

Item 1: Is language describing “WHAT is the procedure” (beyond the medical name) provided for the patient?

<p>What qualifies?</p>	<ul style="list-style-type: none"> • A description of the procedure in language a standard patient could understand (lay terms). • In the instance of multiple procedures written on a single consent form, ALL procedure names should be spelled out and described. 	
<p>What does <u>not</u> qualify?</p>	<ol style="list-style-type: none"> 1. Name of the procedure is stated only in medical terms 2. Acronyms or abbreviations for which each letter is not defined (meaning, not spelled out AND not defined elsewhere on the form) 	
<p>Examples</p>		
<p>Cardiac (Heart) Procedures/Surgery</p>	<ul style="list-style-type: none"> • Coronary Artery Bypass Surgery: <ul style="list-style-type: none"> ○ Surgery to bypass a diseased heart artery ○ Open heart surgery taking healthy arteries to bypass blocked arteries • Surgical or Transcatheter Aortic Valve Replacement: <ul style="list-style-type: none"> ○ Replace a diseased valve with an artificial valve 	<ul style="list-style-type: none"> • Coronary artery bypass grafting • CABG (<i>not elsewhere spelled out and described</i>) • Open heart surgery (<i>without further description</i>) • Transcatheter aortic valve replacement (only the medical name given)
<p>Hip Surgery</p>	<ul style="list-style-type: none"> • Replace left/right hip joint • Hip Replacement • Damaged bone and cartilage from the hip are replaced with prosthetic material 	<ul style="list-style-type: none"> • Left Total Hip Arthroplasty
<p>Prostate Surgery</p>	<ul style="list-style-type: none"> • <u>Robotic Prostatectomy</u>: Robot-assisted procedure to remove the prostate • <u>Prostatectomy</u>: This procedure involves removing portions of the prostate that block urine flow or cause other problems (<i>also qualifies for items 2 and 3</i>) • <u>Cystoscopy</u>: Your doctor will insert a small tube (scope) into your bladder through your urethra. • <u>Transurethral Prostatectomy</u>: removal of portions of the prostate through a catheter (tube) that is inserted through the urethra (<i>also qualifies for item 2</i>) 	<ul style="list-style-type: none"> • Prostate-Prostatectomy Simple • TURP (<i>not elsewhere spelled out and described</i>) • Radical prostatectomy • Transurethral Prostatectomy
<p>Spinal Surgery</p>	<ul style="list-style-type: none"> • Procedure to relieve pressure on the nerves of the spinal cord (<i>also qualifies for item 3</i>) • Surgery to remove bone from the spine • Treatment for a herniated, bulging or degenerated disc. 	<ul style="list-style-type: none"> • Posterior Cervical Decompression with Fusion (<i>not in laymen’s terms</i>) • Laminectomy

Item 2: Is a description of “HOW the procedure will be performed” provided for the patient?

