Palo Alto, CA 94301-2734 USA
www.firstclinical.com
- Journal of Clinical Research Best Practices

Institute of Medicine
www.iom.edu/project.asp?id=3827
- Health Literacy, A Prescription to End Confusion

The National Academies Press
Washington D.C.
www.nap.edu
- Various publications

National Institutes of Health
National Cancer Institute
- Developing Effective Print Materials for Low-Literate Readers
- Clear and Simple

National Quality Forum
Suite 500 North
601 13th Street NW
Washington DC 20005
(202) 785-1300
http://www.quality forum.org
- Improving Patient Safety Through Informed Consent for Patients with Limited Health Literacy

Queensland Health
147-163 Charlotte Street
PO Box 48
Brisbane, QLD 4001
Australia
(07) 3232-0111
- Patient Information Sheets for specific procedures
- 12 Questions to Ask about Your Surgery
- 12 Questions to Ask about Your Child’s Surgery
- Informed Consent Compliance Audit Form for Surgery

Health Literacy Texts
- Health Literacy from A to Z Practical Ways to Communicate Your Health Message by Helen Osborne, from Jones and Bartlett Publishers
  40 Tall Pine Drive
  Sudbury, MA 01776
  info@jbpub.com
  www.jbpub.com
- Effective Patient-Physician Communication from Wescott Professional Publications LLC
  327 Cumberland Street
  Lebanon, PA 17042
  866-379-9818
  www.wescottprofpub.com
  Chicago
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Chief, Family and Community Medicine

Betsy L. Humphreys, MLS
Deputy Director
National Library of Medicine

Robert A. Logan, PhD
National Library of Medicine
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)
[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.”

- 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

  Don’t say:
  “Complications of the Surgery.”

  Do say:
  “Infection is the Most Common Complication.”

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
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

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

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.
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.
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.
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.
### 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
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: _________________________________________________________
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.
**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.

____________________________________________________  

Please initial after reading this page.
IMPORTANT!

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:

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

[Appendix C] Sample Consent Forms

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, TRANFUSIONS 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 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.

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.
[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.

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: _________________________________________________
Relation 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 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.

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

____________________________________________________

Please initial after reading this page______

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**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 _______
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.

Please initial after reading this page _____
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