<p>What qualifies?</p>	<ul style="list-style-type: none"> • Language that explains to patients (in lay terms), “HOW the principal procedure will be performed?” <ul style="list-style-type: none"> ○ In the instance of multiple procedure names, the document must describe how the “principal” procedure (often the first listed) will be performed in order to qualify as satisfying this question • The “HOW” of a procedure usually refers to a technical action/s, such as: <ul style="list-style-type: none"> ○ Inserting a (tube into the artery) ○ Connecting (an artery) ○ Making an incision (in the abdomen) ○ Bypassing (a blocked artery) ○ Taking out (a mass) ○ Passing a (tube/scope/camera into the xxx) 	
<p>What does <i>not</i> qualify?</p>	<p>1. Information about the procedure that does not explain HOW the procedure will be performed</p>	
<p>Examples</p>		
<p>Cardiac (Heart) Procedures/Surgery</p>	<ul style="list-style-type: none"> • Graft a healthy artery from a different part of the body to a blocked artery near the heart 	<ul style="list-style-type: none"> • “My physician has explained to me and I understand the course of the procedure” (<i>generic language that does not specify how the procedure will be done</i>) • Open heart surgery (<i>without further description as to how the procedure will be done</i>)
<p>Hip Surgery</p>	<ul style="list-style-type: none"> • Damaged or diseased parts of the hip joint will be removed and replaced with a mechanical part • To perform a hip replacement your surgeon will make an incision over the front or side of your hip; remove diseased and damaged bone and cartilage, while leaving healthy bone intact; implant the prosthetic socket into your pelvic bone; and then replace the round top of your femur with the prosthetic ball 	<ul style="list-style-type: none"> • Hip Replacement (<i>qualifies for Item 1, but does not indicate how the procedure will be done</i>) • Right Total Hip Replacement with table anterior approach (<i>this is not an adequate description since the ‘how’ is not described in lay terms, though it would still qualify for Item 1</i>)
<p>Prostate Surgery</p>	<ul style="list-style-type: none"> • Robotic-assisted instruments are inserted through several small abdominal incisions. The instruments are controlled by a surgeon who cuts out portions of or the entire prostate. • A single large incision (cut) is made in the lower abdomen to reach and remove the prostate gland. • A catheter (tube) is inserted into the bladder through the urethra (the small duct through which urine passes out of the body). An instrument is passed through the tube to cut out the portion of the prostate that is blocking the urethra and the passage of urine. These portions of the prostate are then removed through the tube 	<ul style="list-style-type: none"> • Removal of prostate • Open prostatectomy • Robot-assisted prostatectomy • Nerve-sparing prostatectomy • Minimally invasive prostatectomy • Catheter-based prostatectomy • To resect prostate
<p>Spinal Surgery</p>	<ul style="list-style-type: none"> • Your surgeon will make an incision on the back of your neck, your muscles and blood vessels will be moved aside to expose your vertebrae, and a portion of the bone pushing on the nerves will be removed 	<ul style="list-style-type: none"> • Removal of indwelling neuro-stimulator (<i>not in laymen’s terms</i>)

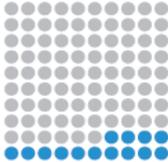
Item 3: Is the clinical rationale (purpose) for “WHY the procedure will be performed” provided?

<p>What qualifies and fully meets criteria?</p>	<ul style="list-style-type: none"> Language that explains “WHY the principal procedure will be performed? WHY is it necessary?” This refers to the medical purpose (intent) of the procedure as it relates to the patient’s condition (disease or symptoms) Look for both a “medical rationale” and a “condition” The medical rationale usually refers to one of the following (or equivalent language): <ul style="list-style-type: none"> to diagnose/rule out to prevent to inform prognosis to improve a patient’s clinical state or condition to treat to execute the patient’s request to fix/replace/repair Medical terms are acceptable for this question since this refers to the medical rationale for the procedure. 	
<p>What qualifies, but does not fully meet criteria?</p>	<ul style="list-style-type: none"> Use this response choice if you are uncertain if the language fully meets the above criteria. In this case, the patient may still be unsure why the procedure is being performed. 	
<p>What does <i>not</i> qualify?</p>	<ol style="list-style-type: none"> Rationale not specified Condition (disease, symptoms) not specified Generic language that states a range of intents, but does not specify which one applies to the patient 	
<p>Examples</p>		
<p>Cardiac (Heart) Procedures/Surgery</p>	<ul style="list-style-type: none"> To treat (medical rationale) a blockage or coronary artery disease (condition) To improve (medical rationale) blood flow where there is a blockage (condition) To bypass (medical rationale) the blocked vessel (condition) (<i>also qualifies for item 2</i>) 	<ul style="list-style-type: none"> To treat CAD (<i>acronym not known to patients</i>) Coronary artery disease or myocardial infarction/heart attack (<i>these are conditions, but there is no information about the intent</i>)
<p>Hip Surgery</p>	<ul style="list-style-type: none"> To treat or replace (medical rationale) a worn out joint/arthritis joint (condition) Arthroplasty is being performed to replace worn out tissue, alleviate pain, and improve function (<i>also qualifies for item 4</i>) 	<ul style="list-style-type: none"> Arthritis To replace the joint (<i>there is no condition; why the joint needs to be replaced is not explained</i>)
<p>Prostate Surgery</p>	<ul style="list-style-type: none"> To remove/treat (medical rationale) cancer (condition) To treat (medical rationale) an enlarged prostate (condition) To treat/reduce (medical rationale) the blockage of urine (condition, symptom) To reduce the size (medical rationale) of the prostate in order to relieve the blockage of urine (condition, symptoms) 	<ul style="list-style-type: none"> Prostate Cancer (this is the condition, but the medical rationale for the procedure is not clear) Benign Prostatic Hypertrophy (this is the condition, but the medical rationale for the procedure is not clear) To either treat prostate cancer or benign prostate hypertrophy (<i>this is generic and not specific to the patient</i>)
<p>Spinal Surgery</p>	<ul style="list-style-type: none"> To prevent (medical rationale) paralysis (condition) To remove (medical rationale) bone spurs in spine (condition) To reduce (medical rationale) back pain (condition, symptom) 	<ul style="list-style-type: none"> Herniated disc To remove the disc (<i>there is no condition; why the disc needs to be removed is not explained</i>)

Item 4: Is any patient-oriented benefit (intended impact on patient’s health, longevity, and/or quality of life) provided for the patient?

<p>What qualifies?</p>	<ul style="list-style-type: none"> • Language that explains how the principal procedure will benefit the individual patient. The benefit is something that the patient will experience. For example, <ul style="list-style-type: none"> ○ Reduced symptoms (e.g., pain, shortness of breath) ○ Improved function (e.g., mobility, urination) ○ Less chance of future problems (e.g., reduced risk of heart attack; prevent bone fracture) ○ Improved chance of survival • The benefit to the patient may not be known. In these cases, it must be stated that the benefit is uncertain. 	
<p>What does <u>not</u> qualify?</p>	<ol style="list-style-type: none"> 1. Language that refers only to the medical rationale (Q3), without referring to a positive effect of the procedure on the patient 2. Generic statement that the benefits were discussed with the patient 3. Language that states possible benefits, not defining the primary (intended) benefit(s) 	
<p>Examples</p>		
<p>Cardiac (Heart) Procedures/Surgery</p>	<ul style="list-style-type: none"> • To alleviate chest pain • To alleviate chest pain and potentially reduce the risk of future heart attack • There may be no benefit to you • To reduce risk of heart failure • To improve longevity 	<ul style="list-style-type: none"> • To improve blood flow to the heart (<i>qualifies for item 3 but does not explain how improving blood flow will help the patient</i>) • Benefits of the procedure were discussed with the patient
<p>Hip Surgery</p>	<ul style="list-style-type: none"> • Repair the torn ligament in order to improve exercise tolerance, mobility, flexibility, strength (<i>meets criteria for Q2, 3, and 4</i>) • To improve mobility • To reduce pain 	<ul style="list-style-type: none"> • To treat diseased joint (<i>qualifies for item 3 but does not explain how improving blood flow will help the patient</i>)
<p>Prostate Surgery</p>	<ul style="list-style-type: none"> • This procedure may make it easier to urinate (<i>includes improvement of a specific symptom</i>) • This procedure may slow the growth of cancer • This procedure may prevent the recurrence of cancer • You may not feel any better but it may improve your chances of survival. 	<ul style="list-style-type: none"> • To minimize the size of the prostate (<i>qualifies for item 3 but does not explain how improving blood flow will help the patient</i>) • To either improve urination or to prevent recurrent infection or to prevent the spread of cancer (<i>generic</i>)
<p>Spinal Surgery</p>	<ul style="list-style-type: none"> • To relieve back pain • To reduce risk of paralysis 	<ul style="list-style-type: none"> • To remove a diseased disc (<i>benefit to the patient not explained</i>)

Item 5: Is a QUANTITATIVE probability provided for any procedure-specific risk?

<p>What qualifies?</p>	<ul style="list-style-type: none"> • A specific number or estimated range describing the likelihood of <i>any procedure-specific</i> risk occurring with the principal procedure <ul style="list-style-type: none"> ○ Can be expressed as percentage or odds ○ May be stated in words ○ May be displayed graphically 	
<p>What does <i>not</i> qualify?</p>	<ol style="list-style-type: none"> 1. Numeric prediction that states the risk is possible but provides no basis for comparison 2. Generic statement that the clinician discussed the risks with the patient 	
<p>Examples</p>		
	<ul style="list-style-type: none"> • 1% (or less than 1% of patients) • 5 out of 10 patients • One in five patients • 1 in 10,000 patients • Or a graphic or other figure that illustrates the risk; e.g., 14 out of 100 people <div style="text-align: center;">  </div> <ul style="list-style-type: none"> • Common risks and complications (in approximately 5% of patients) include: <ul style="list-style-type: none"> ○ Bleeding from the wound that may require blood transfusion. ○ Heart rhythm changes, which are usually temporary. • Rare risks and complications (that can occur in less than 1% of patients undergoing the procedure) include: <ul style="list-style-type: none"> ○ Heart attack ○ Stroke ○ Death 	<ul style="list-style-type: none"> • A greater than 0% chance of complication • < 5% - since the less than sign, "<," may not be understood • My physician has discussed the risks of the procedure with me • I understand that every procedure has risks

Item 6: Is a QUALITATIVE probability provided for any procedure-specific risk?

What qualifies?	<ul style="list-style-type: none"> • QUALITATIVE (non-numeric; non-graphical) procedure-specific descriptor of likelihood 	
What does <u>not</u> qualify?	<ol style="list-style-type: none"> 1. Generic terms that lack relativity/comparability 2. Qualitative terms related to severity of risks (which do not indicate the likelihood of the risk occurring) 3. Generic statement that the clinician discussed the risks with the patient 4. Procedure-Specific risks that do not include likelihood 	
Examples		
	<ul style="list-style-type: none"> • Common/rare • More frequent/less frequent • Likely/unlikely • On occasion • Major chance/minor chance of occurring • Minimal 	<ul style="list-style-type: none"> • Uncertain, possible, or potential • Material risks include: • Serious or major/minor, not followed by term that indicates frequency • My physician has discussed the risks of the procedure with me • All procedures have risks, including: • Some risks associated with this procedure include: (<i>when no likelihood is attached, this does not qualify</i>)

Item 7: Is any alternative provided for the patient?

What qualifies?	<ul style="list-style-type: none"> • Any alternative to the surgical procedure for which the patient is consenting 	
What does <u>not</u> qualify?	<ol style="list-style-type: none"> 1. Generic statements about potential alternatives that are applicable across a range of surgical procedures 2. Generic statement that the clinician discussed the alternatives with the patient 	
Examples		
	<ul style="list-style-type: none"> • Medication for condition management • Watch-and-wait or observation • Alternatives include physical therapy and/or observation 	<ul style="list-style-type: none"> • My provider and health care team have discussed possible alternative treatments, including no treatment • After discussing other options, including no treatment, with my doctor, I give permission.... • You have been told about reasonable therapeutic alternatives and material risks associated with such alternatives

Item 8a: Timing – Date of patient/proxy’s signature

What qualifies?	<ul style="list-style-type: none"> • MM/DD/YYYY that the patient or proxy received the document • If date received is not noted, then the MM/DD/YYYY that the patient or proxy signed the document <ul style="list-style-type: none"> ○ Signature date <i>must</i> be labeled as the signature of the patient/proxy, unless one date is assigned to all signatures on the document, in which case, this signature date would be acceptable ○ If missing, “01/01/1111” <p>If the patient has signed the document at two different times and both are noted on the document, abstract the <i>earlier</i> of the two dates as this date reflects when the patient first “received” the document</p>
What does <u>not</u> qualify?	<ol style="list-style-type: none"> 1. Physician’s signature 2. Witness’s signature

Item 8b: Timing – Date of procedure

What qualifies?	<ul style="list-style-type: none"> • The date associated with when the procedures was performed, as noted in the Operative Report (OP) <ul style="list-style-type: none"> ○ May be referred to as “Date of service” or “Date of operation,” but does not necessarily have to be labeled as such ○ May appear in the header of the operative report or in the body of the report ○ If no date is available, “09/09/9999” • If a date is present but not labeled as the procedure date, use your best judgment. It is acceptable if the date for this question is not as explicitly labeled as the patient/proxy’s signature date.
What does <u>not</u> qualify?	<ol style="list-style-type: none"> 1. Date of dictation 2. Date of OP note 3. Date of Admission

Item 8c: Timing – Opt-out notation

What qualifies?	<ul style="list-style-type: none"> • Notation of patient’s/proxy’s decision to opt-out of receiving the document at least one day (24 hours) before the procedure <ul style="list-style-type: none"> ○ May include: signature, initials, or checkbox • Phone consent (presuming that the patient/proxy has opted out of receiving or signing the consent document in person)
What does <u>not</u> qualify?	<ol style="list-style-type: none"> 1. Notation that indicates “rush for next day surgery,” which would still satisfy the minimum standard to have the patient receive/sign the document at least one day before the procedure